STUDY

Requested by the ENVI committee

European Parliament

Access to medicinal products

Policy Department for Economic, Scientific and Quality of Life Policies
Directorate-General for Internal Policies
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Access to medicinal products

Abstract

There are many factors that can prevent a patient from being able to obtain the medicine they need, ranging from selective marketing decisions by companies to products being too expensive or pharmacy stock-outs. Because of national differences in health systems and market characteristics, access to medicines is not evenly distributed across the European Union.

In response to observed problems with access to medicines, in 2017 the European Parliament adopted a resolution containing 58 recommendations for action to the European Commission and Member States. This Study reviews the main actions taken at the Union level since then that could improve access to medicines. It also includes illustrative examples of actions taken by Member States and other actors.

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This document was requested by the European Parliament's committee on the Environment, Public Health and Food Safety.

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LIST OF ABBREVIATIONS

AMR	Antimicrobial Resistance
ARNA	Antimicrobial Resistance and causes of Non-prudent use of Antibiotics
ATMP	Advanced Therapy Medicinal Product
BBCE	Big Buyers for Climate and Environment initiative
CHMP	Committee for Medicinal Products for Human Use (European Medicines Agency)
CISMED	Centre for Information on the Supply of Medicines
CJEU	Court of Justice of the European Union
COVAX	Covid-19 Vaccines Global Access facility
COVID-19	Coronavirus disease 2019
COVID-ETF	COVID-19 European Medicines Agency pandemic Task Force
C-TAP	COVID-19 technology access pool
CTR	Clinical Trials Regulation
DNDi	Drugs for Neglected Diseases Initiative
EEA	European Economic Area
EAAD	European Antibiotic Awareness Day
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EDCTP3	Third European & Developing Countries Clinical Trials Partnership
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
ENVI	Committee on the Environment, Public Health and Food Safety
EP	European Parliament
EPITT	European Pharmacovigilance Issues Tracking Tool
ERN	European Reference Network
EU	European Union

EUnetHTA	European Network for Health Technology Assessment
EUPATI	European Patients' Academy on Therapeutic Innovation
EURIPID	European Integrated Price Information Database
EXPH	Expert Panel on effective ways of investing in Health
FAAP	Fair & Affordable Pricing Initiative
FAO	Food and Agriculture Organization
GAVI	The Vaccine Alliance (Global Alliance for Vaccines and Immunization)
GVP	Good pharmacovigilance practices
HE	Horizon Europe
HERA	Health Emergency Response Authority
HMA	Heads of Medicines Agencies
HRC	Human Rights Council
HTA	Health Technology Assessment
i-SPOC	Industry Single Point of Contact system for shortage reporting
IHI	Innovative Health Initiative
IIA	Inception Impact Assessment
IMI	Innovative Medicines Initiative
IP	Intellectual Property
ISO	International Organisation for Standardisation
JPA	Joint Procurement Agreement
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
MEAT	Most Advantageous Economic Tender
MEP	Member of the European Parliament
MHRA	Medicines and Healthcare products Regulatory Agency
MHRP	UK Medicines and Healthcare products Regulatory Agency

MRP	Mutual Recognition Procedure
NCA	National Competent Authority
NCP	National Contact Point
OECD	Organisation for Economic Co-operation and Development
OMP	Orphan Medicinal Product
PAS	Post-authorisation study
PASS	Post-Authorisation Safety Study
PIP	Paediatric Investigation Plan
PPP	Public-Private Partnerships
PRAC	Pharmacovigilance Risk Assessment Committee
PSUR	Periodic Safety Update Report
REFIT	The European Commission's regulatory fitness and performance programme
R&D	Research and Development
RWD	Real-world data
SME	Small or Medium-sized Enterprise
SPC	Supplementary Protection Certificate
SPOC	Single Point Of Contact
TFEU	Treaty on the Functioning of the European Union
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UN HRC	United Nations Human Rights Council
UNICEF	United Nations Children's Emergency Fund
Unitaid	Global health initiative for innovation regarding diseases in low- and middle-income countries by the WHO
WHO	World Health Organisation
WHO-ITU	World Health Organisation - International Telecommunication Union partnership
WTO	World Trade Organisation

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EXECUTIVE SUMMARY

Background

The sale of prescription medicines in the European Union is highly regulated. Before a medicine is allowed to be sold, its safety and effectiveness need to be confirmed by an independent regulator. However, even once the medicine is authorised for sale, it is not guaranteed that all patients in need of that medicine will immediately have access to it. Access will depend on such factors as whether pharmaceutical companies will decide to market the medicine in a specific country, whether the national health system or insurance company will agree to reimburse it, whether the local pharmacy will have the medicine available when it is needed and whether the patient can afford to pay whatever costs are not covered by the health system. Because in the European Union (EU) each Member State is individually responsible for the provision of healthcare to its own citizens, countries differ in how they manage these factors. Each Member State has its own policies and practices that will determine to what medicines patients will have access, when and at what cost. The natural consequence of this is that access to medicines is not equally distributed across the Union or across population groups.

Regardless of these variations, whether a patient can receive appropriate treatment in the first place depends on whether suitable medicines have been developed. As innovation in pharmaceutical products is substantially driven by commercial interests, far fewer medicines are developed in economically less attractive fields. The challenge is how best to incentivise innovation in such areas of unmet need, whilst making sure that all patients are able to benefit from these products once they are developed.

Reducing the many barriers to access to medicines is a priority for policy makers across the European Union. In 2017, the European Parliament put forward a resolution offering 58 recommendations for improving access to medicines for consideration by the European Commission and Member States. The recommendations called for action across many different areas of policy, ranging from actions to promote competitive and fair pharmaceutical markets, to actions aimed at directing more pharmaceutical innovation to areas of unmet need, and increased coordination between Member States to align policies.

Aim

In the four years following the Resolution, there have been many changes in the pharmaceutical policy landscape in Europe. This study provides insight into the progress made in the areas of concern raised by the Parliament. It hereto reviews the relevant actions taken at the Union level against these recommendations and their (expected) impact on access to medicines.

Actions are summarised in six distinct thematic areas: 1) patients, 2) market, 3) research, development and innovation, 4) health systems, 5) the regulatory framework and 6) developing countries. Actions relating to general monitoring, evaluation and reporting on access to medicines are discussed separately.

Along with this review of actions at the Union level, the analysis provides examples of initiatives taken by Member States and other organisations. These are presented as options for additional action by other parties, through scale-up or adaptation to national contexts.

Findings

In the period 2017–2021, the Commission has proposed, initiated or even fully implemented actions in all main thematic areas considered. Many of these can be linked in some form to the new **Pharmaceutical Strategy for Europe** that the Commission adopted in 2020 and which offers the blueprint for ongoing and future action by the Commission. The actions are also supported by the Commission's newly adopted **EU4Health Programme**.

Key actions taken to date within the EU legislative framework are:

- A waiver for supplementary protection certificates (SPC) in manufacturing was introduced by the adoption of Amending Regulation 2019/933 (2019).
- An Intellectual Property Action Plan was adopted (2020).
- The European Medicines Agency (EMA) received an extended mandate to facilitate a coordinated EU level response to health threats and to help prevent and mitigate shortages of critical medicines (2020).
- Negotiations have started on a legislative proposal for joint Health Technology Assessment (2021).
- An impact assessment is being conducted for the introduction of the European Health Data Space (2021).
- An impact assessment is being conducted for revision of the legislations for medicines for rare diseases and children (2021).
- A back-to-back evaluation and impact assessment for the revision of the general EU pharmaceutical legislation will be conducted (2021-2022).
- An evaluation of the Cross-Border Healthcare Directive 2011/24/EU will be conducted (2021).

Additionally, the Commission is currently engaged in identifying policy solutions to prevent or mitigate against the impact of medicines shortages and to increase supply chain security. Alongside such changes to the legislative framework, access to medicines is expected to be supported by further investment in medical research and pharmaceutical product development under Horizon Europe. Through the EU Vaccines Strategy, the Commission is working to ensure access to vaccines for the coronavirus disease 2019 (COVID-19) for its own citizens, as well as contribute to global access.

The areas least addressed so far by the Commission relate to the expectation of public return on public investment. Thus far, the Commission has not taken action to systematically include conditions on projects funded with EU public money, based on non-exclusive and voluntary licensing or on affordable pricing guarantees. The proposed revision of the legislation for medicines for rare diseases may result in the introduction of access requirements at the Union level, but this process has not yet been concluded.

Useful actions that have been taken by Member States and other organisations include platforms for patient involvement, joint procurement initiatives, research networks and national funding programmes for research and innovation.

Conclusions

Since 2017, the Commission and Member States have taken many important steps towards improving access to medicines. They have introduced or proposed legislative changes that are aimed at directing more innovation to areas of unmet need whilst placing greater obligations on product developers to ensure affordability and availability of products that benefit from innovation incentives. The regulatory framework for assessment and authorisation of medicines too is undergoing change to accelerate access. Meanwhile, efforts are ongoing to improve cooperation and coordination between Member States in areas such as joint assessment and procurement.

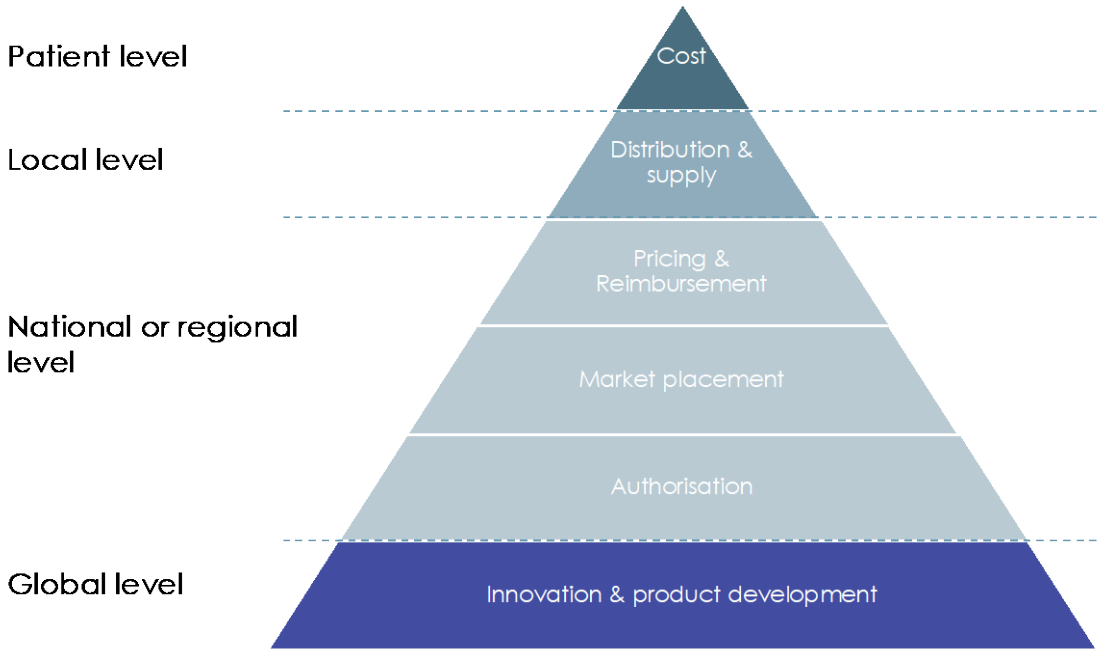
All of these actions can have significant impact on access to medicines for EU citizens. However, the majority of these actions were introduced only within the last 18 months or are still in preparation. For some of the proposed changes it has also not yet fully crystallised out which specific policy adoptions will be brought forward. Therefore, at this time the true impact of these actions cannot yet be properly estimated. Nonetheless, under the Pharmaceutical Strategy for Europe, the Commission is clear in its ambitions towards improving access to medicines and has laid down concrete actions to contribute to this goal.

1. INTRODUCTION

1.1. Access to medicines

The sale of prescription medicines in the European Union is highly regulated. In the interest of protecting public health, before a medicine is allowed to be sold, it needs to be scientifically assessed to determine whether it is sufficiently safe and effective. Only when regulators find this to be the case can a pharmaceutical company obtain a marketing authorisation (MA). However, even once the medicine is authorised for sale, it is not guaranteed that all patients in need of that medicine will immediately have access to it. Access will depend on such factors as whether pharmaceutical companies will decide to market the medicine in a specific country, whether the national health system or insurance company will agree to reimburse it, whether the local pharmacy will have the medicine available on the shelf when it is needed and whether the patient can afford to pay whatever costs are not covered by the health system. Figure 1 shows some of the main factors that can influence access to medicines, highlighting at what level their impact can be felt[1].

Figure 1: Factors influencing access to medicines at different levels



Source: Technopolis Group (2021).

Because in the European Union (EU) each Member State is individually responsible for the provision of healthcare to its own citizens, countries differ in how they manage these factors. For instance, **national pricing policies** influence where and when pharmaceutical companies will **place their products on the market**. Countries where there is a more profitable market will have greater and faster access to products than countries that are economically less attractive to a company.

Member States also differ in their **approaches to reimbursement of medicines**. Increasingly, countries evaluate new medicines on their value for money before deciding whether they should be paid for from national health care budgets. As the assessment criteria for this vary between countries,

[1] This simplified framework leaves out other relevant factors, such as whether there is sufficient manufacturing capacity to produce a medicine (potentially affecting product availability at national or even global levels) or if a medicine has been included in prescription guidelines (affecting whether the medicine is available to specific groups of patients). Rather, the framework focuses on some of the key issues discussed in this analysis.

the same medicine can be reimbursed in one Member State but not in another. Also the time taken for this decision-making can vary substantially, such that some patients have access long before others, depending on what country they live in.

Even when medicines are marketed and reimbursed in a country, patients could still experience instances where they are not able to get their medicine because of problems in the distribution and supply chain. Although medicines shortages are a growing problem in all Member States, not all countries are equally affected. Product availability can be influenced by variations in how countries deal with the risk of shortages, such as by imposing national supply obligations on manufacturers or export bans on specific medicines. Whilst such measures are intended to reduce shortages in one country, they can simultaneously increase shortages elsewhere. For instance, manufacturers may choose to prioritise supplying to countries where they would face penalties for non-compliance with obligations, at the expense of countries that do not impose such penalties. For their part, companies can also decide to impose supply quotas for certain markets to reduce the chances of these products being exported to other countries where they would undercut the manufacturers' profit margins. These quotas mean that there is little reserve stock to absorb demand fluctuations, which can result in temporary shortages.

The final hurdle that needs to be overcome before a patient can obtain their medication is that of cost to the patient. Even if a medicine is mostly reimbursed by the health system or insurance company, patients may still have to cover part of the cost themselves, for instance through co-payments or because their insurance plan has a deductible. If these residual costs are too high, patients may still be unable to access the medicine for financial reasons. The direct costs to patients may vary by country and even by insurance plan.

The natural consequence of all these variations in policy and practice is that access to medicines is not equally distributed across the Union or across population groups. At the global level, there are even greater variations in access to medicines as pharmaceutical companies have traditionally shown much less interest in producing and marketing medicines for populations in developing countries. Although access to medicines can be interpreted at its most basic as a combination of availability and affordability, it can also be taken more broadly by considering whether the *right* products are available to patients. Since most medicines are developed by for-profit pharmaceutical companies, innovation in pharmaceutical products is substantially driven by commercial interests. This means that far fewer products are developed in economically less attractive fields. This includes, for instance, treatments for rare diseases, medicines for children and new antimicrobial medicines. Instead, many new medicines represent marginal added value over already available ones whilst there remain large areas of unmet need.

From the above, it is clear that there are many factors that can hinder access to medicines for patients and that stand in the way of the health gains medicines can deliver when properly used. Reducing unnecessary barriers to access is therefore a priority for Member States and the Union.

1.2. Resolution on EU options for improving access to medicines

The European Parliament (EP) recognises the importance of access to medicinal products, including vaccines. It also is aware that access is not always ensured or equitable. In 2017, it thus passed the Resolution (2016/2057(INI)) on 'EU options for improving access to medicines'[2] (hereafter referred to as 'the Resolution'). In this Resolution, Members of the European Parliament (MEPs) expressed concerns

[2] European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI)), available at: https://www.europarl.europa.eu/doceo/document/TA-8-2017-0061_EN.html.

about inequitable access to medicines across the EU. Member States. They drew attention to such issues as the role of intellectual property rights and competition, differences in how Member States decide on reimbursement, the necessity of driving product development to areas of unmet need, and the role of developments in regulatory science to accelerate availability of products without compromising patient safety. Although the Resolution primarily focused on access to medicines for EU citizens, it also touched on the issue in the context of developing countries.

The Resolution put forward 58 recommendations, calling on the European Commission (hereafter referred to as 'the Commission') and Member States to undertake specific actions aimed at improving the availability of and access to medicines.

1.3. EU policy developments affecting access to medicines since 2017

In the four years since the Resolution was adopted the Commission has undertaken various actions that could impact access to medicines in the EU. These actions have been underpinned by evaluations and studies on different aspects of the EU pharmaceutical legislative framework. These have provided recommendations for, among others, revision of the system of incentives for pharmaceutical development, improved focus on unmet medical needs and simplification of the regulatory system. Building on these recommendations, the Commission is in the process of evaluating and proposing a **revision of the general pharmaceutical legislation**. It has also proposed or introduced revisions to other pieces of the EU pharmaceutical framework, such as to the regulations for medicines for rare diseases and children, and to the intellectual property framework.

These developments form part of the Commission's new **Pharmaceutical Strategy for Europe**[3,4], which was adopted on 25 November 2020. This strategy is based on four pillars, the first of which is aimed specifically at 'ensuring access to affordable medicines for patients and addressing unmet medical needs'. The other three pillars centre on supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry, enhancing crisis preparedness and response mechanisms, and ensuring a strong EU voice in the world. The strategy is a key part of the Commission's vision for a "strong European Health Union, in which all EU countries prepare and respond together to health crises, medical supplies are available, affordable and innovative, and countries work together to improve prevention, treatment and aftercare for diseases such as cancer"[5,6].

The European Health Union will be supported also by the **fourth European Health Programme, EU4Health 2021-2027**[7,8]. After multiple revisions to the foreseen financial envelope, it was finally agreed that under this programme the EU will provide EUR 5.3 billion in funding for actions that complement EU countries' policies and that are aligned with the programme's four main objectives[9].

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3 A pharmaceutical strategy for Europe, European Commission, available at: https://ec.europa.eu/health/human-use/strategy_en.

4 Communication on a Pharmaceutical Strategy for Europe, COM(2020) 761, European Commission, November 2020, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761.

5 European Health Union package: COM(2020) 724, COM(2020) 725, COM(2020) 726, COM (2020) 727.

6 European Health Union, European Commission, available at: https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en, accessed on 03/06/2021.

7 Regulation (EU) 2021/522 of 21 March 2021 on establishing a Programme for the Union's action in the field of heath ('EU4Health Programme') for the period 2021-2027 and repealing Regulation (EU) No 282/2014, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2021.107.01.0001.01.ENG&toc=OJ%3AL%3A2021%3A107%3ATOC, accessed on 03/06/2021.

8 EU4health 2021-2027 – a vision for a healthier European Union, European Commission, available at: https://ec.europa.eu/health/funding/eu4health_en, accessed on 03/06/2021.

9 The programme's other three main objectives are: 1) To improve and foster health in the Union, 2) to protect people in the Union from serious cross-border health threats and 3) To strengthen health systems, their resilience and resource efficiency, available at: https://ec.europa.eu/health/sites/default/files/funding/docs/eu4health_factsheet_en.pdf, accessed on 03/06/2021.

One of these is to make medicines available and affordable by encouraging sustainable production, supply chains and innovation and by supporting the rational use of medicine. The programme will hereto provide financial support for actions under the Pharmaceutical Strategy for Europe.

The generation of new knowledge and development of innovative medicines, with the goal to improve access to treatment in areas of unmet medical need, will furthermore be supported by **Horizon Europe**, the new EU framework programme for research and innovation (2021–2027)[10]. Two institutionalised partnerships will be supported that focus on development of, and access to pharmaceutical products: the **Innovative Health Initiative (IHI)** and the **Global Health EDCTP3 partnership**[11]. Additionally, various other co-funded and co-programmed European Partnerships have been proposed that are expected to support the development of new diagnostics and medicines and the generation of knowledge needed to inform health responses and improve the delivery of health care.

Under Horizon Europe, the European Commission has also made clear its commitment to fighting cancer, by announcing **cancer** as one of its five **mission** areas[12]. Whilst the preparatory phase for this mission is still ongoing, the Mission Board for Cancer in one of its recommendations included a call for "policy support and facilitation of collaboration to accelerate and monitor access to new diagnostics, treatments and drugs"[13].

1.4. UK withdrawal from the Union

On 1 February 2020, the United Kingdom (UK) formally left the Union, concluding a four year long process of withdrawal following the 2016 'Brexit' referendum. In preparation for this, the European Medicines Agency (EMA) relocated from London, UK, to Amsterdam, The Netherlands, on 1 March 2019. EU pharmaceutical law continued to apply to the UK until 31 December 2020[14]. As of 1 January 2021 a new EU-UK Trade and Cooperation Agreement governs the relations between the Union and the UK in areas that may impact access to medicines, such as trade in goods and services, intellectual property and public procurement, as well as thematic cooperation and participation in Union programmes[15].

Whilst the full impact of Brexit on access to medicines, for both the Union and the UK, remains to be seen, the UK's departure created multiple challenges for, among others, the scientific assessment of medicines by the EMA, distribution of English-language packs to other English-speaking countries, imports and export of medicines between the Union and the UK, and research cooperation. Various actions have been taken to mitigate the negative consequences of Brexit on access to medicines, as will be discussed further in the relevant sections of this report.

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[10] Horizon Europe Cluster 1: Health, European Commission, available at: https://ec.europa.eu/info/horizon-europe/cluster-1-health_en.

[11] Press release: EU to set up new European Partnerships and invest nearly €10 billion for the green and digital transition, European Commission (23 February 2021), available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_21_702, accessed on 03/06/2021.

[12] Mission area: Cancer, European Commission, available at: https://ec.europa.eu/info/horizon-europe/missions-horizon-europe/cancer_en, accessed on 03/06/2021.

[13] Proposed Mission – Conquering Cancer: Mission Possible. Report of the Mission Board for Cancer (2020) , available at: https://op.europa.eu/en/publication-detail/-/publication/b389aad3-fd56-11ea-b44f-01aa75ed71a1/, accessed on 03/06/2021.

[14] Brexit: the United Kingdom's withdrawal from the European Union. European medicines Agency, available at: https://www.ema.europa.eu/en/about-us/brexit-united-kingdoms-withdrawal-european-union, accessed on 03/06/2021.

[15] The EU-UK Trade and Cooperation Agreement. European Commission (2020) , available at: https://ec.europa.eu/info/relations-united-kingdom/eu-uk-trade-and-cooperation-agreement_en, accessed on 03/06/2021.

1.5. COVID-19

Access to medicines can be hindered by weaknesses in healthcare systems, particularly when these systems suddenly come under extraordinary stress. The COVID-19 pandemic in particular has highlighted existing vulnerabilities in pharmaceutical supply chains, with critical products going in shortage or threatening to do so and governments unable to rapidly procure additional supplies. Many countries struggled to obtain sufficient personal protective equipment, such as face masks, or medicines used in the treatment of COVID-19 patients, like anaesthetics and antivirals.

In their rush to ensure access to medicines for their citizens, various EU Member States introduced export bans on medical supplies and considered the creation of national stockpiles of critical medicines. Whilst such measures were intended to protect access at the national level, they also risked deepening inequities in access between Member States and creation of a situation whereby scarce supplies were not distributed according to need. Thus, on 8 April 2020, the Commission released guidelines calling on all Member States "to lift unjustified export bans for medicines within the internal market" and urged that "any stockpiling by Member States should be at national level and for moderate quantities based on epidemiological indications" to avoid the creation of shortages, resulting in inequitable access to critical medicines between Member States[16]. The situation showed that consolidation within global pharmaceutical supply chains has reduced their robustness in the face of shocks and that effects in one part of the world can quickly cascade to other parts. It also revealed how protectionist policies can be detrimental to the ideal of European unity.

Simultaneously, the pandemic has brought European countries together to support the development of COVID-19 vaccines. As part of the EU Vaccines Strategy, the Commission has dedicated EUR 350 million to support COVID-19 vaccine development[17]. It is estimated that the Commission has been the largest funder of the research that led to the COVID-19 vaccine developed by Oxford University and AstraZeneca[18]. The Commission has entered into Advance Purchase Agreements with pharmaceutical companies to procure COVID-19 vaccines on behalf of the Member States[19]. Through joint procurement and agreements between the Member States, the EU intends to promote equitable distribution of the vaccine based on population size and need. However, it has also been suggested that the EU's handling of the procurement negotiations has delayed vaccination efforts across Europe[20].

On 6 May 2021, the Commission announced the EU Strategy on COVID-19 therapeutics, which will complement the EU Vaccines Strategy[21]. This new strategy will cover the development, manufacturing

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16 Communication from the Commission: Guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak (C2020) 2272 final), European Commission (8 April 2020) , available at: https://ec.europa.eu/health/sites/health/files/human-use/docs/guidelines_isc_en.pdf, accessed on 03/06/2021.

17 EU support for vaccines, European Commission, available at: https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/coronavirus-research-and-innovation/vaccines_en, accessed on 03/06/2021.

18 Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine? Approximating the funding to the University of Oxford for the research and development of the ChAdOx vaccine technology. Cross S, Rho Y, Reddy H et al. (2021). *Preprint*, available at: https://www.medrxiv.org/content/10.1101/2021.04.08.21255103v1.full.pdf, accessed on 03/06/2021.

19 Coronavirus response: public health, European Commission, available at: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health_en, accessed on 03/06/2021.

20 How Europe fell behind on vaccines. Deutsch J and Wheaton S, Politico (27 January 2021) , available at: https://www.politico.eu/article/europe-coronavirus-vaccine-struggle-pfizer-biontech-astrazeneca/, accessed on 03/06/2021.

21 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. European Commission (6 May 2021), available at: https://ec.europa.eu/info/sites/default/files/communication-strategy-covid-19-therapeutics_en.pdf, accessed on 03/06/2021.

and procurement of COVID-19 treatments, hoping to have the first three new therapeutics available by October 2021.

In light of the Commission's significant investments into development of COVID-19 vaccines and new therapeutics, along with other public funders, the crisis has amplified the debate around fair pricing and public return on public investment in research and development. Although COVID-19 vaccine producers like Moderna and Johnson & Johnson have pledged to ensure their vaccines are affordable as long as there is a pandemic, there are indications they may raise prices as the situation shifts from "pandemic to endemic"[22]. There is also criticism over the unwillingness of pharmaceutical companies to provide access to protected information and know-how, through initiatives such as the COVID-19 technology access pool (C-TAP), which could support increased production by generic manufacturers[23].

1.6. Objective of the Study

It is clear that, since the adoption of the Resolution on EU options for improving access to medicines, the policy landscape, the environment for research and innovation and the broader context in the EU have all changed considerably. This report presents the results of an analysis to better understand these developments and their potential impact on access to medicines for EU citizens. Specifically, it reviews:

- To what extent the recommendations of the European Parliament have been addressed.
- What additional options Member States could take that could help ensure the best possible access to medicines for their citizens.

1.7. Structure of the report

Section 1.8 of this report summarises the methodology underpinning the Study.

The recommendations contained in the Resolution cover a wide range of issues and are not presented in any particular order. To structure the analysis and reporting, the recommendations were categorised against six main thematic areas. Chapters 3 through 9 present the main findings in these areas. Respectively, they cover:

- **Patients (Chapter 2)**: The chapter discusses how patients can and should be involved in issues of access to medicines. It considers the rights of patients, their role in development and assessment of medicines, the right to access to health care in other Member States (cross-border healthcare) as well as measures to promote more effective and efficient use of medicines.
- **Market (Chapter 3)**: Access to medicinal products is substantially shaped by how the market incentivizes and rewards innovation, as well as by the conditions set for trade and competition. Therefore, this chapter addresses developments in intellectual property, and measures to promote an open, fair and competitive market.
- **Research, Development and Innovation (Chapter 4)**: Access to medicines is conditional on the development of suitable treatments. This chapter covers measures to stimulate research and innovation in specific areas of unmet need (antimicrobials, rare diseases, paediatric

[22] Drugmakers promise investors they'll soon hike COVID-19 vaccine prices. Fang L. The Intercept (18 March 2021), available at: https://theintercept.com/2021/03/18/covid-vaccine-price-pfizer-moderna/, accessed on 03/06/2021.

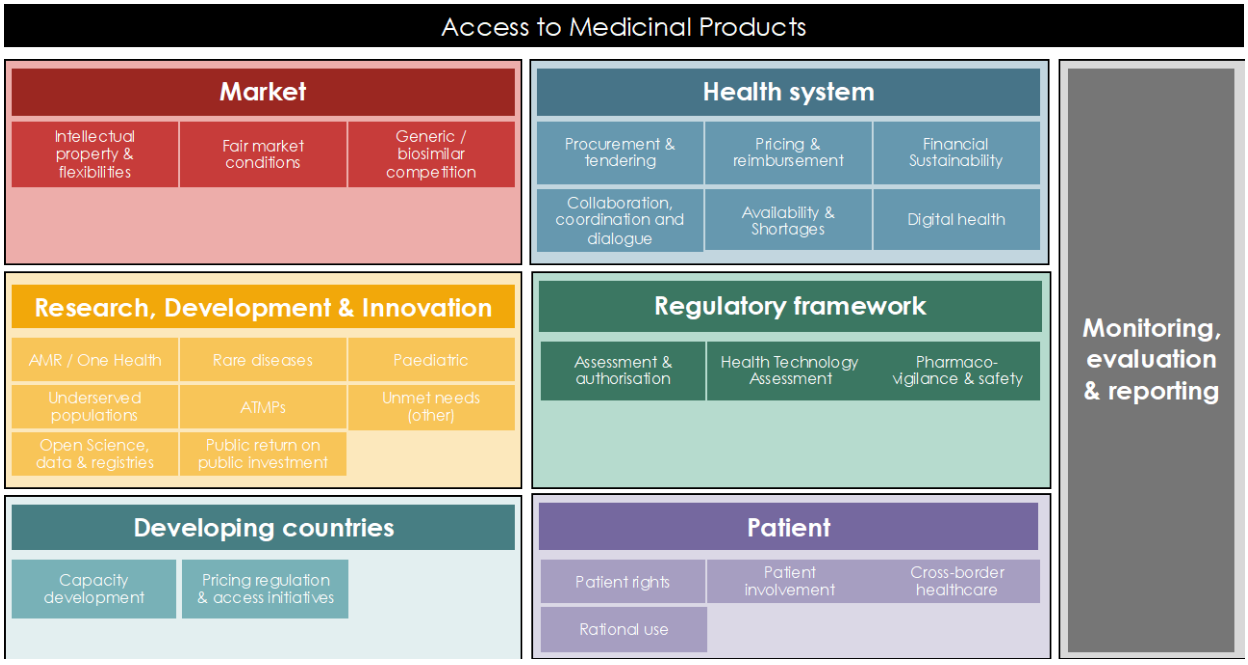
[23] WHO platform for pharmaceutical firms unused since pandemic began. Safi M. The Guardian (22 January 2021), availabla at: https://www.theguardian.com/world/2021/jan/22/who-platform-for-pharmaceutical-firms-unused-since-pandemic-began, accessed on 03/06/2021.

medicine, underserved populations), along with actions to promote sharing of knowledge and data. It concludes on a reflection on actions to promote the link between public investment and public return.

- **Health Systems (Chapter 5)**: This chapter discusses the health system factors that facilitate fast, fair and affordable access to medicinal products across the European Union. This includes measures related to pricing and procurement procedures, as well as developments in the interaction between Member States. It also reflects on actions to tackle the problem of medicine shortages. Attention is also given to the role of digital health tools.
- **Regulatory Framework (Chapter 6)**: In most circumstances, a medicine needs to have been assessed and approved by a regulatory authority before it can be prescribed. Additionally, access to medicines may be contingent on a positive decision for reimbursement. This chapter considers actions within the regulatory framework to accelerate the development and approval of innovative medicines and actions to promote greater alignment between health authorities in the assessment of a medicine's added value and cost-effectiveness. It furthermore reviews actions taken to protect patients from harmful effects of approved medicines.
- **Developing Countries (Chapter 7)**: The Resolution not only focuses on access to medicines for EU citizens but also considers the need for access in developing countries. Therefore, this section investigates actions to support development of medicines of particular relevance for developing countries and measures to promote access and correct use.

Each thematic area and chapter has been further divided into sub-themes, as shown in Figure 2 below. **Chapter 8** addresses recommendations for cross-cutting action related to **monitoring, evaluation and reporting**.

Figure 2: Analytical framework for this Study



Source: Technopolis Group.

Chapter 9 presents **additional options** that were identified for consideration by Member States.

Chapter 10 provides the main **conclusions** that can be drawn from this Study.

Annex A provides an **overview of all recommendations** and signposts the individual sections of this report where these have been addressed. **Annex B** contains the detailed description of the **methodology**.

1.8. Methodology

The basis for this Study is formed by the Resolution of March 2017 on 'EU options for improving access to medicines' (2016/2057(INI)) passed by the European Parliament. To identify the relevant actions undertaken since then, the analysis was structured as follows:

1. Categorisation of each recommendation according to its main theme and sub-theme.
2. Review of documentation to identify relevant actions in each area as undertaken or proposed by the Commission, the Council or EU executive agencies.
3. Review of documentation to identify additional actions taken by Member States with the potential to be adopted at a wider scale.

For each recommendation, the study looked at whether any actions have been taken and, if so, what the specifics of these actions are and what stage of implementation they are in. The analysis distinguishes between:

- **No actions taken**, including no formulation of proposals for action.
- **Actions proposed**, but no steps undertaken yet to further develop these.
- **Actions in preparation**. This could include drafting of policy options, impact assessments for new and revised legislation or preparatory studies.
- **Actions under implementation**. Concrete steps have been taken to introduce the action, such as by commitment of budgets, preparation of work plans, or ongoing negotiations.
- **Implemented actions**. All necessary steps have been taken to complete the action (for instance, the completion of an evaluation) or the action has taken full effect (for instance, the adoption of new legislation).

In case no information on the action could be identified or the recommendation was directed solely at Member States, the status of the action was classified as **unknown**.

A detailed description of the methodology is provided in Annex B to this report and a full list of academic and policy sources used is provided at the end of the report.

2. PATIENTS

2.1. Summary of issues raised

The main beneficiaries of access to medicines are patients for whom medicines offer a way to prevent or cure disease or, at a minimum, alleviate symptoms. The Charter of Fundamental Rights of the European Union recognises the fundamental right of citizens of "access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices", thus putting patients at the centre of the debate around access to medicines[24]. The Resolution recognises that it is "one of the core objectives of the EU and the World Health Organization and of United Nations Sustainable Development Goal 3" that each person should have timely and affordable access to the healthcare and treatment options of their choice and preference without geographical discrimination. Because of this recognition, Members of the European Parliament emphasise the need for sufficient measures at EU-wide and national level to guarantee these rights. In addition, they stress the importance to ensure the equal rights of all patients in cross-border healthcare via a fair implementation of Directive 2011/24/EU[25].

The Resolution furthermore states that patient organisations give a vital voice to patient views and that therefore their involvement is crucial to meeting unmet needs of European patients. It recognises the value of existing patient initiatives, such as the European Charter of Patients' Rights and of the annual European Patients' Rights Day, celebrated in the Member States. At the same time, it expresses concern about the limited level of involvement of patients and patient organisations within development cycles across the Union.

The Resolution contains five recommendations for actions to be undertaken by the Commission, the Council or the Member States in the thematic area of 'Patients'. These are for:

- National and EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, to guarantee the sustainability of EU public healthcare systems, and to ensure future investment in pharmaceutical innovation.
- Member States to implement Directive 2011/24/EU on the application of patients' rights in cross-border healthcare in a fair way, avoiding limitations to the application of the rules on reimbursement of cross-border healthcare, including the reimbursement of medicines, that could constitute a means of arbitrary discrimination or an unjustified obstacle to free movement.
- The Commission to monitor and assess in an effective way the implementation of Directive 2011/24/EU in the Member States, and to plan and carry out a formal evaluation of this Directive that includes complaints, infringements and all transposition measures.
- The Commission and the Member States to identify and/or develop frameworks, structures and methodologies to meaningfully incorporate patient evidence at all stages of the medicines R&D cycle, from early dialogue to regulatory approval, Health technology assessment (HTA),

[24] Charter of Fundamental Rights of the European Union, 2000/ C364/01, Official Journal of the European Communities, December 2000, available at: https://www.europarl.europa.eu/charter/pdf/text_en.pdf, accessed on 03/06/2021.

[25] Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare, available at: https://eur-lex.europa.eu/legal-content/en/ALL/?uri=celex%3A32011L0024, accessed on 03/06/2021.

relative effectiveness assessments, and pricing and reimbursement decision-making, with the involvement of patients and their representative organisations.

- Council to promote rational use of medicines across the EU, promoting campaigns and educational programmes aimed at making citizens aware of the rational use of medicines, with the goal of avoiding overconsumption, in particular of antibiotics, and promoting the use of prescriptions by active principles by healthcare professionals and the generic medicines administration.

The following sections provide a summary of the issues and any identified actions under each of the four sub-themes: patient rights, patient involvement, cross-border healthcare and rational use.

2.2. Patient rights

In recognition of the aforementioned right of all EU citizens to benefit from appropriate medical care, including access to medicinal products, the Resolution calls for national and EU-wide measures "to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies". This call for action has been a focal point in the strategic direction of the Commission since. In 2017, the Commission presented the right to timely access affordable, preventative, and curative care of good quality as one of 20 principles within its proclamation on the European Pillar of Social Rights. In 2021, the Commission reaffirmed its commitment to the Pillar via an action plan towards 2030[26]. The roadmap of the Pillar foresees a number of EU actions related to the recommendation: the implementation of Europe's Beating Cancer Plan (2021)[27], the proposition of the European Health Data Space (2021)[28], and the proposition of new tools to better measure barriers and gaps in access to healthcare (2021-2022)[29].

In 2020, the Commission adopted the Pharmaceutical Strategy for Europe[3]. The strategy has four objectives, two of which relate to the specific recommendations on patient rights:

- Ensuring access to affordable medicines for patients and addressing unmet medical needs.
- Supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high-quality, safe, effective and greener medicines.

In addition, the roadmap of the revision of the pharmaceutical legislation – which is undergoing consultation in the first quarter of 2021 – gives policy options including a revision of system of incentives aimed at ensuring options that attract and promote innovation and accelerating product development and authorisation in areas of unmet need[30].

In the draft work programme 2021-2022 of Horizon Europe's Cluster Health, multiple calls with a total budget of EUR 240 million are proposed be launched with the aim of ensuring access to innovative,

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[26] European Pillar of Social Rights Action Plan, European Commission DG EMPL, March 2021, available at: https://ec.europa.eu/info/publications/european-pillar-social-rights-action-plan_en, accessed on 03/06/2021.

[27] Communication on Europe's Beating Cancer Plan, COM(2021) 44, European Commission, March 2021, available at: https://ec.europa.eu/health/sites/health/files/non_communicable_diseases/docs/eu_cancer-plan_en.pdf, accessed on 03/06/2021.

[28] European Health Data Space, European Commission website, available at: https://ec.europa.eu/health/ehealth/dataspace_en, accessed on 03/06/2021.

[29] Information limited to the reference in the European Pillar of Social Rights Action Plan, available at: https://ec.europa.eu/info/publications/european-pillar-social-rights-action-plan_en, accessed on 03/06/2021.

[30] Revision of the EU general pharmaceuticals legislation Inception impact assessment, Ares(2021)2390324, European Commission, April 2021, available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation, accessed on 03/06/2021.

sustainable and high-quality health care[31]. Under Horizon Europe, the Commission also proposed to set up 10 European institutionalised partnerships with a total investment of EUR 10 billion. One of them, the Innovative Health Initiative (successor of the Innovative Medicines Initiatives) is expected to "help create an EU-wide health research and innovation ecosystem that facilitates the translation of scientific knowledge into tangible innovations"[32].

2.3. Patient involvement

For patients to optimally benefit from access to medicines, it is important that any products that are developed are suitably aligned with the needs and preferences of patients. The Resolution tasks the Commission and Member States to involve patient evidence at all stages of the R&D cycle from early dialogue to regulatory approval, Health Technology Assessment (HTA), relative effectiveness assessments, and pricing and reimbursement decision-making.

The Pharmaceutical Strategy for Europe calls for full implementation of the regulatory framework for clinical trials, which supports innovative trial designs and a more patient-oriented medicine development. It states: "The Commission will work to ensure that the new framework supports innovative trial designs. Moreover, in coordination with the European regulators, patient groups and stakeholders, it will support more patient-oriented design, planning and conduct of clinical trials through harmonised international guidance documents and taking into account the experience acquired from clinical trials for COVID-19 vaccines and treatments ". In addition, the Strategy foresees to then follow the framework of the Clinical Trials Regulation[33] (CTR) as soon as it has been implemented. Although the CTR entered into force in 2014, it has yet to be fully applied. The application is currently waiting on the finalisation of the envisioned clinical trial database. The CTR states that Member States should ensure the involvement of patients or patients' organisations when determining who is to assess clinical trial applications[34].

Another expected action in relation to increasing patient involvement is in the area of health technology assessment (HTA). HTA describes the systematic evaluation of the properties and effects of a health technology that considers evidence regarding clinical effectiveness, safety and cost-effectiveness before a health technology is placed on the market. The proposal for a European Regulation on HTA, which was adopted in 2018, envisions joint clinical assessment reports that give stakeholders (health technology developers, patients, clinical experts and others) opportunities to provide input to ensure a thorough, independent and transparent assessment process[35]. More information on the proposed regulation is provided in Section 6.3. As the Regulation has not yet been enacted, no further actions have been taken.

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[31] Register of Commission Expert Groups and Other Similar Entities, European Commission website, available at: https://ec.europa.eu/transparency/expert-groups-register/screen/home?do=groupDetail.groupMeetingDoc&docid=49106, accessed on 03/06/2021.

[32] EU to set up new European Partnerships and invest nearly €10 billion for the green and digital transition, press release, IP/21/702, European Commission, 23 February 2021, available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_21_702, accessed on 03/06/2021.

[33] Regulation (EU) No 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0536, accessed on 03/06/2021.

[34] See Regulation (EU) No 536/2014, available at: https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf, accessed on 03/06/2021.

[35] Proposal for a regulation on health technology assessment and amending Directive 2011/24/EU, COM(2018) 51, European Commission, January 2018, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52018PC0051, accessed on 03/06/2021.

2.4. Cross-border healthcare

For many patients, appropriate or lifesaving healthcare may not be available close to their home or even within their own country. Cross-border healthcare can offer a solution in cases where the most appropriate treatment is located in another EU country. Directive 2011/24/EU on the application of patients' rights in cross-border healthcare aims to facilitate this access to treatment in other EU Member States, offering patients more possibilities to seek healthcare in other countries[36]. It allows patients to request reimbursement of healthcare costs from their national healthcare insurance provider for treatments abroad and ensures that prescriptions are recognised across borders. National Contact Points (NCPs) are set up in each Member State to assist patients in regard to their rights under the Directive. The Directive facilitated the creation of European Reference Networks (ERNs) for rare diseases and promoted European e-Health initiatives.

While the Directive has helped many patients over the course of its lifetime, discussions are ongoing on aspects of its implementation such as the inclusiveness of the definition of 'healthcare'. The Resolution emphasises the need for a fair implementation in the Member States, and the need for the Commission to monitor and assess this implementation including by means of a formal evaluation. The Directive was monitored by the Commission via a 2018 report covering key provisions, trends and progress for the period 2015-2018[37]. The report proposes recommendations for improving the current level of information provision to patients by NCPs. In addition, the Commission reports Member State data on the Directive on an annual basis[38].

In 2019, a special report by the European Court of Auditors assessed several aspects of the implementation of the Directive, and offered recommendations, among others on the Commission's support for NCPs, the cross-border exchanges of health data, and activities of the ERNs[39]. Also in 2019, the Parliament adopted a Resolution on the implementation of the Cross-Border Healthcare Directive, finding that action is needed, by simplifying administrative procedures and by improving information provision by the NCPs[40]. In October 2020 the Commission set up a study on "enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU" to investigate priority areas in the implementation of the Directive, including prior authorisation, the reimbursement system and the consultation arrangements of the NCPs.

Later in 2021, 10 years after the implementation of the Directive, the Commission will conduct an evaluation of Directive 2011/24/EU[41]. The evaluation will investigate the approaches implemented by Member States in practice, how effective these are and what areas still act as barriers to patients seeking healthcare across borders. Preparatory studies for this evaluation are ongoing.

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[36] See Directive 2011/24/EU, available at: https://eur-lex.europa.eu/legal-content/en/ALL/?uri=celex%3A32011L0024, accessed on 03/06/2021.

[37] Study on cross-border health services: enhancing information provision to patients, European Commission DG SANTE, June 2018, available at: https://op.europa.eu/en/publication-detail/-/publication/542b7b51-af6a-11e8-99ee-01aa75ed71a1, accessed on 03/06/2021.

[38] All Member State Data on cross-border healthcare reports are available at the European Commission's Cross-border healthcare, available at: https://ec.europa.eu/health/cross_border_care/key_documents_en, accessed on 03/06/2021.

[39] EU actions for cross-border healthcare: significant ambitions but improved management required, Special Report No. 07/2019, European Court of Auditors, 2019, available at: https://op.europa.eu/webpub/eca/special-reports/cross-border-health-care-7-2019/en/#chapter10, accessed on 03/06/2021.

[40] Report on the implementation of the Cross-Border Healthcare Directive (2018/2108(INI)), Committee on the Environment, Public Health and Food Safety, European Parliament, 29 January 2019, available at: https://www.europarl.europa.eu/doceo/document/A-8-2019-0046_EN.html#title1, accessed on 03/06/2021.

[41] Cross-border healthcare, European Commission website, available at: https://ec.europa.eu/health/cross_border_care/overview_en, accessed on 03/06/2021.

2.5. Rational use

Although access to medicines implies the absence of any undue barriers for patients, there can be good reason for restricting access to specific products, not only in the interest of the individual patient but also out of wider public health concerns. This can be the case, for instance, when products are potentially highly addictive, such as opioids and sedatives, or when incorrect or unnecessary use of medicine could result in drug resistance. The World Health Organization (WHO) estimates that "more than half of all medicines are prescribed, dispensed or sold inappropriately […]"[42]. Ensuring that medicines are used only if and when strictly necessary is what is referred to as rational use.

In the Resolution, MEPs expressed concerns about the overconsumption of medical products, in particular antibiotics. The Resolution thus calls on the Council to promote rational use of medicines across the EU, promoting campaigns and educational programmes aimed at making citizens aware of the rational use of medicines, with the goal of avoiding overconsumption, in particular of antibiotics. Shortly after the adoption of the Resolution, the concluding study of the EU-funded 'Antimicrobial Resistance and causes of Non-prudent use of Antibiotics' (ARNA) project also supported this call[43]. However, no specific responding actions could be identified at the Commission level that were undertaken between 2017 and 2021. However, the Pharmaceutical Strategy for Europe proposes, via the review of the pharmaceutical legislation, consideration of measures to restrict and optimise the use of antimicrobial medicines and to further promote the prudent use of antibiotics and communication to healthcare professionals and patients.

One promotional measure, the European Antibiotic Awareness Day (EAAD), occurs annually since its implementation in 2008 and is supported by the EMA and the European Centre for Disease Prevention and Control (ECDC).

[42] Promoting rational use of medicines. World Health Organization, available at: https://www.who.int/activities/promoting-rational-use-of-medicines, accessed on 03/06/2021.

[43] Antimicrobial Resistance and causes of non-prudent use of antibiotics in human medicine in the EU, European Commission DG SANTE, April 2017, available at: https://ec.europa.eu/health/sites/default/files/antimicrobial_resistance/docs/amr_arna_report_20170717_en.pdf, accessed on 03/06/2021.

2.6. Summary of identified actions

Table 1: Summary table – Patients

Recommendation	Identified actions	Status
52. National and EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies […].	• Prioritisation of the topic in the European Pillar of Social Rights (EUR 240 million commitment in 2021-2022) • A roadmap for the implementation of the Pharmaceutical Strategy for Europe is underway.	
60. Member States to implement Directive 2011/24/EU on the application of patients' rights in cross-border healthcare in a fair way, avoiding limitations to the application of the rules on reimbursement of cross-border healthcare, including the reimbursement of medicines, that could constitute a means of arbitrary discrimination or an unjustified obstacle to free movement.	• In 2019, a special report by the European Court of Auditors assessed the implementation of the Directive.	
61. Commission to monitor and assess in an effective way the implementation of Directive 2011/24/EU in the Member States, and to plan and carry out a formal evaluation of this directive that includes complaints, infringements and all transposition measures.	• The Directive was monitored by the Commission via a 2018 report and annual data monitoring reports are published. • In 2021, the Commission will conduct an evaluation of Directive 2011/24/EU. Preparatory studies are under way.	
88. Commission and the Member States to identify and/or develop frameworks, structures and methodologies to meaningfully incorporate patient evidence at all stages of the medicines R&D cycle, from early dialogue to regulatory approval, HTA, relative effectiveness assessments, and pricing and reimbursement decision-making, with the involvement of patients and their representative organisations.	• Implementation of the Clinical Trials Regulation regarding increased patient involvement. • The HTA regulation foresees increased patient involvement.	
90. Council to promote rational use of medicines across the EU, promoting campaigns and educational programmes aimed at making citizens aware of the rational use of medicines, with the goal of avoiding overconsumption, in particular of antibiotics, and promoting the use of prescriptions by active principles by healthcare professionals and the generic medicines administration.	• The Pharmaceutical Strategy for Europe proposes to restrict and optimise the use of antimicrobial medicines and further promote the prudent use of antibiotics.	

Legend: ⚪ - Unknown; 🔴 - No action; 🟠 - Proposed; 🟡 - In preparation; 🟢 - Under implementation; 🟢 - Implemented.

Source: Technopolis, 2021.

3. MARKET

3.1. Summary of issues raised

Access to medicinal products is substantially shaped by how authorities incentivize and reward pharmaceutical innovation and how they offset this with measures to promote and protect competition within the market.

Development of medicines is a complex and high-risk undertaking: most candidate compounds that initially seem promising will eventually fail at some stage of clinical development, because they show insufficient efficacy, have safety issues or face other problems. The costs of conducting clinical research are also extremely high. Due to this combination of high risks and costs, late-stage development of medicines is mostly performed by well-resourced pharmaceutical and biotechnology companies. In exchange for their investment, companies and their shareholders expect to receive a significant financial return when a product has been successfully developed. The recouping of costs is made possible by intellectual property (IP) rights, which grant the Marketing Authorisation Holders (MAHs) a period of exclusivity on their product during which they are shielded from direct competition and are free to determine their own prices.

Whilst many believe that IP rights create the economic conditions that foster innovation, others have argued that true innovation requires competition and that IP rights actually reduce innovation[44]. In the Resolution, MEPs take the position that a stable and predictable intellectual property and regulatory framework, as well as the proper and timely implementation thereof, are essential to creating an innovation-friendly environment, thereby supporting patient access to innovative and effective treatments. Nonetheless, they expressed concerns about the abuse or misuse of such rights and welcomed the Council conclusions of 17 June 2016 inviting the Commission to conduct an analysis of the overall impact of IP on innovation as well as on the availability and accessibility of medicinal products.

The granting of IP rights creates a monopoly position that is meant to be temporary. After their expiry, the market is expected to rebalance itself through competition with the effect of driving down prices. Thus, whilst temporary monopoly rights may stimulate product development, access to affordable medicines benefits from a competitive market. Pharmaceutical companies, however, will naturally strive to maintain their monopoly positions for as long as possible, by using the IP framework to its fullest extent. Additionally, they sometimes engage in illegal forms of anti-competitive behaviour, such as 'pay for delay'[45]. Thus, MEPs note that the development of a healthy and competitive market for medicinal products necessitates vigilant competition law scrutiny to monitor and address cases where normal market dynamics have been deliberately distorted. Simultaneously, they encourage measures to support the introduction of biosimilars to the market to increase competition for biotherapeutic medicines.

A separate set of issues threatening the continued availability of medicines was created by the UK's withdrawal from the Union. Prior to this, trade between the UK and other Member States happened

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[44] For instance: Innovation, Intellectual Property, and Development: A Better Set of Approaches for the 21st Century. Baker D, Jayadev A, Stiglitz J (July 2017) , available at: https://cgt.columbia.edu/news/stiglitz-innovation-intellectual-property-development-better-set-approaches-21st-century/.

[45] Pharmaceutical Sector Inquiry Final Report: Competition between originator and generic companies – the issues. European Commission DG Competition (2009) , available at: https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

within the context of the European Single Market and the same rules and legal obligations applied. However, as of 1 January 2021, the UK (except for Northern Ireland[46]) is no longer bound by EU pharmaceutical law and trade relations are now dictated by the EU-UK Trade and Cooperation Agreement. A separate annex to the agreement covers medicinal products[47]. Under the agreement, the UK and the Union agree to mutually recognise inspections and accept each other's official Good Manufacturing Practice documents, whilst maintaining the right to conduct their own inspections; agree to endeavour to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures; agree to mutually respect intellectual property; and agree on the formation of a Working Group on Medicinal Products to support the implementation of the agreement.

3.2. Intellectual property & flexibilities

A substantial part of the current debate around access to medicines concerns the role of intellectual property protections and whether such protections are helpful or harmful for increasing access. The EU intellectual property framework for medicinal products consists of various protection mechanisms, each with its own criteria and duration of protection. Specifically, these are:

- Patents.
- Supplementary Protection Certificates (SPC)[48].
- Data and market protection.
- Paediatric extension to the SPC[49].
- Market exclusivity for orphan medicinal products.

Whilst some forms of protection run consecutively or are mutually exclusive, others may co-exist as illustrated in Figure 3. The full constellation of protection mechanisms defines the effective protection period on a product during which no generic or biosimilar competition can occur. In its 2017 resolution, MEPs expressed concerns that the EU IP framework limits access to medicines by unnecessarily delaying generic entry and enabling abuses of monopoly power. Simultaneously, they raised questions about whether the framework sufficiently incentivises pharmaceutical innovation in Europe. Consequently, they called on the Commission to "analyse the overall impact of IP on innovation on, and on patient access to, medicines, by means of a thorough and objective study, as requested by the Council in conclusions of 17 June 2016, and, in particular, to analyse in this study the impact of

[46] Northern Ireland will continue to be aligned to EU legislation and regulations in respect of medicines as a requisite of the Ireland/ Northern Ireland Protocol. This protocol has resulted in changes to regulations regarding medicines in relation to importation requirements and compliance with the EU Falsified Medicines Directive. The UK and EU agreed to a phased in approach of these regulatory requirements until 31 December 2021. Under the Protocol, new customs rules and procedures for the movement of medicines from Great Britain to Northern Ireland will apply from 1 January 2021. EU Exit – Frequently Asked Questions. Irish Department of Health, available at: https://www.health-ni.gov.uk/eu-exit-frequently-asked-questions, accessed on 03/06/2021.

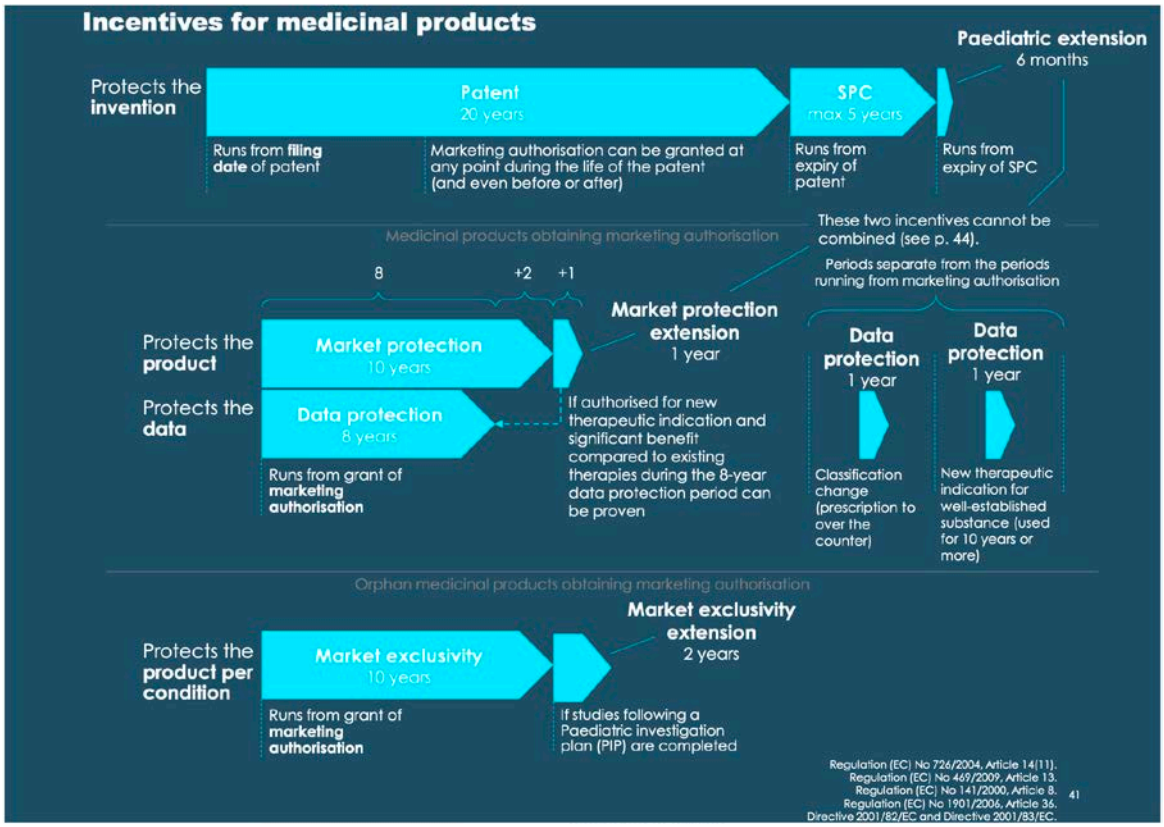
[47] Trade and cooperation agreement between the European Union and the European Atomic Energy Community, of the one part, and the United Kingdom of Great Britain and Northern Ireland, of the other part. Official Journal of the European Union L149, volume 64 (30 April 2021), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2021:149:FULL&from=EN, accessed on 03/06/2021.

[48] Supplementary Protection Certificates serve as an extension to a patent right, with a maximum period of five years, available at: https://ec.europa.eu/growth/industry/policy/intellectual-property/patents/supplementary-protection-certificates_en, accessed on 03/06/2021.

[49] A pharmaceutical product developer can receive an additional 6-month extension to the SPC for compliance with a Paediatric Investigation Plan (PIP) which outlines the additional clinical trial data that will be collected to determine if the medicine can be used safely and effectively in children. The paediatric SPC extension is mutually exclusive with the orphan market exclusivity. Marketing authorisation holders of orphan medicinal product can instead receive a 2-year extension of the orphan market exclusivity for compliance with the PIP, available at: http://data.europa.eu/eli/reg/2006/1901/oj, accessed on 03/06/2021.

supplementary protection certificates (SPCs), data exclusivity and market exclusivity on the quality of innovation and competition".

Figure 3: Overview of IP-based incentives for medicinal products in the EU



Source: Copenhagen Economics (2018)[50].

In 2017 the Commission contracted two studies on the EU system of IP-based incentives and rewards, in particular the SPC system. The first analysed the economic impact of SPCs, pharmaceutical incentives and rewards in Europe. The study was published in May 2018[50]. That same year, a separate study on the legal aspects of SPCs in the EU was published[51]. Together, these two studies formed the basis for the joint evaluation of the Regulation (EC 469/2009) concerning the SPCs for medicinal products and Regulation (EC 1610/96) concerning the creation of a SPC for plant protection products performed by the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW). The resulting Staff Working Document (SWD) was published in November 2020[52]. In it, the Commission concludes that "both SPC Regulations appear to support research on new active ingredients and are still fit for purpose (i.e. relevant) and coherent with the patent and related pharmaceutical legislation in the EU. Both SPC regulations appear to have brought EU added value." The evaluation could not establish a clear link between SPC protection and the location of R&D but suggested that the system

[50] Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe. Copenhagen Economics (2018) , available at: https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmaceuticals_incentives_study_en.pdf, accessed on 03/06/2021.

[51] Study on the legal aspects of supplementary protection certificates in the EU. Max Plank Institute for Innovation and Competition (2018), available at: https://op.europa.eu/en/publication-detail/-/publication/6845fac2-6547-11e8-ab9c-01aa75ed71a1/language-en/format-PDF/source-search, accessed on 03/06/2021.

[52] SWD(2020)292 – Evaluation of EU Regulations 469/2009 and 1610/96 on supplementary protection certificates for medicinal and plant protection products. European Commission (2020), available at: https://ec.europa.eu/docsroom/documents/43847, accessed on 03/06/2021.

can be particularly helpful for small or medium-sized enterprises (SMEs) and start-ups with fewer resources to invest in product development. It furthermore determined that the fact that SPCs are administered and managed at national level limits the effectiveness and efficiency of the system and that the overall transparency of the SPC system is suboptimal. The Commission indicates that the evaluation may facilitate future initiatives regarding the SPC legislation.

Separately, on 20 May 2019, an amending Regulation (2019/933) was adopted concerning the SPCs for medicinal products[53]. This amendment introduced a specific new exception called the manufacturing waiver. This waiver allows for the production of generic and biosimilar medicines that remain under SPC protection in the EU for the purpose of exporting them to countries without SPCs or where these have expired earlier. The amendment officially went into effect on 1 July 2019. SPCs that had already been granted prior to this date are not affected. The waiver is expected to contribute to greater access to medicines particularly in developing countries, as well as promote competitiveness of EU-based pharmaceutical companies in the global market. A 2017 study by Charles River Associates estimated that the SPC waiver could result in EUR 3.1 billion in savings to EU pharmaceutical spending[54]. The European trade association for the generics industry, Medicines for Europe, has also indicated that the waiver should enable generics companies to start providing to the EU market on the first day after expiry of the SPC rather than have to wait to start up EU manufacturing[55].

In November 2020, the Commission adopted a new Action Plan on Intellectual Property to support the EU's recovery and resilience[56]. In this, they comment on SPCs and also aim to look closely at how to further optimise incentives and rewards to boost innovation, address unmet needs, foster affordability by ensuring a swift market launch as well as a continuous supply of medicines, including generics and biosimilars. The action plan urges Member States to align their IP policies with the objectives set out.

Under the new EU-UK trade agreement, there are some provisions that both parties are expected to recognise in relation to IP protections, including SPCs and trade secrets, that are intended to "facilitate the production, provision and commercialisation of innovative and creative products and services [...]" and to "ensure an adequate and effective level of protection and enforcement of intellectual property rights"[57]. As both the Union (as well as individual Member States) and the UK are members of the World Trade Organization (WTO), they both remain bound by the agreements made in the WTO, as well as by other treaties they signed. However, the UK retains the flexibility to develop an IP system in line with its domestic priorities[58]. It is not yet clear how this may impact on the mutual recognition of IP rights and, consequently, on the availability of medicines protected in either territory by such rights.

As indicated, the EU IP framework recognises and awards other forms of IP rights, including the paediatric extension to the SPC and the market exclusivity for orphan medicinal products. The

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53 Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products. European Commission (2019) , available at: http://data.europa.eu/eli/reg/2019/933/oj, accessed on 03/06/2021.

54 Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe. Charles River Associates (2017), available at: https://op.europa.eu/en/publication-detail/-/publication/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1/language-en, accessed on 03/06/2021.

55 SPC Manufacturing waiver. Medicines for Europe, available at: http://www.spcwaiver.com/en/, accessed on 03/06/2021.

56 Making the most of the EU's innovative potential – An intellectual property action plan to support the EU's recovery and resilience. European Commission (2020) , available at: https://ec.europa.eu/docsroom/documents/43845, accessed on 03/06/2021.

57 The trade and Cooperation Agreement and its impact on IP, Pharma and Medical Devices. Herbert Smith Freehills (11 January 2021), available at: https://hsfnotes.com/ip/2021/01/11/the-trade-and-cooperation-agreement-and-its-impact-on-ip-pharma-and-medical-devices/, accessed on 03/06/2021.

58 UK-EU trade and cooperation agreement – Summary (December 2020), available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/962125/TCA_SUMMARY_PDF_V1-.pdf, accessed on 03/06/2021.

ParliamenResolution raises also over the extent to which these rights offer an appropriate balance between stimulating innovation and ensuring access. As discussed in more detail in Sections 4.3 and 4.4, revisions to the legislative framework under which these rights are provided are foreseen.

Even though Member States are expected to respect patent rights and other forms of IP that apply, since 1995 the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement) allows for patent flexibilities, such as compulsory licensing, in cases of urgent public health concerns. The Resolution contains a recommendation, calling on the Commission and Member States, to make use of these flexibilities and to coordinate and clarify their use when necessary. In turn, in the IP Action Plan, the Commission calls on the Member States "to ensure that effective systems for issuing compulsory licenses are in place"[56].

Compulsory licensing has received renewed attention during the COVID-19 pandemic, mainly in relation to global access to vaccines. In October 2020, India and South Africa introduced a proposal to the World Trade Organisation for a waiver of IP protections (TRIPS waiver) for COVID-19 vaccines[59]. Although the proposal garnered support of over 100 countries, the European Union, along with the United States and United Kingdom, opposed the proposal. However, on 5 May 2021, the United States Administration reversed its stance and announced it would support the waiver[60]. Although this announcement was met with great excitement by the global health community, the Commission and EU Member States maintained the position that IP protections were not the main obstacle for access. Instead, they flagged the lack of exports from, in particular, the United States as a bottleneck for access to vaccines. Under mounting public pressure, the Commission has since indicated that it is open to discuss with all WTO Members how to facilitate the implementation of the TRIPS Agreement flexibilities[61]. MEPs will debate a proposal for a COVID-19 TRIPS waiver on 19 May 2021 and a resolution is expected to be put to a vote in the first half of June[62].

3.3. Fair market conditions

A fair market for medicines is one in which pharmaceutical companies are granted monopoly rights only where these are justified, where parties do not abuse their dominant market position to charge excessive prices and where competition is not delayed or prevented by anti-competitive behaviours. Fair markets thus require a clear and common understanding of the legal constraints within which companies operate, but also pro-active monitoring thereof by competition authorities.

In the Resolution, MEPs warn against "the potential misuse of IP protection rules allowing the 'evergreening' of patent rights and avoidance of competition". The term evergreening is typically used to describe strategies for extending the protection on a medicinal product through accumulation of monopoly rights – such as secondary patents on formulations or new combinations of active ingredients, as well as other forms of exclusivity – beyond what could be considered fair and envisioned

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59 Waiver from certain provisions of the Trips agreement for the prevention, containment and treatment of COVID-19: Communication from India and South Africa. World Trade Organisations (2 October 2020) , available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True, accessed on 03/06/2021.

60 Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver. Office of the United States Trade Representative (5 May 2021), available at: https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver, accessed on 03/06/2021.

61 Statement by President von der Leyen at the joint press conference with President Michel and Prime Minister Costa following the informal meeting of EU Leaders and the EU-India leaders' meeting. European Commission (8 May 2021), available at: https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_21_2361, accessed on 03/06/2021.

62 Parliament to discuss call for waiver of COVID-19 vaccine patents. European Parliament Newsletter (17-20 May 2021), available at: https://www.europarl.europa.eu/news/en/agenda/briefing/2021-05-17/0/parliament-to-discuss-call-for-waiver-of-covid-19-vaccine-patents, accessed on 03/06/2021.

by law makers. This concern aligns with the call, detailed also in Section 3.2, on the Commission to analyse the impact of IP not only on innovation but also on the availability and accessibility of medicinal products. The aforementioned evaluation[52] by the Commission, however, focuses mainly on the role of the SPC system and not on the IP system as a whole or the interactions between different forms of IP. As such, it does not provide information on the extent to which the IP system affects access to medicines. Also the underlying study on the legal aspects of the SPC[51] is hesitant to draw any conclusions about whether the SPC system has encouraged evergreening, noting that the concept is not defined in law. Using survey responses, the study observes that most generic companies see a correlation between SPC Regulations and evergreening, but that originator companies disagree. There is some recent jurisprudence whereby the Court of Justice of the European Union (CJEU) has warned that SPCs should not be used to evergreen protection. For instance, in 2018 in a case brought by four generic manufacturers against Gilead Sciences concerning an SPC for the product Truvada®[63], the Court stated that: "to accept that an SPC could grant […] protection which goes beyond […] the invention it covers, would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health […]"[64].

The Resolution furthermore highlights specific concerns over abuse of market position. It calls on the Commission "to observe and reinforce the EU competition legislation and its competencies on the pharmaceutical market, as well as to continue and, where possible, intensify the monitoring and investigation of potential cases of market abuse". In response to these concerns, in 2019, the Commission published the report 'European competition authorities working together for affordable and innovative medicines' on competition enforcement in the pharmaceutical sector[65]. The report covered the period from 2009-2017, involving 29 antitrust decisions and over 100 other cases. It notes that European competition authorities together had imposed sanctions with fines totalling over EUR 1 billion. Whilst the report is mostly summative, it concludes that the past enforcement record "provides a solid basis for competition authorities to build on and continue their commitment to rigorously enforce competition law in the pharmaceutical sector in the future" and emphasizes that ensuring effective competition law will remain a priority for the Commission. In this regard, the report stresses that the national competition authorities of the Member States are fully empowered to apply Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU)[66].

The Resolution additionally called on the Commission and the CJEU "to clarify, in accordance with Article 102 TFEU, what constitutes an abuse of a dominant position by charging high prices". In April 2018, the CJEU issued a ruling in case C-525/16, involving alleged price discrimination[67]. Whilst the case involved parties from the media sector rather than pharmaceutical companies, in its ruling the CJEU

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63 A product used for the treatment and prevention of HIV.

64 Judgement of the Court (Grand Chamber) in Case C-121/17. Court of Justice of the European Union (25 July 2018), available at: https://curia.europa.eu/juris/document/document.jsf?text=&docid=204388&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=593243, accessed on 03/06/2021.

65 Competition Enforcement in the Pharmaceutical Sector (2009-2017): European competition authorities working together for affordable and innovative medicines. European Commission (2019), available at: https://ec.europa.eu/competition/publications/reports/kd0718081enn.pdf, accessed on 03/06/2021.

66 Article 101 of the TFEU prohibits trade practices between EU countries which could prevent, restrict or distort competition (see: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:l26114, accessed on 03/06/2021). Article 102 of the TFEU states that any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States, available at: http://data.europa.eu/eli/treaty/tfeu_2008/art_102/oj, accessed on 03/06/2021.

67 Judgment of the Court (Second Chamber) in case C-525/16. Court of Justice of the European Union (19 April 2018), available at: https://curia.europa.eu/juris/document/document.jsf?text=&docid=201264&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=38862, accessed on 03/06/2021.

provided general guidance in assessing the validity of discriminatory pricing practices under EU rules[68]. It indicated that discriminatory pricing is abusive only where it "tends to distort competition", meaning that abusive practices can only be considered as such on the basis of an analysis of their effects. Later that same year, in November 2018, the European Union contributed a note on excessive pricing in pharmaceutical markets for the 130th meeting of the Organisation for Economic Co-operation and Development (OECD) Competition Committee meeting[69]. The note uses case law to describe accepted methods for establishing whether prices are excessive and unfair, using price-cost tests or comparator tests.

One particular area where the Parliament has expressed concerns about abusive pricing is in the repurposing of medicines. Repurposing refers to the use of medicines for new indications other than those for which they have been originally approved. It is most commonly used in the treatment of rare diseases. To incentivise research on existing, often off-patent, medicines, the Regulation on orphan medicinal products[70] offers market exclusivity if a developer is able to demonstrate that the medicine also offers clinical benefit and is safe for use in treatment of a rare disease. This gives the marketing authorisation holder a monopoly position, even if the medicine had already been in well-established use for the condition. This, in turn, enables the marketing authorisation holder to raise the medicine's price even if a version of it had previously been used off-label. For well-established use products developers can obtain authorisation without having to submit results of preclinical tests or clinical trials and the development costs are consequently much lower than for new active substances. This situation, whereby the costs made by a developer can be minimal but the financial rewards substantial, has raised questions whether this is a desirable situation.

The study to support the evaluation of the Regulation on orphan medicinal products assessed how often market exclusivity has been granted to products with demonstrated well-established use[71]. It found this to be the case in only 4% of all authorised orphan medicines but recognised that some repurposed medicines had been authorised as new active substances, obscuring the full extent of the practice. Although the study provided anecdotal evidence of practices of alleged abusive pricing of repurposed medicines, neither this study, nor any other study has looked in-depth at the relation between repurposing and pricing.

3.4. Generic and biosimilar competition

As highlighted, the entry of generic and biosimilar[72] medicines provides the impetus for reduction of the price of a medicine and thereby alleviates pressure on healthcare budgets whilst promoting access. Simultaneously, increased competition can spur on innovation, as companies are encouraged to improve their existing products to differentiate themselves from others. It is therefore important that there are no undue impediments to the timely introduction of such products to the market once

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68 C-525/16 MEO: CJEU on Price Discrimination under Article 102 TFEU. Gugliotta L, European Law Blog (21 June 2018), available at: https://europeanlawblog.eu/2018/06/21/c-525-16-meo-cjeu-on-price-discrimination-under-article-102-tfeu/, accessed on 03/06/2021.

69 Excessive prices in pharmaceutical markets – Note by the European Union. OECD (28 November 2018), available at: https://one.oecd.org/document/DAF/COMP/WD(2018)112/en/pdf, accessed on 03/06/2021.

70 Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products as amended by Regulation (EC) No 596/2009 and Regulation (EU) 2019/1243, available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:32000R0141, accessed on 03/06/2021

71 Study to support the evaluation of the Regulation on orphan medicinal products. Technopolis Group. (July 2019), available at: https://ec.europa.eu/health/sites/health/files/files/paediatrics/docs/orphan-regulation_study_final-report_en.pdf, accessed on 03/06/2021.

72 The EMA defines biosimilar medicines as "biological medicine highly similar to another already approved biological medicine (the "reference medicine"), available at: https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview, accessed on 03/06/2021.

protections on the reference product have expired. Concerns have been raised over practices where generic or biosimilar entry is delayed due to such practices as 'pay for delay'. This practice means that innovators offer generic manufacturers some form of value (such monetary payment or licensing rights) to postpone their market entry. Pay-for-delay agreements may be part of patent dispute settlement. However, as delayed generic competition means a longer period of high prices and reduced access to medicines for patients, these type of arrangements are controversial and may be considered in violation of EU competition law.

In the Resolution, MEPs ask the Commission and Member States to monitor "unfair practices in accordance with Articles 101 and 102 TFEU, and to present a biannual report in this regard", as well as monitor "patent settlement agreements between originator and generic industry that may be misused to restrict the market entry of generics". The aforementioned 2019 report by the Commission on competition enforcement summarises several cases where national competition authorities brought suit against companies that engaged in alleged anti-competitive behaviour through pay-for-delay agreements[65]. The report also describes various other practices hindering market entry of generic medicines, such as misuse of the regulatory framework, and disparaging generics to curb demand. The Commission has not yet announced any plans to follow up on this report to cover the period after 2019.

More generally, in the Resolution MEPs asked the Commission "to set up a framework to promote, guarantee and reinforce the competitiveness and use of generic and biosimilar medicines". The new Pharmaceutical Strategy for Europe[3], along with the IP Action Plan[56], proposes to review the pharmaceutical legislation to address market competition considerations and thus improve access to generic and biosimilar medicines. This will include strengthening and harmonising between Member States the 'Bolar exemption'. This exemption allows third parties, including generics manufacturers, to use a still-patented invention for research and testing purposes. This is necessary for the development and subsequent authorisation of generic versions. The exemption thus allows for timelier entry to market for generics. This review, together with an evaluation of the current pharmaceutical legislation, will be initiated in 2021.

In promotion of access to generic and biosimilar medicines, the Resolution asks the Commission "to revise the Transparency Directive with a focus on guaranteeing timely entry into the market for generic and biosimilar medicines, ending patent linkage according to the Commission's guidelines". Patent linkage refers to the relationship between the market approval of a generic medicine and the patent status of its branded equivalent[73]. Under patent linkage, a generic manufacturer seeking an approval must attest to the responsible regulatory body that its product does not infringe on any patent rights of the MAH of the reference product and must notify that MAH accordingly. Whilst originator companies consider patent linkage a way of ensuring that regulatory bodies do not promote patent infringement, it has the effect of deterring and delaying generic competition. Although under EU law patent linkage is not allowed, forms of the practice have continued to occur in some Member States, prompting the call issued in the Resolution. In November 2020, Medicines for Europe – which represents the interests of the EU's generic medicines industry – published a white paper with a review of barriers to generic and biosimilar market entry[74]. It herein notes that, whilst the Commission's view on patent linkage is clear, in various Member States patent status remains linked to decisions on pricing and reimbursement approval, to the ability to be included in product or prescription listings or to

[73] Patent linkage: Balancing patent protection and generic entry. DrugPatentWatch blog page, available at: https://www.drugpatentwatch.com/blog/patent-linkage-resolving-infringement/, accessed on 03/06/2021.

[74] Anatomy of a Failure to Launch: a review of barriers to generic and biosimilar market entry and the use of competition law as a remedy. Vidal R, Drew C, Lavin B, Ellis B and Bruce W, Legal Affairs Committee of Medicines for Europe (2020), available at: https://www.medicinesforeurope.com/docs/2020.11.04-Medicines-for-Europe-Whitepaper.pdf, accessed on 03/06/2021.

possibility to participate in tenders. As described in more detail in Section 5.3, the Commission has not yet taken any steps towards the revision of the Transparency Directive.

In its recommendations pertaining to timely entry into the market for generic and biosimilar medicines, the Resolution asks for consideration of accelerated pricing and reimbursement decisions for generics and precluding the multiple reassessments of the elements supporting marketing authorisation. These recommendations are echoed in a 2018 report by Medicines for Europe on country specific market access policies[75]. This report details different policy approaches countries have taken to increase access to generic and biosimilar medicine and offers country specific recommendations to further promote this.

[75] Medicines for Europe: country specific market access policies. Medicines for Europe (2018) , available at: https://www.medicinesforeurope.com/wp-content/uploads/2018/05/20180524-Medicines-for-Europe-recommendations_V1.0.pdf, accessed on 03/06/2021.

3.5. Summary of identified actions

Table 2: Summary table – Market

Recommendation	Actions taken	Status
55. Notes that the repurposing of existing drugs for new indications can be accompanied by a price increase; asks the Commission to collect and analyse data on price increases in cases of drug repurposing and to report back to Parliament and to the Council on the balance and proportionality of the incentives that encourage industry to invest in drug repurposing.	Analysis of orphan market exclusivity for repurposed medicines included in the study to support the evaluation of the Regulation on orphan medicinal products. No systematic collection of data or reporting on the issue.	
57. Calls on the Commission to revise the Transparency Directive with a focus on guaranteeing timely entry into the market for generic and biosimilar medicines, ending patent linkage according to the Commission's guidelines […].	No new steps taken to revise Transparency Directive Patent linkage is prohibited under EU law, but forms of it have been reported at Member State level.	
72. Calls on the Commission to analyse the overall impact of IP on innovation on, and on patient access to, medicines, by means of a thorough and objective study, as requested by the Council in conclusions of 17 June 2016, and, in particular, to analyse in this study the impact of supplementary protection certificates (SPCs), data exclusivity and market exclusivity on the quality of innovation and competition.	Independent study on supplementary protection certificates, pharmaceutical incentives and rewards completed in 2018.	
80. Calls on the Commission and the Member States to set up a framework to promote, guarantee and reinforce the competitiveness and use of generic and biosimilar medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 TFEU, and to present a biannual report in this regard; calls as well on the Commission to monitor patent settlement agreements between originator and generic industry that may be misused to restrict the market entry of generics.	The Pharmaceutical Strategy for Europe and the IP Action Plan propose to review the pharmaceutical legislation to improve access to generic and biosimilar medicines, including by strengthening and harmonising the 'Bolar exemption'. In 2019, the Commission published a summary report on 'Competition Enforcement in the Pharmaceutical Sector (2009-2017)'. Not known whether this report will be updated in 2021.	

Recommendation	Actions taken	Status
81. Calls on the Commission to continue and, where possible, to intensify the monitoring and investigation of potential cases of market abuse, including so-called 'pay for delay', excessive pricing and other forms of market restriction specifically relevant to the pharmaceutical companies operating within the EU, in accordance with Articles 101 and 102 TFEU.	In 2019, the Commission published a summary report on 'Competition Enforcement in the Pharmaceutical Sector (2009-2017)'. Not known whether this report will be updated in 2021.	
82. Calls on the Commission to introduce an SPC manufacturing waiver to Regulation (EC) No 469/2009 allowing the production of generic and biosimilar medicines in Europe, with the purpose of exporting them to countries without SPCs or where these have expired earlier, without undermining the exclusivity granted under the SPC regime in protected markets […].	On 20 May 2019, amending Regulation (2019/933) was adopted, introducing an SPC manufacturing waiver.	
83. Calls on the Commission to observe and reinforce the EU competition legislation and its competencies on the pharmaceutical market in order to counter abuse and promote fair prices for patients.	The Commission indicates that Member States are fully empowered to apply Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU).	
96. Calls on the Commission and national antitrust authorities to monitor unfair practices with a view to protecting consumers from artificially high prices on medicines.	The 2019 Commission report on competition enforcement summarises where national antitrust authorities have undertaken action against companies deemed to engage in unfair practices. This will be an ongoing activity.	
97. Calls on the Commission and the Court of Justice of the European Union to clarify, in accordance with Article 102 TFEU, what constitutes an abuse of a dominant position by charging high prices.	In its 2018 ruling in case C-525/16, the CJEU clarified its interpretation of abuse of dominant position. Newer case law may continue to evolve this interpretation.	
98. Calls on the Commission and the Member States to make use of the flexibilities under the WTO TRIPS agreement and to coordinate and clarify their use when necessary.	The IP Action Plan calls on Member States to ensure that effective systems for issuing compulsory licenses are in place. In the context of COVID-19, the EU has signalled readiness to discuss (temporary) lifting of IP protections.	

Legend: ⚪ - Unknown; 🔴 - No action; 🟠 - Proposed; 🟡 - In preparation; 🟢 - Under implementation; 🟢 - Implemented.

Source: Technopolis, 2021.

4. RESEARCH, DEVELOPMENT & INNOVATION

4.1. Summary of issues raised

Without research and development (R&D) the pipeline of innovative medicines will run dry, to the detriment of patients whose needs are insufficiently met by the range of products currently available. The development of medicines is a very expensive undertaking that requires a combination of public and private investment. The Commission is a major funder of R&D, supporting the full spectrum from fundamental research on disease aetiology to late-stage clinical trials for innovative medicines. EU funding is provided through the EU Framework Programmes for research and innovation, as well as through a variety of corporate subsidies and incentives. The Resolution explicitly recognises the role of the Horizon 2020 programme and of European research projects and SMEs in supporting the development of medicines. However, it also notes that development has lagged in specific areas and that consideration should be given to how best to incentivise innovation in such areas of unmet need.

One area where MEPs note a need for greater innovation is in the field of new antimicrobial medicines to tackle the emerging antimicrobial resistance (AMR) crisis. The Resolutions expresses concern over the fact that, despite a growing number of deaths due to infections caused by resistant bacteria, only one novel class of antibiotics has been developed in the past 40 years. It also draws attention to the rise of multidrug-resistant tuberculosis.

A second area of unmet need highlighted in the Resolution is that of medicinal products for the treatment of rare diseases, known also as orphan medicines. It is indicated that, although Regulation (EC) No 141/2000 on the development of orphan medicines[76], which has the purpose to stimulate the development of new medicines for treatment of rare diseases, has provided an important framework for promoting research on orphan medicines, there are concerns about its application, particularly in regard to the designation criteria and the balance between incentives and rising costs.

The Resolution furthermore observes that Regulation (EC) No 1901/2006 on paediatric medicines has not proven effective in driving innovation in medicines for children, particularly in the fields of oncology and neonatology. It thus calls on the Commission to examine existing obstacles and to propose measures to promote advancement in this area, including by promoting initiatives for guiding public and private-sector research towards the field. It simultaneously calls on the Commission to amend the legislation by revising the criteria for allowing a Paediatric Investigation Plan (PIP) waiver and by ensuring that PIPs are implemented early in a medicine's development.

A specific category of products where MEPs feel there has been insufficient development concerns that of advanced therapy medicinal products (ATMPs). The Resolution states that, although Regulation (EC) No 1394/2007 on advanced therapy medicinal products was introduced to promote EU-wide innovation in this area while ensuring safety, only eight novel therapies had been approved to date. The Commission is thus called on to take further action to foster the development of, and patient access to, ATMPs.

The Resolution additionally contains calls on the Commission and Member States to promote independent research in areas of public health interest that are insufficiently addressed by commercial research and to patient populations normally excluded by clinical studies, such as children, pregnant

[76] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products as amended by Regulation (EC) No 596/2009 and Regulation (EU) 2019/1243, available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:32000R0141, accessed on 03/06/2021.

women and the elderly. Simultaneously, it highlights the importance of both public and private R&D efforts in discovering new treatments and stresses that research priorities must address patients' health needs.

Alongside calls for increased focus on development of medicines in areas of unmet need, the Resolution emphasises concerns over rising prices of innovative medicines that have been developed in part with public investment. It contains a recommendation to the Commission and the Member States to ensure the public a health return on public investment, and to introduce conditional funding based on non-exclusive licencing and affordable medicines.

4.2. Antimicrobial resistance (AMR) / One Health

Antimicrobial resistance is an urgent and growing global threat. Microorganisms, such as bacteria, fungi, viruses and parasites, continuously and rapidly evolve and, when exposed to medicine, may develop resistance. When bacteria lose sensitivity to antibiotics this increases the risk of people dying from previously harmless infectious diseases. The fight against AMR is also addressed in the Resolution and it calls upon the Commission to increase its activities targeting AMR and to promote R&D for novel anti-microbicides. Moreover, a new and comprehensive EU Action Plan to combat AMR, based on the One Health approach, was requested. The One Health approach reflects the combined efforts of multiple disciplines on local, national and global level to achieve optimal health for people, animals and the environment.

In June 2017, the Commission adopted the EU One Health Action Plan against AMR[77]. This Action Plan provides a framework for the actions the Commission will take against AMR, specifically to make Europe a best-practice region, to boost R&D on AMR, to shape the global agenda and to monitor the effectiveness and performance of the actions taken. In 2020, a progress report on the AMR Action Plan was published, which highlighted concrete activities that have been, or are expected to be, carried out[78]. Essential activities that have been completed are:

- The adoption of the new legislation on the monitoring and reporting of AMR in zoonotic and commensal[79] bacteria[80].
- Adoption of the new regulation on safe and effective veterinary medicinal products[81].
- The development of the OECD model to help Member States in assessing the economic burden that AMR imposes on people and the effectiveness of national policies to reduce this.
- The development of EU guidelines for the prudent use of antibiotics.

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77 A European One Health Action Plan against Antimicrobial Resistance (AMR), European Commission, April 2017, available at: https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf, accessed on 03/06/2021.

78 Progress Report 2017 EU AMR Action Plan (Update 2020), European Commission, Q4 2020, available at: https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2018-2022_actionplan_progressreport_en.pdf, accessed on 03/06/2021.

79 A commensal is an organism that uses food supplied in the internal or the external environment of the host, without establishing a close association with the host, available at: https://www.sciencedirect.com/topics/immunology-and-microbiology/commensal accessed on 03/06/2021.

80 Implementing Decision (EU) 2020/1729 of 17 November 2020 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Implementing Decision 2013/652/EU, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32020D1729&from=EN, accessed on 03/06/2021.

81 Regulation (EU) 2019/6 of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0006&from=EN, accessed on 03/06/2021.

- The launch of calls, and reporting of projects, on AMR addressing topics such as the clinical management of AMR, new diagnostic and intervention tools on AMR, early signalling and assessing of zoonotic threats and preventive vaccines.
- Active contribution to the development of standards and guidelines in cooperation with the World Health Organization, the World Organisation for Animal Health, the Food and Agriculture Organization of the United Nations, and the FAO/WHO Codex Alimentarius[82].
- Drawing continuous political attention and commitment to AMR and related activities.

In 2018 the Global AMR R&D Hub was established[83]. This global partnership includes 17 countries, the Commission and philanthropic foundations. The initiative acts as knowledge centre for R&D in the field of AMR. It aims to provide guidance and support in evidence-based decision making on AMR-related issues by helping set priorities and maximise impact of all resources invested in R&D to combat AMR. Moreover, the initiative aims to strengthen collaboration and coordination, and create awareness and knowledge on AMR.

The Commission states in its Pharmaceutical Strategy for Europe that it aims to provide pull incentives for novel antimicrobials by means of piloting innovative approaches to R&D and public procurement for antimicrobials and their alternatives. The new EU Health Emergency Response Authority (HERA), which is expected to become operational in the third quarter of 2021, will be one of the flagship initiatives of the Commission's strategy aimed at combatting antimicrobial resistance. Already prior to the start of HERA's operations, the Commission will promote investment and coordinate R&D, manufacturing, deployment, and use of novel antibiotics[3]. The restriction and optimisation of use of antimicrobial medicines are covered under the policy options that are outline in the Commission's inception impact assessment for the revision of the general pharmaceutical legislation, which is expected to be formalised by the end of 2022[84].

To further achieve the objectives of the European One Health Action Plan against AMR, as well as the WHO Global Action Plan on AMR, a co-funded European Partnership focused on One Health/AMR has been proposed under Horizon Europe. Calls under this programme are expected to open in 2023[85]. The initiative aims to coordinate and align activities and funding amongst countries as well as with the Commission. Additionally, the Partnership should facilitate national coherence between different actors responsible for various aspects of AMR, such as human health, agriculture, environment, industry and finances.

4.3. Rare diseases

As pharmaceutical product development largely trends with commercial potential, patients with rare diseases typically have far less access to medicines than patients with more common conditions. In 2000, European Member States adopted Regulation 141/2000 on orphan medicinal products (the 'Orphan Regulation')[86]. The Orphan Regulation provides product developers a period of market

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82 FAO/WHO Codex Alimentarius Commission, available at: http://www.fao.org/fao-who-codexalimentarius/en/, accessed on 03/06/2021.

83 Global AMR R&D Hub: About. (2021), available at: https://globalamrhub.org/about/, accessed on 03/06/2021.

84 Revision of the EU general pharmaceuticals legislation: inception impact assessment. European Commission (2021) , available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en, accessed on 03/06/2021.

85 Horizon Europe: the next generation of European partnerships. European Commission (18 March 2021) , available at: https://op.europa.eu/en/publication-detail/-/publication/3f2505fb-8864-11eb-ac4c-01aa75ed71a1, accessed on 03/06/2021.

86 Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products as amended by Regulation (EC) No 596/2009 and Regulation (EU) 2019/1243, available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:32000R0141, accessed on 03/06/2021.

exclusivity for authorised products with a confirmed orphan designation. A product is eligible for such a designation if a developer can establish:

- That it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the Community when the application is made; or
- That it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Community and that without incentives it is unlikely that the marketing of the medicinal product in the Community would generate sufficient return to justify the necessary investment.

And:

- That there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition.

Since the introduction of the Regulation the number of orphan medicines on the market in the EU has grown considerably. As of 2020, 150 OMPs had been approved in the EU[87]. However, the rise in OMPs has been accompanied by concerns over aspects of the application of the Regulation. In its Resolution, MEPs called on the Commission to evaluate the implementation of the regulatory framework for orphan medicines (especially as regards the concept of unmet medical need), to provide guidance on priority unmet medical need, to evaluate existing incentive schemes to facilitate the development of effective, safe and affordable medicines for rare diseases compared to the best available alternative, to promote the European register of rare diseases and reference centres, and to ensure the legislation is correctly implemented.

In 2019, a study to support the evaluation of the Orphan Regulation was conducted[71]. The report found that development of new OMPs had increasingly clustered around a limited number of therapeutic areas and indications, calling into question whether the market exclusivity incentive remains needed in areas where the market appears to provide for sufficient economic stimuli. By contrast, for the vast majority of rare diseases no products have been developed. This, in turn, gave rise to the suggestion that other forms of incentives or a differentiation of incentives may be needed to draw innovation to areas of greatest unmet need. The evaluation furthermore noted that the regulatory framework may not be sufficiently fit-for-purpose in the face of new scientific and regulatory developments. It also observed significant inequities in access to OMPs across the Member States, though noted that these are largely the result of forces beyond the control of the Orphan Regulation.

The conclusions were supported by the Commission's joint evaluation of the paediatric and orphan regulations published in 2020[88]. As a result, the Commission is proposing revisions to both regulations. In November 2020, the Commission initiated a public consultation on the inception impact assessment (IIA) for these revisions. The IIA offers four options, each building on the previous with progressively radical changes to the eligibility criteria and incentives available. Each option includes elements to foster development in areas of greatest unmet medical needs, to improve availability and accessibility

[87] Orphan medicines Figures 2000-2020. European Medicines Agency, available at: https://www.ema.europa.eu/en/documents/other/orphan-medicines-figures-2000-2020_en.pdf, accessed on 03/06/2021.

[88] Commission Staff Working Document: Joint evaluation of Regulation (EC) No 1901/2006 of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 141/2000 of 16 December 1999 on orphan medicinal products. European Commission (2020), available at: https://ec.europa.eu/health/sites/health/files/files/paediatrics/docs/orphan-regulation_eval_swd_2020-163_part-1.pdf, accessed on 03/06/2021.

across Member States and for more flexible criteria for designation to accommodate for scientific developments[89]. The public consultation was closed in January 2021. A legislative proposal on the revisions, taking into account the outcomes of the consultation, is expected in the first quarter of 2022.

Since the UK is no longer part of the Union, it is no longer a party to the Regulation on orphan medicinal products. It has since announced the introduction of a new UK-wide orphan marketing authorisation. The designation criteria mirror those that are currently used for EU orphan designation, except that they are based on disease prevalence in Great Britain and the absence of other satisfactory treatments there[90]. The UK will likewise grant designated orphan medicines a period of 10-year market exclusivity upon authorisation. It will, however, not offer free protocol assistance or scientific advice. As the scheme has only just been introduced, it is unclear how it will impact on the development and availability of medicines for rare diseases, both for patients in the UK and those in the Union.

4.4. Paediatric medicine

One particular patient group for whom access to medicines is often problematic is formed by children. Because children represent a relatively small part of the population and clinical research in children is complicated for multiple reasons, pharmaceutical companies tend to prioritise the development of medicines for which there is a substantial adult population. As a result, physicians have few approved treatment options for children and frequently have to resort to off-label use.

The Paediatric Regulation 1901/2006[91] was enacted in 2007 to encourage development of suitable medicines for children, promote high quality research, improve the information available on the use of medicines in children, and to prioritise the therapeutic needs in this group. It combined new legal obligations with economic rewards for product developers, with the intent of stimulating research, innovation and medicinal product development. For marketing authorisation of any new (including adult) medicine, companies have to develop a 'paediatric investigation plan' (PIP) and conduct studies to gather data on whether the medicine is safe and effective for use in children. If a PIP is completed, the Regulation provides a developer with economic benefits through an extension of the Supplementary Protection Certificate or prolonged market exclusivity for the product.

A 2016 study on the economic impact of the Paediatric Regulation, including its rewards and incentives concluded that the Regulation had led to an increase in the amount and quality of research and information available for use of medicines in children and that the share of paediatric trials had increased[92]. However, it also noted that therapeutic areas remained where significant unmet need continues to exist, such as in the field of paediatric oncology. This observation is echoed in the Resolution which observes that the regulation has not been sufficiently effective in driving innovation in medicines for children, namely in the fields of oncology and neonatology and calls on the Commission to examine existing obstacles and to propose measures to promote advancement in this area.

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89 Inception Impact Assessment for the revision of the EU legislation on medicines for children and rare diseases. European Commission (2020), available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12767-Revision-of-the-EU-legislation-on-medicines-for-children-and-rare-diseases, accessed on 03/06/2021.

90 Orphan medicinal products – Guidance. UK Medicines and Healthcare products Regulatory Agency (31 December 2020), available at: https://www.gov.uk/guidance/orphan-medicinal-products-in-great-britain, accessed on 03/06/2021.

91 Regulation (EC) No 1901/2006 of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004. European Commission (2006), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32006R1901, accessed on 03/06/2021.

92 Study on the economic impact of the Paediatric Regulation, including its rewards and incentives. Technopolis Group (2016), available at: https://ec.europa.eu/health/sites/health/files/files/paediatrics/docs/paediatrics_10_years_economic_study.pdf, accessed on 03/06/2021.

The joint evaluation of the regulations for medicines for children and rare diseases published by the Commission in 2020 underwrites the conclusions of the 2016 independent study. It confirms an increase in the number of paediatric products authorised after the adoption of the regulation and improved data availability, but also finds that the regulation has not been an effective instrument for channelling R&D into specific therapeutic areas[88]. In the aforementioned IIA for the joint revision of the EU legislation on medicines for children and rare diseases four policy options have been articulated for the revision of the Paediatric Regulation[89]. As with the Orphan Regulation, the proposed options build on each other with all options including steps to improve identification of unmet medical needs in children, to address issues related to availability and access to medicines and to tackle current inefficiencies. Along with proposed changes in the eligibility for the 6-month SPC extension, the options provide for the formulation of other rewards for medicines that address unmet needs for children. As noted previously, a legislative proposal on the revisions, taking into account the outcomes of the public consultation, is expected in the first quarter of 2022.

As of 1 January 2021, the UK MHRA will decide on its own requirements for paediatric investigations for new medicines whilst still recognising decisions made by the EMA before this date[93]. It is unclear if the UK will offer any incentives for completing paediatric investigations of its own.

4.5. Advanced Therapeutic Medicinal Products (ATMPs)

Advanced Therapeutic Medicinal Products (ATMPs) are medicines for advanced therapy, such as cell- and gene therapy. ATMPs have a great potential for the treatment of serious and rare diseases which currently remain untreated or where limited treatment options exist. So far, though, only a small number of ATMPs have been authorised in the EU. In response to this, the Resolution calls asks the Commission to take further action to foster the development of and access to ATMPs.

In October 2017, the Commission and the EMA published a joint action plan on ATMPs[94]. The action plan is intended to align activities and better address the specific requirements of ATMP developers. As part of this joint action plan, in 2018 the EMA published an update to the procedural advice on the evaluation of ATMPs[95]. In the same year, it revised the guideline on safety and efficacy follow-up and risk management of ATMPs, which takes into account the growing experience in authorisation of ATMPs and includes advice on appropriate post-authorisation study design and early risk detection during development[96]. Furthermore, the EMA has published a strategic reflection on its future regulatory science strategy until 2025[97]. Part of the core recommendations of this reflection is the

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93 Procedures for UK Paediatric Investigation Plans (PIPs). UK Medicines and Healthcare products Regulatory Agency (31 December 2020), available at: https://www.gov.uk/guidance/procedures-for-uk-paediatric-investigation-plan-pips, accessed on 03/06/2021.

94 European Commission DG Health and Food Safety and European Medicines Agency Action Plan on ATMPs, EMA/European Commission, n.d., available at: https://www.ema.europa.eu/en/documents/other/european-commission-dg-health-food-safety-european-medicines-agency-action-plan-advanced-therapy_en-0.pdf, accessed on 03/06/2021.

95 Procedural advice on the evaluation of advanced therapy medicinal product in accordance with Article 8 of Regulation (EC) No 1394/2007, EMA, January 2018, available at: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-advice-evaluation-advanced-therapy-medicinal-product-accordance-article-8-regulation-ec/2007_en.pdf, accessed on 03/06/2021.

96 Guideline on safety and efficacy follow-up and risk 6 management of Advanced Therapy Medicinal Products, EMA, January 2018, available at: https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-safety-efficacy-follow-risk-management-advanced-therapy-medicinal-products-revision_en.pdf, accessed on 03/06/2021.

97 EMA Strategic reflection on EMA Regulatory Science to 2025, EMA, 2020, available at: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf, accessed on 03/06/2021.

support of the translation of ATMPs into clinical practice. The actions, as proposed by the EMA, that underly this translation are targeting:

- Increased awareness of ATMPs.
- Identification of therapies that target unmet medical needs.
- Support of evidence generation.
- Assistance in planning, development, and clinical evaluation.
- Decentralised ATMP manufacturing and delivery.
- Fostering of global convergence.
- Strengthening of interaction with European institutions.

The EMA reflection was an important element in the development of the next European Regulatory Network Strategy to 2025, in cooperation with Member States, the Commission and EMA stakeholders and was adopted in 2020[98].

4.6. Research for underserved populations

Inequality in access to medicines across populations is a public health concern. Often, research areas that are of interest to national health services are insufficiently picked up by commercial research because of economical unattractiveness. Various European initiatives exist or are planned to promote independent research in these fields of research. To keep momentum, in the Resolution, MEPs urge Member States to build on existing examples to promote research in these areas. Furthermore, Member States are requested to build on other existing initiatives that promote research in areas of interest to underserved populations normally excluded in clinical studies, such as children, pregnant women and elderly. At the level of the Commission no specific activities were identified that are specifically aimed at stimulating research in such underserved populations beyond those discussed in Section 4.4 in relation to paediatric medicines. No information was available on whether Member States have independently heeded this call.

In order to solve gender inequality in research and development and aim for fairer access for male as well as female patients, the Resolution called upon the Commission to promote public- as well as private sector research into pharmaceutical products for female patients. In line with this, the Pharmaceutical Strategy for Europe underlines that clinical trial design should be tailored to represent the populations affected by the outcome, taking into account gender and age[99]. However, no further concrete actions have yet been identified.

[98] European medicines agencies network strategy to 2025, EMA & HMA, 2020, available at: https://www.ema.europa.eu/en/documents/report/european-union-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf, accessed on 03/06/2021.

[99] Communication on a Pharmaceutical Strategy for Europe, COM(2020) 761, European Commission, November 2020, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761, accessed on 03/06/2021.

4.7. Focus on unmet needs

Alongside the specific areas of unmet need described in the preceding five paragraphs (4.2 to 4.6), the Resolution urges for a greater linkage between public investment in research and unmet needs. Several of the calls on the Commission and the Member States should be seen against this background, namely calls:

- "to foster R&D driven by patients' unmet needs, […] by coordinating public resources for healthcare research in an effective and efficient manner, and by promoting the social responsibility of the pharmaceutical sector";
- "to build on the example of existing initiatives in the EU aimed at promoting independent research in areas of interest to national health services that are insufficiently addressed by commercial research […]";
- "for the framework conditions in the areas of research and medicine policy to be established in a way that promotes innovation, particularly against diseases, […] that cannot yet be treated to a satisfactory degree"; and
- "to enhance dialogue on unmet medical needs between all relevant stakeholders, […] throughout the life spans of medicines".

In the more detailed elaboration of these calls, several refer to areas already discussed, such as AMR. More importantly, however, they reflect a sense that public investment should not be directed too much towards areas where sufficient commercial potential exists to attract private investment. Rather, public money should be used to support R&D where industry has been reluctant to engage. The Pharmaceutical Strategy for Europe signals the Commission's agreement with this stance, indicating that policies are needed to stimulate innovation in areas of unmet needs and that pharmaceutical innovation should become more patient-centred, health system oriented and take account of multi-disciplinary requirements[3]. The Pharmaceutical Strategy hereto indicates the Commission's actions for a reflection on how to tailor the system of incentives to stimulate innovation in areas such as neurodegenerative and rare diseases and paediatric cancers. The proposed revision of the regulations for medicines for rare diseases and children, described respectively in Sections 4.3 and 4.4, are part of this action.

Additionally, the Pharmaceutical Strategy indicates that it expects to contribute to greater attention for areas of unmet need by promoting collaboration between regulators, HTA bodies and payers on defining unmet needs and evidence generation. The ongoing work on the regulation for joint HTA, described in more detail in Section 6.3, is hereto cited, although it is unclear if or how this regulation would support refocusing of R&D priorities.

In 2016, the EMA launched the PRIME scheme for PRIority MEdicines. The scheme is designed for "medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients with no treatment options"[100]. If a candidate medicine is selected for the PRIME scheme, the EMA offers the developer scientific advice at key development milestones. Most importantly, the medicine becomes eligible for accelerated assessment at the time of an application for a marketing authorisation. Two years later, the EMA published a progress report on the PRIME scheme[101]. It

[100] Launch of PRIME – Paving the way for promising medicines for patients. European Medicines Agency (press release 7 March 2016), available at: https://www.ema.europa.eu/en/news/launch-prime-paving-way-promising-medicines-patients, accessed on 03/06/2021.

[101] PRIME: a two-year overview. European Medicines Agency (2018), available at: https://www.ema.europa.eu/en/documents/report/prime-two-year-overview_en.pdf, accessed on 03/06/2021.

highlighted that, between 2016 and 2018, 36 medicines had been accepted into the scheme of which 30 were for rare diseases. The register of products granted eligibility, last updated in April 2021, shows by now 45 products have been accepted[102]. This includes 32 ATMPs and three vaccines (against tuberculosis, Zika virus and Chikungunya). In the Pharmaceutical Strategy, the Commission states that it is foreseen that by 2022 the PRIME scheme will become integrated in the regulatory framework to accelerate product development and authorisation in areas of unmet needs.

4.8. Open Science, data & registries

Access to medicines benefits from access to information, which allows researchers to share important data and study results with each other. This facilitates further R&D and can accelerate product development, thus contributing to better and faster access to medicines.

In light of a public return of investment, MEPs requested that the Commission promotes the concept of open data in pharmaceutical research in which public funding is involved. In 2019, the Public Sector Information Directive, was replaced by the Open Data Directive[103]. The Directive enforces the re-usability of public sector or publicly funded data. Moreover, in case of projects funded by EU public grants (e.g. Horizon 2020 and IMI), the resolution asked for encouragement of affordable pricing and non-exclusivity or co-ownership of intellectual property. This, however, is not an identified requirement for calls under Horizon 2020. Moreover, the IP regulations for calls under IMI, which is for 50 percent funded by industry, do not emphasise co-ownership or affordable pricing. Yet, the first strategic plan for the period 2021-2024 of Horizon Europe states that it will introduce novelties in methods of encouraging project partners to disseminate and deploy their research and innovation. Specifically, more emphasis will be put on managing and uptake of knowledge assets, including intellectual property.

4.9. Public return on public investment

As highlighted at the start of this chapter, the European Union is a major funder of health research and innovation. The final work programme (2018 – 2020) for Horizon 2020 alone had a total budget of EUR 1.04 billion for actions under the area 'health, demographic change and wellbeing'[104]. The EU additionally contributed EUR 1.64 billion to the second programme of the Innovative Medicines Initiative (IMI2) and EUR 683 million to the second programme of the European and Developing Countries Clinical Trial Partnership (EDCTP2). Whilst this funding covered actions other than those with a linkage to medicinal product development, it underscores the EU's very significant investment of public funds in biomedical R&D. Member States likewise often have extensive programmes for supporting research and innovation in this space.

Many of the innovative medicines on the market today have their origins in research that was conducted in academic institutions and that was supported with public money. When that research had advanced beyond the early and pre-clinical stages, the capital requirements for further development typically become too high for these institutions to continue and private parties, such as pharmaceutical companies, take over. This typically happens through licensing deals, whereby the

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[102] List of products granted eligibility to PRIME (updated 29 April 2021). European Medicines Agency (2021) , available at: https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines, accessed on 03/06/2021.

[103] Directive (EU) 2019/1024 of 20 June 2019 on open data and the re-use of public sector information, available at: https://eur-lex.europa.eu/eli/dir/2019/1024/oj, accessed on 03/06/2021.

[104] Horizon 2020 Work Programme 2018-2020, 8. Health, demographic change and wellbeing. European Commission (2020), available at: https://ec.europa.eu/research/participants/data/ref/h2020/wp/2018-2020/main/h2020-wp1820-health_en.pdf, accessed on 03/06/2021.

academic institution either gives an existing company the rights to exploit its IP in exchange for royalty payments or it spins-out a new entity to continue the development, with a need for attracting venture capital.

It is widely understood that pharmaceutical product development requires capital and expertise beyond what typical academic institutions can provide and that the R&D ecosystem relies on both the public and private sector. However, there is a growing public debate about whether taxpayers are effectively 'paying twice' for their medicines when pharmaceutical companies justify the observed high prices for some medicines by referring to the high costs of R&D[105]. It is argued that greater transparency about the true costs of R&D in the pharmaceutical industry is needed such that fairness of prices can be assessed in the light of investments made. Additionally, research funders and institutions should be setting conditionalities on their funding to protect against unfair pricing and ensure access to medicines developed with public funding.

Recognising these issues, the Resolution calls on the Commission "to encourage conditions such as affordable pricing and non-exclusivity, or co-ownership of IP for projects funded by EU public grants such as Horizon 2020 and IMI". This is echoed in a separate but highly similar recommendation which asks both the Commission and the Member States "to ensure the public a health return on public investment, and to introduce conditional funding based on non-exclusive licencing and affordable medicines". Alongside these recommendations, the Resolution calls on the Commission "to promote ethical behaviour and transparency in the pharmaceutical sector, especially regarding clinical trials and the real cost of R&D, in the authorisation and assessment of innovation procedure".

In May 2020, the Commission opened a call under Horizon 2020 for innovative and rapid health-related approaches to respond to COVID-19[106]. The call text included an obligation for grantees "to ensure that results or resulting products/services will be available and accessible, promptly and at fair and reasonable conditions including an obligation to grant non-exclusive licences for this purpose". Aside from this specific example, which happened under the exceptional circumstances of the COVID-19 pandemic, no indications were found that signalled a more comprehensive policy change under Horizon 2020 or IMI that would have set such conditions for the purposes of promoting fair pricing and access.

In the Pharmaceutical Strategy for Europe, the lack of transparency about R&D costs and its relationship to price setting is described as an area of concern for the Commission. Potential conditionalities are suggested in connection to specific innovation incentives, such as those for medicines for rare diseases and children, but there are no indications that under Horizon Europe, including the European Partnerships, the Commission intends to introduce conditions for affordable pricing or non-exclusivity.

[105] For instance, the report Overpriced – published jointly by SOMO and WEMOS argues that through research grants and subsidies taxpayers are significantly funding the development of medicines without any safeguards to protect them from excessive and unfair pricing. Overpriced: Drugs Developed with Dutch Public Funding. SOMO, WEMOS (2019) , available at: https://www.somo.nl/overpriced/, accessed on 03/06/2021.

[106] Second call for an Expression of Interest for innovative and rapid health-related approaches to respond to COVID-19 and to deliver quick results for society for a higher level of preparedness of health systems (H2020-SC1-PHE-CORONAVIRUS-2020-2). European Commission (2020), available at: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/sc1-phe-coronavirus-2020-2d, accessed on 03/06/2021.

4.10. Summary of identified actions

Table 3: Summary table – Research, development & innovation

Recommendation	Actions taken	Status
62. Calls on the Commission and the Member States to foster R&D driven by patients' unmet needs, such as by researching new antimicrobials, coordinating public resources for healthcare research in an effective and efficient manner, and promoting the social responsibility of the pharmaceutical sector.	Revision of the pharmaceutical legislation foresees in changes to existing incentives, as well as new ones, to promote R&D in areas of unmet need. PRIME scheme for priority medicines in areas of unmet need expected to become part of the regulatory framework.	
63. Calls on the Member States to build on the example of existing initiatives in the EU aimed at promoting independent research in areas of interest to national health services that are insufficiently addressed by commercial research (e.g. AMR) and to patient populations normally excluded by clinical studies, such as children, pregnant women and the elderly.	Activities at the level of the Member States were not analysed for this study.	
64. Calls on the Commission to increase its actions to combat AMR, to promote R&D in this area, and to present a new and comprehensive EU Action Plan based on the 'One Health' approach.	Co-funded European Partnership for One Health/AMR proposed under Horizon Europe. Global AMR R&D Hub established (2018). Pharmaceutical Strategy for Europe foresees new pull incentives for novel antimicrobials. EU Health Emergency Response Authority (HERA) will promote investment and coordinate R&D, manufacturing, deployment, and use of novel antibiotics.	
65. Acknowledges that the incentives put forward by the Paediatric Medicines Regulation (EC) No 1901/2006 have not proved effective in driving innovation in medicines for children, namely in the fields of oncology and neonatology; calls on the Commission to examine existing obstacles and to propose measures to promote advancement in this area.	Revision of the pharmaceutical legislation is expected to improve existing or new introduce incentives for paediatric product development.	

Recommendation	Actions taken	Status
66. Calls on the Commission to promote initiatives for guiding public and private-sector research towards bringing out innovative medicines for curing childhood illnesses.	As previous.	
67. Calls on the Commission to begin immediate work on the report required under Article 50 of the Paediatric Medicines Regulation, and to amend the legislation to address the lack of innovation in paediatric oncology treatments, by revising the criteria for allowing a Paediatric Investigation Plan (PIP) waiver and by ensuring that PIPs are implemented early in a drug's development, so that children are not waiting longer than necessary for access to innovative new treatments.	Joint evaluation on the legislation for medicines for rare diseases and children completed (2020). Impact assessment for the revision of the legislation for medicines for children ongoing.	
68. Calls on the Commission to promote public and private-sector research into medicines for female patients, to remedy gender inequality in research and development and to allow all citizens to benefit from fairer access to medicines.	The Pharmaceutical Strategy for Europe underwrites that clinical trial design should take into account gender and age; no specific actions identified.	
70. Calls for the framework conditions in the areas of research and medicine policy to be established in a way that promotes innovation, particularly against diseases, such as cancer, that cannot yet be treated to a satisfactory degree.	Revisions to the pharmaceutical legislation, including legislations for medicines for rare diseases and children, are expected to improve existing or introduce new incentives for innovation in areas of unmet need Cancer is one of five missions included under Horizon Europe. PRIME scheme for priority medicines in areas of unmet need expected to become part of the regulatory framework.	
71. Calls on the Commission to take further action to foster the development of, and patient access to, ATMPs.	EMA strategic reflection on Regulatory Science until 2025 recommends support of the translation of ATMPs into clinical practice.	

Recommendation	Actions taken	Status
73. Calls on the Commission to evaluate the implementation of the regulatory framework for orphan medicines (especially as regards the concept of unmet medical need, how this concept is interpreted and what criteria need to be fulfilled in order to identify unmet medical need), to provide guidance on priority unmet medical need, to evaluate existing incentive schemes to facilitate the development of effective, safe and affordable medicines for rare diseases compared to the best available alternative, to promote the European register of rare diseases and reference centres, and to ensure the legislation is correctly implemented.	Joint evaluation on the legislation for medicines for rare diseases and children completed (2020). Impact assessment for the revision of the legislation for medicines for rare diseases ongoing.	
76. Calls on the Commission to promote open data in research on medicines where public funding is involved, and to encourage conditions such as affordable pricing and non-exclusivity, or co-ownership of IP for projects funded by EU public grants such as Horizon 2020 and IMI.	The Open Data Directive adopted in 2019 enforces the re-usability of public sector or publicly funded data. In a COVID-19 related call under Horizon 2020, the Commission obliged grantees to ensure availability and accessibility of results, including though granting of non-exclusive licenses. However, no similar conditions were identified in other calls nor was any action found to include such conditions under Horizon Europe.	
84. Calls on the Commission to enhance dialogue on unmet medical needs between all relevant stakeholders, patients, healthcare professionals, regulators, HTA bodies, payers and developers throughout the life spans of medicines.	Through the development of the regulation for joint HTA, the Commission expects to encourage stakeholder dialogue on areas of unmet need.	
89. Calls on the Commission and the Member States to promote major public-funded investment in research based on unmet medical needs, to ensure the public a health return on public investment, and to introduce conditional funding based on non-exclusive licencing and affordable medicines.	Under Horizon Europe, the Commission foresees major new investment in areas of research based on unmet medical needs. No actions identified to set funding conditions on research funding to ensure availability and access to medicines.	

Legend: ⚪ - Unknown; 🔴 - No action; 🟠 - Proposed; 🟡 - In preparation; 🟢 - Under implementation; 🟢 - Implemented.

Source: Technopolis, 2021.

5. HEALTH SYSTEMS

5.1. Summary of issues raised

European public health systems are essential to guarantee universal access to healthcare for all European citizens. However, these systems face challenges such as increasing demand from an ageing population, a rise in chronic diseases and increasingly high-priced innovative medicines. A further challenge comes from a rise in medicine shortages. This problem is based on multiple factors, including practices by marketing authorisation holders (MAHs), manufacturing issues and reimbursement decisions. All these challenges are creating concerns about affordable and sustained access to medicines.

In the Resolution, MEPs expressed concerns that especially smaller and lower income Member States are lacking the bargaining power to ensure affordable access to medicines. In addition, they stressed the need to define and identify the true therapeutic benefit of innovative medicinal products for a unified procurement and tendering system and to increase transparency of pricing and reimbursement decisions. The Resolution furthermore states that digital health presents a pathway to facilitate the development of safe, reliable, accessible, modern and sustainable new health care models.

In response to the observed challenges, the Resolution calls for a large number of actions to be undertaken in the thematic area of health systems. Specifically, these are:

- The Council and the Commission are to reinforce the negotiation capacities of Member States in order to ensure affordable access to medicines across the EU.
- The Commission is to propose a new directive on transparency of price-setting procedures and reimbursement systems to replace Directive 89/105/EEC.
- The Commission is to propose legislation on a European system for health technology assessment, to introduce compulsory relative effectiveness assessments at EU level as a first step for new medicines, to ensure that HTA output jointly produced at EU level is used at national level and to foster early dialogue.
- The Council is to increase cooperation between the Member States as regards price-setting procedures.
- The Commission and the Council are to analyse the clinical, economic and social criteria that some national HTA agencies already apply.
- The Commission and the Member States are to agree on a definition of 'added therapeutic value'.
- The Member States to ensure accessibility of pharmacies.
- The Commission and the Council to develop measures that ensure affordable access to medicines such as horizon scanning, early dialogue, voluntary joint procurement or delinkage mechanisms.
- The Commission is to define with all relevant stakeholders how the most economically advantageous tender (MEAT) criterion could apply to medicines tenders at national level.
- The Commission and the Member States are to launch a high-level strategic dialogue with all the relevant stakeholders on current and future developments in the pharmaceutical system in the EU.

- The Commission and the Council are to define the concept and analyse the causes of shortages of medicines and establish a list of essential medicines that are of short supply.
- The Commission and Council are to establish a mechanism whereby medicine shortages across the EU can be reported upon on an annual basis.
- The Commission and Council are to review the statutory basis of the EMA, and to give consideration to enhancing its remit to coordinate pan-European activity aiming at tackling medicines shortages in the Member States.
- The Commission and the Member States are to develop a single eHealth and mHealth roadmap.
- The Commission and the Member States are to adopt strategic plans to ensure access to life-saving medicines; the Resolution calls, in this regard, for the coordination of a plan to eradicate hepatitis C in the EU using tools such as European joint procurement.

5.2. Procurement & tendering

To ensure timely and affordable access to medicines, parties responsible for procurement of medicines need to base their assessment of tenders on reliable criteria. The Resolution called on the Commission to define with all relevant stakeholders how the most economically advantageous tender (MEAT) criterion, as described in the 2014 modernised EU Public Procurement Directive[107] could best be applied to medicines tenders in hospitals at national level to enable a sustainable and responsible supply of medicine. A Commission notice from 2018, offering guidance on innovation procurement (2018)[108], underlines that MEAT is the only criterion mentioned in the directive and that a smart setting of MEAT award criteria, requiring both quality and price, could significantly improve innovation procurement practices. In January 2021, the Commission responded to a similar question from the European Parliament by noting that it is promoting MEAT award criteria in public tenders and referenced the aforementioned guidance[109]. The Commission also indicated it had created "a new group of representatives of Member States from the health sector" to boost further the use of MEAT criteria. No further information has as yet been identified about the composition of this group, its objectives or any actions it has initiated.

The Pharmaceutical Strategy for Europe suggests the procurement method in the SME Strategy, the Big Buyers for Climate and Environment[110] initiative as a possible future alternative for 'winner-takes-all' procedures. In addition, it outlines the development of a group of competent authorities that focusses on mutual learning and best-practice exchange in, among others, the field of procurement and payment policies.

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[107] Directive 2014/23/EU (available at: http://data.europa.eu/eli/dir/2014/23/oj, accessed on 03/06/2021), Directive 2014/24/EU (available at: http://data.europa.eu/eli/dir/2014/24/oj, accessed on 03/06/2021) and Directive 2014/25/EU (available at: http://data.europa.eu/eli/dir/2014/25/oj, accessed on 03/06/2021).

[108] Commission notice on Guidance on Innovation Procurement, C(2018) 3051, European Commission, May 2018, available at: https://ec.europa.eu/transparency/regdoc/rep/3/2018/EN/C-2018-3051-F1-EN-MAIN-PART-1.PDF, accessed on 03/06/2021.

[109] Answer to European Parliamentary Questions E-005528/2020, E-005638/2020 on behalf of the European Commission, 17 December 2020, available at: https://www.europarl.europa.eu/doceo/document/E-9-2020-005528-ASW_EN.html#def1, accessed on 03/06/2021.

[110] Big Buyers for Climate and Environment, Sustainable Procurement Platform website, available at: https://sustainable-procurement.org/big-buyers/, accessed on 03/06/2021.

In a response to a 2020 European Parliament resolution 'on the shortage of medicines – how to address an emerging problem'[111], the Commission acknowledged that "pharmaceutical pricing policies that solely aim to contain expenditure may not allow for price adjustments to reflect objective changes in cost of goods, manufacturing, regulatory procedures and distribution, and may have a negative effect on supply reliability". An ongoing study by the Commission on medicine shortages will include discussion on the role of public procurement procedures in the occurrence of shortages and offer possible solutions to address this[112].

5.3. Pricing & Reimbursement

One of the factors behind inequitable access to medicines between Member States is the fact that pricing and reimbursement is not decided at the EU level. Instead, each Member State has its own pricing policies and criteria for assessing whether a medicine should be admitted into its reimbursement system. Consequently, medicines may be accessible to patients in some countries but not in others.

With prices of innovative medicinal products on the rise, clear and aligned price-setting and rational reimbursement decisions have become cornerstones of affordable healthcare. Directive 89/105/EEC aims "to ensure that any measures taken by EU countries to set the prices of and to reimburse medicinal products are transparent"[113]. After a review of the Directive, in 2012 the Commission proposed a new directive to simplify procedures and reduce decision times[114]. However, this proposal was withdrawn in March 2015 because of opposition from Member States[115]. Nonetheless, the Resolution reiterates the call on the Commission to propose a new directive to replace the current Transparency Directive. This new directive should provide effective controls and ensure full transparency on the procedures used to determine the prices and the reimbursement of medicinal products in the Member States. The call for a revision of the directive was supported by Affordable Medicines Europe, which represents the interests of the European parallel distribution industry. In 2020 this group issued a position paper in which it advocated for "an ambitious revision" of the directive and offered recommendations on the inclusion of voluntary/secret agreements within the scope of the directive, on making prices of winning tenders accessible, on inclusion of generic medicines and on a reduction of the timeframes for pricing and reimbursement decisions[116]. However, no active steps to amend or introduce a new directive appear to be under way.

The Resolution furthermore calls on the Commission and the Council to strengthen the negotiation capacities of Member States and to develop and adopt measures such as horizon scanning, early

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[111] European Parliament resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem (2020/2071(INI)), available at: https://www.europarl.europa.eu/doceo/document/TA-9-2020-0228_EN.html, accessed on 03/06/2021.

[112] Future proofing pharmaceutical legislation: study on medicine shortages. Technopolis Group, Ecorys, Milieu Law & Policy Consulting (study ongoing. Results expected in 2021).

[113] Directive 89/105/EEC on the transparency of measures regulating the prices of medicines for human use and their inclusion in the scope of national health insurance systems, European Commission, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Al21144, accessed on 03/06/2021.

[114] Proposal for a Directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems. European Commission, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52012PC0084, accessed on 03/06/2021.

[115] Medicine pricing and reimbursement: EU. Ranson P, Morgan, Lewis & Bockius UK LLP (2021). Thomson Reuters Practical Law, available at: https://uk.practicallaw.thomsonreuters.com/w-005-2025?transitionType=Default&contextData=(sc.Default)&firstPage=true, accessed on 03/06/2021.

[116] Transparency Directive Revision Position Paper, Affordable Medicines Europe, December 2020, available at: https://affordablemedicines.eu/wp-content/uploads/2020/12/Position-paper_Transparency-Directive-Revision_211220.pdf, accessed on 03/06/2021.

dialogue, delinkage, voluntary joint procurements and voluntary cooperation in price negotiations to ensure affordable patient access. The Joint Procurement Agreement (JPA) for medical countermeasures was approved by the Commission on 10 April 2014. As of April 2020, the JPA has been signed by 37 countries, including all EU and EEA countries, the United Kingdom, Albania, Montenegro, North Macedonia, Serbia, Bosnia and Herzegovina, and Kosovo. Neither the Council nor the Commission have initiated specific actions that directly reinforce the negotiation capacities of Member States to ensure affordable access to medicines across the EU. However, there are currently several joint procurement mechanisms ongoing in the Union between a select number of Member States[117]. An overview of these joint actions is provided in Chapter 9.4.

The COVID-19 pandemic has intensified European collaboration regarding price negotiations and procurement, sparking discussions and initiatives that future actions can draw on. By uniting as a bloc, European countries were able to increase their negotiating power towards pharmaceutical companies. The pandemic has prompted the Commission to propose a new health security framework that includes strengthening of the JPA[118]. In line with this, in the Pharmaceutical Strategy for Europe, the Commission announces a European Health Emergency Response Authority (HERA). HERA will anticipate specific threats and enable technologies through horizon scanning and foresight[119].

In addition, the European Integrated Price Information Database (EURIPID) project[120], funded under the third Health Programme, is a voluntary collaboration between mostly European countries on building up and maintaining a database with information on national prices and pricing regulations of medicinal products. It contains data on medicinal products that are published by national authorities in line with the Transparency Directive 89/105/EC and runs from 2019 to 2022.

The Resolution furthermore urges Member States to consider 'delinkage'. Whilst there is no single understanding of what delinkage looks like, in general the concept refers to a separation of the costs of R&D from medicine prices[121]. This can be achieved, for instance, by use of R&D grants or subsidies and setting conditions on the price of products resulting from these public investments. Other mechanisms include introduction of incentives that do not involve granting of new or extended monopoly rights, such as innovation prize funds. In July 2019, the UN Human Rights Council (UNHRC) adopted a resolution on "access to medicines and vaccines in the context of the right of the highest attainable standard of physical and mental health"[122]. Herein, the UNHRC called upon Member States "to continue to collaborate, as appropriate, on models and approaches that support the delinkage of the cost of new research and development from the prices of medicines, vaccines and diagnostics for diseases that predominantly affect developing countries, including emerging and neglected tropical diseases, so as to ensure their sustained accessibility, affordability and availability and to ensure access

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[117] Marco Rauland, Cross Country Collaborations in Europe: The Future of Pricing & Access Negotiations?, Pharma Boardroom, November 2020, available at: https://pharmaboardroom.com/articles/cross-country-collaborations-in-europe-the-future-of-pricing-access-negotiations/, accessed on 03/06/2021.

[118] Communication on building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, COM(2020) 724, European Commission, November 2020, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0724&qid=1605690513438, accessed on 03/06/2021.

[119] Communication on a Pharmaceutical Strategy for Europe, COM(2020) 761, European Commission, November 2020, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761, accessed on 03/06/2021.

[120] Supporting Member States voluntary cooperation in the area of pricing through the EURIPID Collaboration - EURIPID (available at: EURIPID Collaboration), Ref. Ares(2019)36522 - 07/71/2019, available at: https://euripid.eu/about/, accessed on 03/06/2021.

[121] What is delinkage? Delinkage.org, available at: https://delinkage.org/overview/, accessed on 03/06/2021.

[122] Resolution 41/10 of 19 July 2019 on Access to medicines and vaccines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, United Nations Human Rights Council, available at: https://digitallibrary.un.org/record/3834569v, accessed on 03/06/2021.

to treatment for all those in need"[123]. Whilst this statement underlines the role envisaged for delinkage in promoting access to medicinal products, the emphasis here is primarily on its connection to access in developing countries and not on how delinkage could be applied in a European context. While some EU Member States, along with patient organisations have publicly endorsed delinkage[124], no specific actions could be identified where the concept has been introduced at the Member State level.

5.4. Collaboration, coordination, and dialogue

As described in the preceding sections, the fact that policies pertaining to the procurement, pricing and reimbursement of medicines are national competences rather than European ones contributes to uneven access to medicines. Joint actions and collaboration of Member States could help combat market fragmentation, ensure a transparent and efficient joint HTA procedure or address pan-European challenges such as medicine shortages or cross-border healthcare. The Resolution therefore stresses that both Member States and the Commission need to emphasise the strengthening of collaboration, coordination, and dialogue. Member States, supported by legislation proposed by the Commission, should collaborate and work on criteria to instruct pricing and reimbursement decisions at a national level. In addition, the Resolution urged the Commission to propose legislation for a collaboration on joint HTA as soon as possible and, in line with this, to agree on a common definition of 'added therapeutic value' with the Member States. A high-level strategic dialogue on this issue with all the relevant stakeholders, together with representatives of the Commission, Parliament, the Member States, patient organisations, paying agencies, healthcare professionals, and representatives from the academic and scientific world as well as from industry has yet to take formal shape.

Since 2017, collaboration and coordination between Member States has increased, in part necessitated by the COVID-19 pandemic. In 2018, the Commission put forward a proposal for a regulation on joint HTA with the key element of establishing procedures and structures for cooperation on joint work at EU level. Further information on this is provided in Section 6.3. The European Network for Health Technology Assessment (EUnetHTA)[125] and the EURIPID project aim to facilitate collaboration between Member States in relation to pricing, reimbursement, and strategic procurement by sharing information and mutual learnings.

The Commission is in the process of conducting a high-level structured dialogue with stakeholders on security of medicines supply[126]. No other high-level dialogues have been formalised in recent past. Similarly, no unified concept of 'added therapeutic value' has as of yet been defined. In a recent paper, three representatives of the EMA signalled the need to differentiate between 'innovation' and 'added therapeutic value' and argue that "eliminating scientifically justified flexibility in drug development and authorization, although well intentioned, may not produce good results for patients and health-care systems"[127]. Instead, the authors suggest a collaborative approach for definition upfront by mutual understanding among all relevant decision-makers on clinical trial designs.

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[123] Transparency and delinkage embedded into the Human Rights Council's agenda on access to medicines. Knowledge Ecology International (11 July 2019), available at: https://www.keionline.org/31188, accessed on 03/06/2021.

[124] Endorsements. Delinkage.org, available at: https://delinkage.org/endorsements/, accessed on 03/06/2021.

[125] About EUnetHTA, EUnetHTA website, available at: https://eunethta.eu/about-eunethta/, accessed on 03/06/2021.

[126] Structured dialogue on security of medicines supply. European Commission (2021), available at: https://ec.europa.eu/health/human-use/strategy/dialogue_medicines-supply_en, accessed on 03/06/2021.

[127] Eichler HG, Enzmann H, Rasi G., 'Added therapeutic benefit and drug licensing', *Nat Rev Drug Discov*. September 2017, available at: https://pubmed.ncbi.nlm.nih.gov/31477854/, accessed on 03/06/2021.

5.5. Availability & shortages

Increasingly, patients in the EU are finding themselves unable to obtain their prescribed medications. Member States and pharmacy organisations have signalled a rise in shortages of medicinal products. In 2019, a survey of 400,000 community pharmacies across Europe found that all 24 responding Member States experienced medicine shortages in the past year[128]. Most of them (87%) indicated a worse situation compared to the previous year. The COVID-19 pandemic was expected to further exacerbate the situation as early in the outbreak European countries reported critical increases in shortages of medicines used in intensive care units in the treatment of the disease and its complications[129]. Although it appears that for the most part the situation did not reach criticality, the pandemic further exposed fragilities in the system.

Whilst shortages are widely considered a main area of concern, the full extent of the problem and its underlying causes is not sufficiently understood. Part of the reason for this is the lack of a common definition of medicine shortages and of a shared reporting mechanism. In the Resolution, MEPs stressed the importance of a clearly defined concept of shortages and argued for the creation of a list of essential medicines on which shortages can be reported upon via a reliable mechanism. To tackle medicine shortages, Members of Parliament call on the Commission and Council to review the statutory basis of the EMA, and to consider enhancing its remit to coordinate pan-European activities.

Since the adoption of the Resolution, concerns about shortages of medicine have intensified. In 2019, the EMA released their 'Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA)' which developed the following definition of a medical shortage in collaboration with EMA, the Heads of Medicines Agencies (HMA) and other stakeholders: 'A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level[130]. Whilst the EMA definition has been adopted by a number of Member States, many continue to operate with their own definitions.

In December 2016, the EMA and HMA created a 'Task Force on the Availability of Authorised Medicines for Human and Veterinary Use'. Since 2019, the Task Force has been running a pilot programme on establishing a single point of contact (SPOC) network on shortages to improve information sharing between Member States, the EMA and the Commission and to coordinate actions to help prevent and manage shortages[131]. On 11 November 2020, the Commission adopted a legislative proposal to extend the mandate of the EMA to facilitate a coordinated EU level response to health threats. Amongst others this includes monitoring and mitigating the risk of shortages of critical medicines and medical devices[132]. This is also to include a digital platform for reporting information provided by national agencies regarding available stocks and shortages of medicines.

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[128] PGEU Medicine Shortages Survey 2019 Results, PGEU, 2020, available at: https://www.pgeu.eu/wp-content/uploads/2019/03/PGEU-Medicine-Shortages-Survey-Results-2019-1.pdf, accessed on 03/06/2021.

[129] EU authorities agree new measures to support availability of medicines used in the COVID-19 pandemic, press release, EMA, 6 April 2020, available at: https://www.ema.europa.eu/en/news/eu-authorities-agree-new-measures-support-availability-medicines-used-covid-19-pandemic, accessed on 03/06/2021.

[130] Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA), EMA, July 2019, available at: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf, accessed on 03/06/2021.

[131] Availability of medicines, EMA website, , available at: https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines, accessed on 03/06/2021.

[132] Extension of the Mandate of the European Medicines Agency (EMA) / 2020-11, European Parliament, April 2021, available at: https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-ema-mandate-extension#:~:text=On%2011%20November%202020%2C%20the,State%20of%20the%20Union%20address, accessed on 03/06/2021.

The Horizon 2020-funded project 'Digital Health Europe' developed the Centre for Information on the Supply of Medicines (CISMED), a pharmacy-based system for medicine shortage detection system, which sets up a mechanism to exchange information on medicine shortages among four currently participating countries (Spain, Portugal, France, Italy)[133]. The data can be used by the Competent Authorities to put the necessary measures in place to prevent future medicine shortages or to mitigate existing ones. To effectively respond to and prevent the escalation of shortages, such as those caused by the COVID-19 pandemic, in March 2020 the EMA set up an EU Executive Steering Group on shortages of medicines caused by major events. Jointly with the pharmaceutical industry, the Steering Group is currently setting up an early-warning shortage notification system (i-SPOC). Other measures such as regulatory actions to support increased manufacturing capacities and overall greater regulatory flexibility are under consideration.

In 2020, the European Parliament adopted a non-legislative resolution 'on the shortage of medicines – how to address an emerging problem' regarding medicines shortages, their underlying causes and proposed both legislative and non-legislative policy options[134]. The Commission responded to the points raised in turn[135], outlining that it launched a study providing:

- an overview of medicines in shortage in the EU, including their characteristics, and an analysis of root causes of shortages;
- an evidence-based assessment of whether the current framework (at EU and national level) is fit for purpose to address the issue of shortages; and
- an overview of potential solutions to address shortages, taking into account their root causes and the shortcomings of the current system.

This study is currently ongoing and results are expected to become available towards the end of 2021.

Further action to tackle the problem of medicine shortages is foreseen under the newly adopted EU4Health Programme. Here, the Commission has indicated that the programme should support actions to monitor shortages and "can finance additional emergency reserves of medicines, medical devices and other health supplies to complement national reserves"[136].

The Commission also acknowledged the lack of transparency of supply stock and confirmed that it is "supporting the national authorities working together under the EU Executive Steering Group on Shortages of Medicines Caused by Major Event to develop a more robust and coordinated assessment of the demand side by aggregating information from the national authorities". However, according to the Commission, it is not currently feasible to use digital tools to provide real-time and up-to-date data on the availability, location, quantity and price of a given medicine.

Increased risk of shortages has also been associated with the UK's withdrawal from the Union. There is a significant flow of medicines between the Union and the UK: in 2018, it was estimated that the Union

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[133] CISMED, Digital Health Europe website, available at: https://digitalhealtheurope.eu/twinnings/dhe-twinning-results/cismed/, accessed on 03/06/2021.

[134] Resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem, available at: https://www.europarl.europa.eu/doceo/document/TA-9-2020-0228_EN.html, accessed on 03/06/2021.

[135] Response to Resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem, European Commission, February 2021, available at: https://oeil.secure.europarl.europa.eu/oeil/spdoc.do?i=53337&j=0&l=en, accessed on 03/06/2021.

[136] Questions and Answers: EU4Health Progarmme 2021–2017: will it also address shortages of medicines and personnel? European Commission (26 March 2021), available at: https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_1345, accessed on 03/06/2021.

imported 45 million packs from the UK every month, whilst sending 37 million packs to the UK[137]. Following the withdrawal, medicines licenced in the UK can no longer be legally supplied to other countries unless they are separately licenced there as well. Additional trade barriers, such as border inspections, export quotas or even export bans, could significantly disrupt the flow of supplies in both directions. In particular, Member States such as Ireland and Malta that require packaging in English rely significantly on exports from the UK. To minimise the potential impact of this, the EMA, the Commission and national competent authorities of the Member States have been working closely together since May 2017, providing advice to companies on how to plan and act accordingly[138]. For UK-based marketing authorisation holders, this includes the transfer of the license to an entity based in an EU/EEA Member State. As discussed in Section 3.1, the EU-UK Trade Agreement, which includes mutual recognition of inspections, is intended to reduce some barriers that could delay supplies and result in shortages. The Department of Health for Northern Ireland has worked with the UK Medicines and Healthcare products Regulatory Agency (MHRA) and other departments to mitigate supply chain risks resulting from Brexit. Despite these preparatory actions, there have been reports that suggest an increase of medicine shortages, mainly for generic medicines, in Northern-Ireland following Brexit[139]. Thus far, there are no wide-scale reports of shortages in Member States as a direct result of UK withdrawal.

At the beginning of 2021, tensions rose between the Commission and the UK government over the delivery of COVID-19 vaccines produced by AstraZeneca. After the company fell short of its delivery targets to the Union, whilst continuing to fulfil its obligations to the UK, the Commission threatened to impose export restrictions. Specifically, it threatened to invoke a clause from the Northern Ireland Protocol to prevent vaccine supplies for Ireland from moving to the UK via Northern Ireland. The threat followed a claim by the president of the European Council that the UK had imposed a ban on the export of vaccines and vaccine components, a claim that was dismissed by the UK government[140]. Following heavy criticism, the Commission swiftly reversed its decision. However, as part of the EU Vaccine Strategy, the Commission announced its export authorisation scheme which would allow it to restrict exports of vaccines it had procured through its Advance Purchase Agreements to any country with a domestic production capability and a higher vaccine rollout than the Union[141]. This would allow restricting exports also to the UK. The dispute between the Union and the UK over the AstraZeneca vaccine continues, as the Union pursues legal action against the company over its failure to meet its contractual obligations[142].

Equitable access to medicines involves not only product availability at a national level but also equitable access to products at a local level. For this reason, the Resolution calls on the Commission to ensure accessible and well-equipped pharmacies in both rural and urban areas. Thus far, the

[137] Brexit and the potential impact on patients access to medicines and medical devices. European Federation of Pharmaceutical Industry Associations. (27 March 2018), available at: https://www.efpia.eu/news-events/the-efpia-view/blog-articles/27032018-brexit-and-the-potential-impact-on-patients-access-to-medicines-and-medical-devices/, accessed on 03/06/2021.

[138] Brexit: the United Kingdom's withdrawal from the European Union. European medicines Agency, available at: https://www.ema.europa.eu/en/about-us/brexit-united-kingdoms-withdrawal-european-union, accessed on 03/06/2021.

[139] Brexit red tape threatens drugs supplies in Northern Ireland. Neville S, Foster P. The Irish Times (19 April 2021), available at: https://www.irishtimes.com/business/health-pharma/brexit-red-tape-threatens-drugs-supplies-in-northern-ireland-1.4541226, accessed on 03/06/2021.

[140] EU rejects accusations of 'vaccine nationalism'. Chalmers J, Abnett K. Reuters (9 March 2021), available at: https://www.reuters.com/article/us-health-coronavirus-eu-michel-id USKBN2B11YM, accessed on 03/06/2021.

[141] EU Vaccines Strategy. European Commission, available at: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en#transparency-and-authorisation-mechanism-for-exports-of-vaccines, accessed on 03/06/2021.

[142] EU demands immediate access to UK-made vaccines in AstraZeneca legal battle. Guarascio F. Reuters (28 April 2021), available at: https://www.reuters.com/world/europe/eu-legal-case-against-astrazeneca-begins-brussels-court-2021-04-28/, accessed on 03/06/2021.

Commission has not announced any actions in this field. Whilst such actions may exist at the Member State level, these could not be identified in the analysed documentation.

5.6. Digital health

Rational and safe use of medicine can be supported by the use of digital health solutions. These solutions can also be used to collect, analyse and share important clinical data to support new medicinal product development. The digital transformation of healthcare presents an opportunity to rethink existing European health and care systems to ensure they shift towards innovative health outcomes-driven healthcare. To support this transition, the Resolution calls on the Commission to develop a single eHealth and mHealth road map including the development of pilot projects, the modernisation of reimbursement models and the digital empowerment of healthcare professionals and other stakeholders.

In the Communication from 24 May 2018 'on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society'[143], the Commission identifies three priorities for digital health:

- Secure access to health data, including across borders.
- Personalised medicine through shared European data infrastructure.
- Citizen empowerment with digital tools for user feedback and person-centred care using digital tools to empower people to look after their health.

The European Health Data Space, an initiative on eHealth linking into the priorities identified by the Commission, is currently undergoing public consultation and an initial impact assessment[144]. The Commission is planning to propose the regulation in Q4 2021. It will encourage the access to and use of health data for research, policy-making and regulation by means of a governance framework and upholding data-protection rules. In addition, it will support research on treatments, medicines, medical devices and outcomes, support digital health services and promote safe exchange of patients' data (including when they travel abroad) and citizens' control over their health data.

In addition, the eHealth Network, initially created under Article 14 of Directive 2011/24/EU entered its third multiannual work programme from 2018-2021 with the support of the joint action eHAction[145]. The work programme states four priority areas in eHealth and mHealth: Empowering people; innovative use of health data; enhancing continuity of care; and overcoming implementation challenges. Actions under these areas include equipping healthcare professionals with the necessary skills for eHealth services. As part of the project, eHAction mapped National eHealth strategies in 2019[146], listing and comparing the number and type of projects at national level.

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[143] Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, Com(2018) 233, European Commission, April 2018), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A233%3AFIN, accessed on 03/06/2021.

[144] European Health Data Space, European Commission website), available at: https://ec.europa.eu/health/ehealth/dataspace_en, accessed on 03/06/2021.

[145] Framework, eHAction website), available at: http://ehaction.eu/mwp-2018-2021/, accessed on 03/06/2021.

[146] D8.1 – Report on National eHealth strategies, eHAction, November 2019), available at: http://ehaction.eu/wp-content/uploads/2020/05/13.1_D8.1-Integration-in-national-policies-and-sustainability_eHAction_16th-eHN_ANNEX.pdf, accessed on 03/06/2021.

In the area of mHealth, the World Health Organisation (WHO) and the International Telecommunication Union (ITU) began a project to create a 'WHO-ITU mHealth Hub in the EU'. The project was funded under Horizon 2020 with a European Commission contribution of EUR 3 million and is running from 2017-2022. It aims to create a European mHealth hub to allow the identification of best practices and standardized guidelines between Member States[147].

[147] WHO - ITU mHealth Hub in EU, European Commission website), available at: https://cordis.europa.eu/project/id/737427, accessed on 03/06/2021.

5.7. Summary of identified actions

Table 4: Summary table – Health system

Recommendation	Actions taken	Status
53. Calls on the Council and the Commission to reinforce the negotiation capacities of Member States in order to ensure affordable access to medicines across the EU.	No action taken by the Council or the Commission on strengthening negotiation capacities of Member States. Joint Procurement Agreement (JPA) for medical countermeasures signed by multiple Member States.	
56. Calls on the Member States to develop closer collaboration in order to fight such market fragmentation, in particular by developing shared HTA processes and results, and to work on shared criteria to instruct price and reimbursement decisions at national level.	Negotiations initiated on a proposal for a regulation on joint HTA with the key element of establishing procedures and structures for cooperation on joint work at EU level.	
58. Calls on the Commission to propose a new directive on transparency of price-setting procedures and reimbursement systems, taking into account the challenges of the market.	No active steps to introduce a new directive on transparency of price-setting under way	
59. Calls for a new Transparency Directive to replace Directive 89/105/EEC with the aim of ensuring effective controls and full transparency on the procedures used to determine the prices and the reimbursement of medicinal products in the Member States.	No active steps to amend the transparency directive or introduce a new directive under way.	
69. The Commission and the Member States to adopt strategic plans to ensure access to life-saving medicines; calls, in this regard, for the coordination of a plan to eradicate hepatitis C in the EU using tools such as European joint procurement.	Whilst the Commission supports various projects to improve care for viral hepatitis, no specific action was identified on joint procurement of Hepatitis C medicines.	
85. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, to harmonise transparent HTA criteria in order to assess the added therapeutic value of medicines compared with the best available alternative taking into account the level of innovation and value for the patients among others, to introduce compulsory	Negotiations initiated on a proposal for a regulation on joint HTA with the key element of establishing	

Recommendation	Actions taken	Status
relative effectiveness assessments at EU level as a first step for new medicines, and to put in place a European classification system to chart their therapeutic added value level, using an independent and transparent procedure that avoids conflicts of interests […]; calls, furthermore, on the Commission to strengthen early dialogues and to consider a coordination mechanism based on an independent body, which could foster cooperation between national HTA bodies while at the same time ensuring that expertise on HTA remains within national (and regional) HTA.	procedures and structures for cooperation on joint work at EU level. The EUnetHTA Joint Action 3 was extended until May 2021. No information on its continuation under Horizon Europe.	
86. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order that they may share information about, in particular, negotiation agreements and good practices, and avoid unnecessary administrative requirements and delays; calls on the Commission and the Council to analyse the clinical, economic and social criteria that some national HTA agencies already apply, while respecting the competences of the Member States.	The European Integrated Price Information Database (EURIPID) collaboration will run until January 2022.	
91. Calls on the Member States to ensure accessibility of pharmacies, including their density in both urban and rural areas, professional staff number, appropriate opening hours, qualitative advice and counselling service.	No information available from Member States.	
92. Calls on the Commission and the Council to develop measures that ensure affordable patient access to medicines, and benefit to society, whilst avoiding any unacceptable impact on healthcare budgets, to employ different measures, such as horizon scanning, early dialogue, innovative pricing models, voluntary joint procurements and voluntary cooperation in price negotiations, as is the case in the initiative between the Benelux countries and Austria, and to explore the numerous tools based on delinkage mechanisms for neglected areas of research such as AMR and poverty-related diseases.	No central action at EU level.	
	Joint procurement initiatives exist between different groups of Member States.	
	Delinkage was publicly endorsed by several Member States and stakeholder groups; no action identified at EU level.	

Recommendation	Actions taken	Status
93. Calls on the Commission to define with all relevant stakeholders how the most advantageous economic tender (MEAT) criterion – as described in the Public Procurement Directive, and which does not imply only the lower cost criteria – could best apply to medicines tenders in hospitals at national level, in order to enable a sustainable and responsible supply of medicines; encourages the Member States to transpose into their national legislation, in the best way, the most economic advantageous tender criterion for medicinal products.	MEAT criteria have not centrally been defined at EU level.	
	The Pharmaceutical Strategy for Europe suggests adoption of the Big Buyers for Climate and Environment (BBCE) initiative in the health context.	
	A Commission study into shortages of medicines currently under way will consider role or tendering criteria in product availability.	
94. Calls on the Commission and the Member States to launch a high-level strategic dialogue with all the relevant stakeholders, […], on current and future developments in the pharmaceutical system in the EU, with the aim of establishing short-, medium- and long-term holistic strategies for ensuring access to medicines and for the sustainability of healthcare systems and a competitive pharmaceutical industry, leading to affordable prices and faster access to medicines for patients.	The Commission has initiated a high-level structured dialogue with stakeholders on security of medicines supply. No action on high-level strategic dialogue on sustainability of healthcare systems or competitiveness of industry identified.	
101. Calls on the Commission and the Council to formulate a better definition of the concept – and analyse the causes – of shortages of medicines, and, in this regard, to assess the impact of parallel trade and supply quotas, to establish and update together with the Member States, the EMA and relevant stakeholders a list of essential medicines which are short of supply, using the WHO list as a reference, to monitor compliance with Article 81 of Directive 2001/83/EC on shortages of supply, to explore mechanisms to address the withdrawal of effective medicines from the market purely for commercial reasons, and to take actions to remedy these shortages.	A definition of 'medicine shortages' has been formulated by the EMA, the Heads of Medicines Agencies (HMA) and other stakeholders; not yet universally adopted at Member State level. The EU Executive Steering Group on shortages of medicines caused by major events set up an early-warning shortage notification system (i-SPOC). Digital Health Europe developed a pharmacy-based system for medicine shortage detection (CISMED).	

Recommendation	Actions taken	Status
102. Calls on the Commission and Council to establish a mechanism whereby medicine shortages across the EU can be reported upon on an annual basis.	The SPOC network has collected and circulated shortage notifications; this, however, does not represent a single mechanism for Member States to report shortages annually.	
103. Calls on the Commission and Council to review the statutory basis of the EMA, and to give consideration to enhancing its remit to coordinate pan-European activity aiming at tackling medicines shortages in the Member States.	On 11 November 2020, the Commission adopted a legislative proposal to extend the mandate of the EMA to facilitate a coordinated EU level response to health threats including medicines shortages.	
105. Calls on the Commission and the Member States to develop a single eHealth and mHealth road map, including, in particular, the development and valorisation of pilot projects at national level, the modernisation of the reimbursement models stimulating a shift towards health outcomes-driven healthcare systems and the definition of incentives to stimulate the healthcare community to engage in this digital revolution, and to enhance education of healthcare professionals, patients and all relevant stakeholders in order to enable their empowerment.	Impact assessment ongoing for the launch of the European Health Data Space. The WHO-ITU project funded under Horizon 2020 will run until 2022 and aims to create a European mHealth hub. The Commission supports the third multiannual work programme of the eHealth Network (2018 – 2022).	

Legend: - Unknown; - No action; - Proposed; - In preparation; - Under implementation; - Implemented.

Source: Technopolis, 2021.

6. REGULATORY FRAMEWORK

6.1. Summary of issues raised

A strong and predictable regulatory framework forms the basis for pharmaceutical innovation, patient access, public interest and market fairness. Currently, the EU regulatory framework experiences a level of fragmentation that results in losses of effectiveness and transparency. In the Resolution, MEPs signal that health technology assessment (HTA) is an important factor within this regulatory framework and that, while HTA agencies are already using clinical, economic and social benefit criteria to evaluate new medicines, these criteria vary between them leading to fragmentation. The Resolution expresses a wish for a unified HTA system to avoid the duplication of efforts and misallocation of resources and decrease the time to market of an innovation. Moreover, the introduced measures for fast-tracking of marketing authorisations present options to get medicines to patients in a significantly shorter timeframe. At the same time, MEPs stress that this should not become the rule and that a higher emphasis on pharmacovigilance is necessary in cases where this procedure has been applied. The Resolution calls for the following specific actions:

- The Commission, the EMA and the Member States are to continue the monitoring and public reporting of the implementation of the pharmacovigilance legislation, and to guarantee post-authorisation assessments of the effectiveness and adverse effects of medicines.
- The Commission and the EMA to put in place guidelines to ensure patient safety in adaptive pathways.
- The European Commission is to guarantee a thorough assessment of quality, safety and efficacy in any fast-track approval process and to ensure that it is only used in exceptional circumstances.
- The Commission is to propose legislation on a European system for HTA as soon as possible, to harmonise transparent HTA criteria, to put in place a European classification system to chart their therapeutic added value level, to strengthen early dialogues and to consider a coordination mechanism based on an independent body.
- The Council is to increase cooperation between the Member States as regards price-setting procedures so that they may share information about, in particular, negotiation agreements and good practices, and avoid unnecessary administrative requirements and delays.
- The Commission is to recommend measures to improve the rate of approval of novel therapies and supply of these to patients.
- The Commission and the Council are to define clear rules on incompatibility, conflicts of interest and transparency in the EU institutions and for experts involved in issues related to medicines.
- The experts involved in the authorisation process should publish their CVs and sign declarations of absence of conflict of interest.

6.2. Assessment & authorisation

Before medicines can enter the European market and become accessible to patients, they must be assessed by a regulatory authority. The scientific assessment process needs to consider the available evidence to determine whether the new medicine is sufficiently safe and effective. To ensure that

medicines reach patients in need in a timely way, the assessment should be completed as soon as reasonably possible, but without compromise to the rigour of the process.

In the EU, most new medicines are assessed by the EMA, often in consultation with experts, healthcare professionals and patients. The EMA submits its recommendation for whether or not to grant a marketing authorisation to the Commission, which makes the final decision. This process is known as the 'centralised procedure'[148]. It is the compulsory authorisation route for several classes of medicines, including all oncology medicines, vaccines, orphan medicines, ATMPs and medicines derived from biotechnology processes. Alternatively, companies may submit an application for authorisation in one or more Member States through a national procedure. The application is then assessed by a national competent authority (NCA) rather than by the EMA. An authorisation issued by an NCA in one Member State can subsequently be recognised in another without the need to repeat the scientific assessment by use of the Mutual Recognition Procedure (MRP). This process can be repeated to obtain authorisation in multiple Member States. Most generic and over-the-counter medicines in the EU are assessed and authorised nationally.

With the departure of the UK from the Union, it is no longer possible for a company to use approval by the UK's Medicines and Healthcare products Regulatory Agency (MHRA) to gain approval in a Member State through the MRP. Previously, the UK frequently was the first Member State in which products were authorised, after which the MRP was used to enter additional markets. The Coordination Group for Mutual Recognition and Decentralised Procedures has since prepared practical guidance for marketing authorisation holders for products approved via national procedures on what actions they should take to make sure that medicines become (or remain) available in both the Union and the UK[149].

Brexit has also posed challenges for the scientific assessment of new medicines. The assessment is led by committee members delegated by the Member States who act as 'rapporteur' and 'co-rapporteur'. Before the UK's departure, a large share of all evaluations included a rapporteur or co-rapporteur from the UK. By July 2019, the entire UK portfolio of over 370 dossiers for centrally authorised medicines had been reassigned to other EU Member States, Iceland or Norway to prevent further disruption once the withdrawal became formalised[14].

The Resolution calls on the Commission to recommend measures to improve the rate of approval of novel therapies and the supply of these to patients. Whilst this recommendation is broad in nature, the Commission envisions concrete plans for this within a narrower scope. In its Beating Cancer Plan, the Commission commits to launching an EU platform "to improve access to cancer medicines to support the repurposing of existing medicines in 2021"[150]. To achieve this, it will devise and test models for closer collaboration among stakeholders and will leverage, pool and share existing data using new digital tools.

The Pharmaceutical Strategy for Europe outlines that the Commission aims to bring EU regulatory approval times on par with those in other parts of the world by evaluating procedures and exploring new approaches to assessing scientific evidence for the safety and efficacy of medicines as part of the review of the legislation[4]. Learning from the COVID-19 pandemic and the possibilities of digital

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[148] Authorisation of medicines. European Medicines Agency), available at: https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines#national-authorisation-procedures-section.

[149] Practical guidance for procedures related to Brexit for medicinal products for human use approved via MRP/DCP. Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (April 2021)), available at: https://www.hma.eu/535.html.

Communication on Europe's Beating Cancer Plan, COM(2021) 44, European Commission (March 2021)), available at: https://ec.europa.eu/health/sites/health/files/non_communicable_diseases/docs/eu_cancer-plan_en.pdf.

technology and artificial intelligence will support regulatory decision-making and increase efficiency. In addition, it states that the Commission aims to revisit existing regulatory tools in the development of innovative products for unmet medical needs (e.g. priority review and scientific advice to support companies, especially SMEs).

Between 2014 and 2016, the EMA ran a pilot project on adaptive pathways, which provided a framework for informal dialogue with stakeholders, including HTA bodies, along the development path to accelerate development and approval[151]. As of July 2017, the EMA has been offering similar consultations with the EUnetHTA. In the Resolution, MEPs note that adaptive pathways, which are a form of fast-track approval, bring with them increased risks to patient safety when the data collected on safety and effectiveness is incomplete. The Resolution thus calls upon the Commission to ensure that fast-track approvals are made possible by means of conditional authorisation. It is furthermore specified that such approvals should only be possible when it addresses a clear unmet need and a thorough assessment of quality, safety and efficacy is guaranteed. It also asks that a transparent and accountable post-authorisation process and sanctions for non-compliance are ensured. In 2005, the EMA had adopted its guidelines on accelerated assessments procedures and conditional marketing authorisation to allow for a faster assessment of innovative medicines targeting diseases for which no treatment is available yet or providing a major advantage over existing treatments. These guidelines were revised in 2015 and now include a clarification on fulfilment of unmet medical needs[152]. No further updates to the guidelines have been introduced thereafter. In its Strategic Reflection on Regulatory Science to 2025, the EMA also recommends the promotion of the use of real-world data (RWD) in decision-making as well as the inclusion in development plans of requirements for post-licensing evidence generation[153]. Such actions are expected to increase the evidence-base for assessment of safety and effectiveness, needed to convert a conditional marketing authorisation into a non-conditional one. The EMA reflection notes that initiatives for this already exist but will need to be expanded.

The 2018 EMA plan for emerging health threats outlines the response procedure for crisis situations[154]. The plan states that regulatory processes are to be shortened to respond adequately but emphasises that pharmacovigilance activities in such a crisis situation of an emerging health threat should be enhanced. In particular, the rapid exchange of information on pharmacovigilance issues between the EMA, Member States and the Commission is to take place through the European Pharmacovigilance Issues Tracking Tool (EPITT). Furthermore, the current COVID-19 pandemic resulted in accelerated support and evaluation of vaccines. The flexible and fast review of these products is supported by EMA's pandemic Task Force (COVID-ETF), which is formed to support the Member States and the Commission in taking quick and coordinated regulatory actions on the development, authorisation and safety monitoring of treatments and vaccines against COVID-19. The Task Force is accountable to and works closely with EMA's human medicines committee (CHMP) for optimal and fast coordination of activities.

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151 Adaptive pathways. European medicines Agency (2016)), available at: https://www.ema.europa.eu/en/human-regulatory/research-development/adaptive-pathways.

152 Fast track routes for medicines that address unmet medical needs, press release, EMA (27 July 2015)), available at: https://www.ema.europa.eu/en/news/fast-track-routes-medicines-address-unmet-medical-needs.

153 EMA Regulatory Science to 2025: Strategic reflection. European Medicines Agency (2020)), available at: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf.

154 EMA plan for emerging health threats, EMA, December 2018), available at: https://www.ema.europa.eu/en/documents/other/ema-plan-emerging-health-threats_en.pdf.

A separate point that was raised in regard to the scientific assessment of medicines is that of transparency and conflict of interest of the institutions and experts involved. In 2021, the EMA adopted an updated policy on the handling of competing interests of scientific committees' members and experts. Its main objective is to ensure that members of the scientific committees and experts participating in procedures have no interests in the pharmaceutical industry. Expert are required to provide a signed declaration of interests[155].

6.3. Health technology assessment (HTA)

The role of reimbursement decision-making and its relation to access to medicines was previously discussed in Section 5.3. Whilst many medicines are automatically accepted for reimbursement once they have been authorised, payers increasingly rely on Health Technology Assessment (HTA) to support their decision-making for the reimbursement of high-cost innovative medicines. HTA is the systematic evaluation of the properties and the direct and indirect effects of medical technology. It is a multidisciplinary form of policy analysis that studies the medical, social, ethical and economic implications of the development, dissemination and use of medical technology and interventions. To ensure the most rational use of limited resources, in the context of ever rising healthcare costs worldwide, HTA has become an increasingly important policy tool. However, there is a large variation in HTA of new medicines across countries.

Harmonisation of HTA across European Member States is an important element in the 2017 resolution. It is foreseen that legislation on a system for HTA on European level ensures that HTA output that is jointly produced at EU level is used at national level. The Resolution calls upon the Commission to act on the following:

- Propose legislation on a European system for HTA.
- Harmonise transparent HTA criteria.
- Introduce compulsory relative effectiveness assessments at EU level.
- Put in place a European classification system.

In 2018, the Commission proposed a regulation on joint HTA, establishing the procedures and structures for cooperation and joint work at EU level[156]. The proposal includes a clear instruction on how joint HTA results are to be used at national level. It also outlines the support that the Commission provides in this to be mostly administrative, scientific, and IT-related. The proposal was sent to the Parliament and Council for adoption by 2019. On 24 March 2021, after lengthy debates within the Council, Member States agreed on a partial mandate to start negotiations with the Parliament on a legislative proposal concerning joint HTA[157]. In its press statement, the Council indicates that it expects that the proposed legislation will "lead to cost savings and reduce duplication of work". However, the proposal has been heavily criticised by the trade groups EFPIA and MedTech Europe[158] who fear it will

[155] European medicines Agency policy on the handling of competing interests of scientific committees' members and experts. European Medicines Agency (2020)), available at: https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees_en-0.pdf.

[156] Proposal for a Regulation on health technology assessment and amending Directive 2011/24/EU, COM(2018) 51, European Commission, January 2018), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52018PC0051.

[157] Health Technology Assessment: Council agrees its negotiating position, press release, Council of the European Union, 24 March 2021), available at: https://www.consilium.europa.eu/en/press/press-releases/2021/03/24/health-technology-assessment-council-agrees-its-negotiating-position/.

[158] EFPIA is the European Federation of Pharmaceutical Industries and Associations), available at: https://www.efpia.eu/. MedTech Europe is the European trade association representing the medical technology industries), available at: https://www.medtecheurope.org/.

lead to greater inefficiency and unpredictability[159,160]. They argue the Regulation may in fact delay access to innovation rather than accelerate it.

The Resolution calls on the Commission to enhance early dialogues and consider a coordination mechanism based on an independent body. This fosters cooperation between national HTA bodies but keeps HTA expertise at national levels. The European Network for Health Technology Assessment (EUnetHTA) was already established in 2008 and the network currently includes over 80 organisations that direct their efforts to facilitating high-quality HTA collaboration in Europe. As of July 2017, the EMA offers consultations, also referred to as early dialogues, in close coordination with EUnetHTA[161]. Together they now provide medicine developers with the option of receiving coordinated and simultaneous advice on their development plans. Previous to this initiative, medicine developers needed to contact Members States' HTA bodies individually in order to request for parallel advice by the national HTA bodies and the EMA. It is expected that this initiative will structure the interaction between the EMA and HTA bodies and improve coordination and participation of HTA bodies.

6.4. Pharmacovigilance & safety

Once a medicine becomes available, patients should be able to trust that these products are safe. Even though every authorised medicine has been assessed for safety on the basis of available clinical trial data, the full understanding of a medicine's benefit-to-risk profile can only be developed once it is used at a larger scale outside of the controlled trial setting. This requires careful monitoring of real-world outcomes in a process known as pharmacovigilance. It refers to a set of methods to evaluate and prevent the risk of adverse reactions to a medicine after it has reached the market. It includes the collection, analysis and interpretation of data as well as the dissemination of results to health professionals and possibly patients.

In the Resolution, MEPs welcomed the pharmacovigilance legislation of 2010 and 2012. The pharmacovigilance legislation was developed to improve data collection and facilitate rapid and robust assessment of safety issues[162,163]. In 2012, the legislation was followed by an implementing regulation, which outlined the operational details[164]. Moreover, in 2012 the legislation was amended to allow for swift notification and assessment of safety issues and to strengthen the system[165,166]. In this

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159 EFPIA statement in response to the Council compromise agreement on the Commission Proposal for a Regulation on Health Technology Assessment. EFPIA (26 March 2021)), available at: https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/efpia-statement-in-response-to-the-council-compromise-agreement-on-the-commission-proposal-for-a-regulation-on-health-technology-assessment/.

160 MedTech Europe calls for stronger recognition of medical technologies' specificities in upcoming trilogue on HTA. MedTech Europe (30 March 2021)), available at: https://www.medtecheurope.org/news-and-events/press/medtech-europe-calls-for-stronger-recognition-of-medical-technologies-specificities-in-upcoming-triloque-on-hta/.

161 Parallel consultation with regulators and health technology assessment bodies, EMA website), available at: https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance/parallel-consultation-regulators-health-technology-assessment-bodies.

162 Regulation 1235/2010 (EU) of 15 December 2010 amending Regulation (EC) No 726/2004 and Regulation (EC) No 1394/2007), available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:348:0001:0016:EN:PDF.

163 Directive 2010/84/EU of 15 December 2010 on amending Directive 2001/83/EC), available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:348:0074:0099:EN:PDF.

164 Regulation 520/2012 (EU) of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC), available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:159:0005:0025:EN:PDF.

165 Regulation 1027/2012 (EU) of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance), available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0038:0040:EN:PDF.

166 Directive 2012/26/EU of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance), available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:299:0001:0004:EN:PDF.

respect, the Resolution calls on the Commission, the EMA, and the Member States to continue monitoring and reporting on the implementation of this legislation. The EMA, in cooperation with the Commission and Member States, operates the European pharmacovigilance system EudraVigilance[167]. To increase the quality of data reported to the pharmacovigilance system, from June 2022 it will become mandatory to use a data format based on international standards outlined by the International Organisation for Standardisation (ISO) to report side effects to the system. In line with the pharmacovigilance legislation, MAHs of medicinal products are obliged to submit periodic safety update reports (PSURs) to the PSUR repository hosted by the EMA. These PSURs are in turn assessed by the EMA through the single assessment procedure. The EMA reports on its activities related to the pharmacovigilance system on an annual basis[168]. The latest regular Commission report on pharmacovigilance activities dates back to 2019, covering the period 2015-2018[169].

The "Terminology" project under the third European Health Programme aimed to harmonise the identification of medicinal products worldwide, primarily for pharmacovigilance purposes[170]. By means of the Standard Terms database of harmonised terms and definitions, the project fosters post-marketing safety activities and monitoring of adverse events across the globe.

The Resolution recommended for guarantee of post-authorisation assessments of the effectiveness and adverse effects of medicines. The EMA, specifically the Pharmacovigilance Risk Assessment Committee (PRAC), is responsible for the assessment of the protocols of imposed post-authorisation safety studies (PASSs) and assessment of their results. All protocols, abstracts and study reports of these PASSs are published by the EMA on the EU post-authorisation study (PAS) register[171].

The Resolution notes the use of adaptive pathways to accelerate access to medicines, while simultaneously underlining the uncertainty of safety and effectiveness of the medicines produced through these pathways. It is also considered that adaptive pathways should be limited to critical issues of high unmet medical need. Hence, the Resolution calls on the Commission and the EMA to put in place guidelines to ensure patient safety. In 2016, the EMA, after a successful pilot project, has put in place guidance for companies that consider adaptive pathways[172]. Apart from this guidance, no further guidelines have been developed.

Patient registries are essential in the monitoring of medicine safety. Pharmaceutical companies and regulatory bodies currently encounter various obstacles when using existing, or when establishing new patient registries, such as data-sharing and transparency, sustainability and harmonisation of protocols, methods and data structures. In the Resolution, MEPs requested the Commission, together with the EMA and its stakeholders, to draft a Code of Practice to enforce the reporting of adverse events

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167 EudraVigilance, EMA website), available at: https://www.ema.europa.eu/en/human-regulatory/research-development/pharmacovigilance/eudravigilance.

168 EudraVigilance, EMA website), available at: https://www.ema.europa.eu/en/human-regulatory/research-development/pharmacovigilance/eudravigilance.

169 Report on pharmacovigilance tasks from EU Member States and the European Medicines Agency (EMA), 2015- 2018, EMA December 2019), available at: https://ec.europa.eu/health/sites/health/files/files/pharmacovigilance/pharmacovigilance-report-2015-2018_en.pdf.

170 Report om the implementation of the third programme of EU action in the field of health in 2017, COM(2020) 88, European Commission, March 2020), available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM%3A2020%3A0088%3AFIN, accessed on 03/06/2021.

171 The European Union electronic Register of Post-Authorisation Studies (EU PAS Register), ENCEPP website), available at: http://www.encepp.eu/encepp_studies/indexRegister.shtml, accessed on 03/06/2021.

172 Guidance for companies considering the adaptive pathways approach, EMA, August 2016), available at: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-companies-considering-adaptive-pathways-approach_en.pdf, accessed on 03/06/2021.

and outcomes for off-label use of medicines. Additionally, MEPs asked for patient registries to strengthen the evidence base and mitigate risks for patients.

In 2012, the Guidelines on Good Pharmacovigilance Practices were put in place by the EMA [173]. Module IV of the guidelines deals with the collection, management and submission of reports on adverse reactions to medicines. This module was updated in August 2017, and now includes guidance on the management of reports on off-label use. The guidance requires MAH to collect individual reports of suspected adverse reactions in the case of off-label use when becoming aware of them. It also indicates that, where there is a scientific rationale that an adverse clinical outcome might be associated with the off-label use of the product, the adverse reaction should be included in the list of safety concerns of the risk management plan.

[173] Guidelines on good pharmacovigilance practices (GVP), EMA, July 2017), available at: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-collection-management-submission-reports_en.pdf, accessed on 03/06/2021.

6.5. Summary of identified actions

Table 5: Summary table – Regulatory framework

Recommendation	Actions taken	Status
74. Calls on the Commission, the EMA and the Member States to continue the monitoring and public reporting of the implementation of the pharmacovigilance legislation, and to guarantee post-authorisation assessments of the effectiveness and adverse effects of medicines.	MAHs of medicinal products are obliged to submit periodic safety update reports to the EMA for routine assessment and annual reporting. From June 2022, reporting of side-effects into the European pharmacovigilance system EudraVigilance will follow a standardised data format.	
75. Calls on the Commission to collaborate with the EMA, and with stakeholders, with a view to introducing a Code of Practice for mandatory reporting of adverse events and of outcomes for off-label use of medicines, and to ensuring patients' registries in order to strengthen the evidence base and mitigate risks for patients.	In 2017, the EMA updated its Guidelines on Good Pharmacovigilance Practices to include guidance on the management of reports on off-label use. It requires MAH to report suspected adverse reactions when becoming aware of them and stipulates that adverse clinical outcomes should be included in the list of safety concerns of the risk management plan.	
78. Notes the use of adaptive pathways to promote faster access to medicines for patients; underlines the higher degree of uncertainty regarding the safety and effectiveness of a new medicine when it enters the market; highlights the concern expressed by healthcare professionals, civil society organisations and regulators regarding adaptive pathways; stresses the crucial importance of the proper implementation of the post-marketing surveillance system; considers that adaptive pathways should be restricted to specific cases of high unmet medical need, and calls on the Commission and the EMA to put in place guidelines to ensure patient safety.	Post-licensing product assessment is embedded into the procedures of the EMA. Increased use of real-world data by regulators and HTA bodies is expected to improve the evidence for safety and effectiveness of medicines approved on a conditional basis.	
79. Calls on the Commission to guarantee a thorough assessment of quality, safety and efficacy in any fast-track approval process, and to ensure that such approvals are made possible by means of conditional authorisation, and only	See recommendation 78.	

Recommendation	Actions taken	Status
in exceptional circumstances where a clear unmet medical need has been identified, and to ensure that a transparent and accountable post-authorisation process to monitor safety, quality and efficacy is in place, as well as sanctions for non-compliance.		
85. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, to harmonise transparent HTA criteria in order to assess the added therapeutic value of medicines compared with the best available alternative taking into account the level of innovation and value for the patients among others, to introduce compulsory relative effectiveness assessments at EU level as a first step for new medicines, and to put in place a European classification system to chart their therapeutic added value level, using an independent and transparent procedure that avoids conflicts of interests […]; calls, furthermore, on the Commission to strengthen early dialogues and to consider a coordination mechanism based on an independent body, which could foster cooperation between national HTA bodies while at the same time ensuring that expertise on HTA remains within national (and regional) HTA.	Negotiations initiated on a proposal for a regulation on joint HTA with the key element of establishing procedures and structures for cooperation on joint work at EU level. The EUnetHTA Joint Action 3 was extended until May 2021. No information on its continuation under Horizon Europe.	
95. Calls on the Commission and the Council to define clear rules on incompatibility, conflicts of interest and transparency in the EU institutions and for experts involved in issues related to medicines; calls on the experts involved in the authorisation process to publish their CVs and to sign declarations of absence of conflict of interest.	The EMA has adopted a new policy on handling of competing interests for committee members and experts.	
100. Calls on the Commission to recommend measures to improve the rate of approval of novel therapies and the supply of these to patients.	Revision of the pharmaceutical legislation is expected to reduce regulatory approval times in the EU by evaluating procedures and exploring new approaches to assessing scientific evidence.	

Legend: ⚪ - Unknown; 🔴 - No action; 🟠 - Proposed; 🟡 - In preparation; 🟢 - Under implementation; 🟢 - Implemented.

Source: Technopolis, 2021.

7. DEVELOPING COUNTRIES

7.1. Summary of issues raised

In developing countries, essential medicines are often not available to those who need them, because they have not been placed on these markets, are sold only at prohibitive prices or because of variable quality of medicines and healthcare. MEPs recognise the importance of ensuring global access to medicines from a perspective of global responsibility and equity, but also with an eye towards preventing the spread of common infectious diseases and the emergence of chronic disease epidemics.

Compared to Europe, the pharmaceutical sector in developing countries is typically less well regulated and the extent to which regulation is in place strongly depends on level of income, policies and the national vision on healthcare. This leads to unavailability and unaffordability of medicines. The World Health Organisation (WHO) has recently updated its guidelines on implementation of effective pharmaceutical pricing policies for low- and middle-income countries[174]. When carefully planned, carried out and monitored, strong pharmaceutical pricing policies can improve the affordability of medicines. The EU Tiered Pricing Regulation was applied in 2003 and was intended to set up a system to enable producers of pharmaceutical products to sell essential medicines at reduced prices to developing countries without these products finding their way back to Europe[175]. However, in the Resolution, MEPs recall that tiered pricing does not necessarily lead to affordability of medicines and call upon the Commission to open a broad and transparent discussion on pricing regulation and strategies that improve access to quality and affordable medicines.

Access to medicines in the developing world could be improved through local R&D and manufacturing of medicines. Developing countries, however, lack sufficient productive capacity, a reality that was brought back in the spotlights during the current COVID-19 pandemic[176]. As a result, health in developing countries is improving at a slower rate. In its resolution, MEPs stressed the need to develop local pharmaceutical research capacity in developing countries. Capacity development in these countries is considered a sustainable solution in bridging the gap between research and production of medicines. It is foreseen that this is done through public-private partnerships (PPPs) and the creation of open centres for research and production. PPPs can strengthen healthcare systems by building infrastructures at trial sites, providing equipment, education and training to strengthen research capacity in developing countries[177]. Moreover, such partnerships have shown to promote the transfer of knowledge and new medical technologies to developing as well as developed countries[177].

7.2. Capacity development

To address access to medicines in developing countries, efforts should be directed to the development of capacity in these countries. This issue is addressed in the Resolution, while MEPs urge the Commission to step up its efforts to improve capacity in developing countries and support in designing working and sustainable health systems, which aim at improving access to services. They also highlight

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[174] WHO guideline on country pharmaceutical pricing policies, WHO, September 2020), available at: https://www.who.int/publications/i/item/9789240011878, accessed on 03/06/2021.

[175] Regulation 953/2003 (EU) of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=LEGISSUM:l21166, accessed on 03/06/2021.

[176] COVID-19 heightens need for pharmaceutical production in poor countries, press release, UNCTAD, 27 May 2020), available at: https://unctad.org/news/covid-19-heightens-need-pharmaceutical-production-poor-countries, accessed on 03/06/2021.

[177] Stevens, H., & Huys, I., 'Innovative Approaches to Increase Access to medicines in Developing Countries', *Frontiers in Medicine*, December 2017), available at: https://www.frontiersin.org/articles/10.3389/fmed.2017.00218/full, accessed on 03/06/2021.

that the transfer of health-related technologies to developing countries can enable recipient countries to produce products locally and may result in increased access to the product and improved health. Alongside these recommendations, the Resolution advocates for building strong surveillance and delivery systems at all levels, including community to district, provincial and national, could make access to medicines in developing countries more feasible.

In 2020, the Commission published a draft of a partnership proposal for the Global Health Partnership, the third programme of the European and Developing Countries Clinical Trials Partnership (EDCTP3). The new partnership builds upon two previous EDCTP programmes. It is intended to support international research partnerships in accelerating clinical evaluation of medicines, vaccines and diagnostics for major infectious diseases in sub-Saharan Africa[178]. Additionally, the partnership will support innovative approaches for surveillance systems and control of (re-)emerging infections, as well as strengthen clinical research capacity in developing countries. In doing so, the partnership is expected to increase access to medicines and medical interventions in developing countries and help protect regional and global health security.

The proposal sets out key targets regarding capacity building, such as funding for at least 50 specific capacity-building projects and at least 250 fellowships. Herewith, it plans to reinforce the clinical trial environment in sub-Saharan countries taking into account the countries' fundamental ethical principles and relevant legislation at national, regional and international level. The proposal for a regulation, under which the Global Health EDCTP3 partnership will be established along with nine other European R&D partnerships, awaits adoption by the Council, following consultation with the European Parliament and the Economic and Social Committee[179]. The partnership is expected to operate with a budget of EUR 800 million to EUR 1 billion provided by the Commission, matched with contributions from governments and funders[180].

The Commission has also expressed commitment to global health and capacity development under the new EU4Health Programme. In the specific objectives, the Commission indicates that the programme will support "global commitments and health initiatives by reinforcing the Union's support for actions by international organisations, in particular actions by the WHO, and fostering cooperation with third countries"[7].

7.3. Pricing regulation & access initiatives

Global programmes and initiatives promoting access to medicines in developing countries have been instrumental in advancing health goals and have greatly improved access to medicines and vaccines. This is stimulated by MEPs and, to keep momentum, is addressed in the recommendation directed to the Commission to step up its support of global programmes and initiatives. In line with this, in 2016 the Commission expressed its full support when least developed countries were exempted from obligations to provide protection of pharmaceutical products via patents to support access to

[178] Draft proposal on the EDCTP3: EU–Africa Global Health Partnership, European Commission, August 2020), available at: https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/edctp3_draft_proposal_14_august_2020.pdf, accessed on 03/06/2021.

[179] EU to set up new European Partnerships and invest nearly €10 billion for the green and digital transition. Press Release by the European Commission (23 February 2021)), available at: https://ec.europa.eu/commission/presscorner/detail/en/IP_21_702, accessed on 03/06/2021.

[180] Commission begins work on €10 billion in new R&D partnerships. Hudson RL. Science|Business), available at: https://sciencebusiness.net/framework-programmes/news/commission-begins-work-eu10-billion-new-rd-partnerships, accessed on 03/06/2021.

medicines until at least 2033[181]. Moreover, as part of its commitment to the global strategy and plan of action by the WHO, the EU established its own Global Health Strategy.

A major new global access initiative is the Covid-19 Vaccines Global Access (COVAX) facility. COVAX was launched in April 2020 by the World Health Organization, the Commission and France to bring together a wide range of actors, including governments and vaccine manufacturers, to improve global access to COVID-19 vaccines[182]. It is a risk-sharing mechanism to jointly procure and distribute vaccines. Countries that participate in the facility will have equal access to vaccines. In February 2021, the Commission announced that it doubled its previous commitment of EUR 500 million to the facility, raising it to EUR 1 billion[183]. The United States has thus far pledged USD 4 billion. As of 12 May 2021, COVAX had distributed over 59 million vaccines to 122 participating countries[184].

The Resolution also called upon the Commission to open a broader and transparent discussion on pricing regulation and strategies that ensure access to quality and affordable medicines and stressed that the REFIT review of the EU Tiered Pricing Regulation[185] should aim at further promoting lower prices in developing countries. The 2016 evaluation of the Tiered Pricing Regulation concluded that the Regulation was of limited added value but that, taking into account the low administrative burden and the benefits that were realised, it maintained its role in the future in the context of the Commission's commitment to improve access to medicines in developing countries[186]. The regulation has been subject to many incremental amendments addressing its shortcomings since it entered into force in 2003. To codify all these amendments, the regulation was replaced in 2016 by Regulation (EU) 2016/793[187]. No specific EU actions in relation to tiered pricing or pricing regulation in developing countries were identified after the Resolution was issued.

[181] Executive Summary of the REFIT Evaluation of the Council Regulation (EC) 953/2003 to avoid trade diversion into the European Union of certain key medicines, SWD(2016) 125, European Commission, April 2016), available at: https://trade.ec.europa.eu/doclib/docs/2016/april/tradoc_154439.pdf, accessed on 03/06/2021.

[182] What is COVAX. Gavi, the Vaccine Alliance), available at: https://www.gavi.org/covax-facility#what, accessed on 03/06/2021.

[183] EU doubles contribution to COVAX to €1 billion to ensure safe and effective vaccines for low and middle-income countries. European Commission press release (21 February 2021)), available at: https://ec.europa.eu/commission/presscorner/detail/en/IP_21_690, accessed on 03/06/2021.

[184] Weekly operational update on COVID-19 - 17 May 2021, press release, 17. May 2021, World Health Organization), available at: https://www.who.int/publications/m/item/weekly-operational-update-covid-19---17-may-2021, accessed on 03/06/2021.

[185] Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines), available at: medicineshttps://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32003R0953, accessed on 03/06/2021.

[186] Commission Staff Working Document: REFIT evaluation of Regulation (EC) 953/2003 to avoid trade diversion into the European Union of certain key medicines, SWD(2016) 125, European Commission, June 2016), available at: https://trade.ec.europa.eu/doclib/docs/2016/april/tradoc_154439.pdf, accessed on 03/06/2021.

[187] Regulation (EU) 2016/793 of 11 May 2016 to avoid trade diversion into the European Union of certain key medicines), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2016.135.01.0039.01.ENG&toc=OJ%3AL%3A2016%3A135%3ATOC, accessed on 03/06/2021.

7.4. Summary of identified actions

Table 6: Summary table – Developing countries

Recommendation	Actions taken	Status
104. Stresses that building strong surveillance and delivery systems at all levels, from community to district, provincial and national, and supported by high-quality laboratory services and strong logistical systems, could make access to medicines more feasible, while the transfer of health-related technologies (through licence agreements, and the provision of information, know-how and performance skills to technical materials and equipment) to developing countries can enable recipient countries to produce the product locally, and may result in increased access to the product and improved health.	Under EDCTP2, the Commission has invested in development of research and disease surveillance capacity in developing countries. It is expected to continue this under EDCTP3.	
107. Urges the EU to step up efforts to improve developing countries' capacities and help them design working health systems that aim at improving access to services, particularly for vulnerable communities.	See recommendation 104.	
108. Stresses that the ongoing REFIT review of the EU Tiered Pricing Regulation (EC) No 953/2003 should aim at further promoting lower prices in developing countries, and calls on the EU to open a broader and transparent discussion on pricing regulation and strategies that ensure access to quality and affordable medicines.	No relevant actions identified after 2016.	
109. Urges the EU to step up its support of global programmes and initiatives promoting access to medicines in developing countries, as these programmes have been instrumental in advancing health goals and greatly improved access to medicines and vaccines.	Under Horizon Europe, the Commission is expected to contribute EUR 800 million to EUR 1 billion to the Global Health EDCTP3 partnership. Relevant research is expected under other actions within Horizon Europe. The EU4Health programme provides financial support to global health initiatives and will support international and multilateral organisations.	

Legend: ⚪ - Unknown; 🔴 - No action; 🟠 - Proposed; 🟡 - In preparation; 🟢 - Under implementation; 🟢 - Implemented.

Source: Technopolis, 2021.

8. MONITORING, EVALUATION & REPORTING

8.1. Summary of issues raised

Along with specific actions aimed at ensuring and promoting access to medicines, the Resolution included several recommendations aimed at monitoring and evaluating of existing legislation and processes affecting access to medicines and reporting the results of such activities back to the Parliament. Furthermore, the Resolutions requests the Commission to submit a report, at least every five years, on access to medicines in the EU, and to report more regularly in cases of exceptional problems regarding access to medicines.

8.2. Key issues

At various points throughout this report, reference has been made to specific pieces of legislation that have been evaluated in the years since the adoption of the Resolution or for which the evaluation is ongoing. On 11 August 2020, the European Commission published its joint evaluation on the legislation for medicines for rare diseases and for children [188], prompting a proposal for a revision of both regulations. The Commission is in the process of initiating the back-to-back evaluation and impact assessment for the revision of the EU's general pharmaceutical legislation. Revisions to the legislation are aimed at ensuring access to affordable medicines, fostering innovation, including in areas of unmet medical need and ensuring a future-proof and crisis-resistant medicines regulatory system [189].

The Resolution encouraged Member States to evaluate healthcare pathways and policies with a view to improving patient outcomes and the financial sustainability of the system, by fostering digital solutions to improve healthcare delivery to patients and to identify waste of resources. No information was identified on specific actions undertaken by Member States in response to this recommendation. The Pharmaceutical Strategy for Europe proposes an action to continue the assessment through the European semester of the adequacy and sustainability of national health systems and issue country specific recommendations as relevant to ensure they are accessible and efficient [190].

[188] Joint evaluation of Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Regulation (EC) No 141/2000 on orphan medicinal products, SWD(2020) 163, European Commission, August 2020), available at: https://ec.europa.eu/health/sites/health/files/files/paediatrics/docs/orphan-regulation_eval_swd_2020-163_part-1.pdf, accessed on 03/06/2021.

[189] Revision of the EU general pharmaceuticals legislation, European Commission website), available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Evaluation-and-revision-of-the-general-pharmaceutical-legislation, accessed on 03/06/2021.

[190] Communication on a Pharmaceutical Strategy for Europe, COM(2020) 761, European Commission, November 2020), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761, accessed on 03/06/2021.

8.3. Summary of identified actions

Table 7: Summary table – Monitoring, evaluation & reporting

Recommendation	Actions taken	Status
99. Calls on the Commission to submit a report, at least every five years, to the Council and to Parliament on access to medicines in the EU, and to report more regularly in cases of exceptional problems regarding access to medicines.	No specific action identified beyond the study presented in this report.	
106. Encourages the Member States to evaluate healthcare pathways and policies with a view to improving patient outcomes and the financial sustainability of the system, in particular by fostering digital solutions to improve healthcare delivery to patients and to identify waste of resources.	No actions at Member State level identified.	

Legend: - Unknown; - No action; - Proposed; - In preparation; - Under implementation; - Implemented.

Source: Technopolis, 2021.

9. ADDITIONAL OPTIONS

Whilst most of the analysis in this report has focused on actions to increase access to medicines undertaken at the level of the Commission, the Union or EU executive agencies, independent actions have also been initiated by Member States and other actors. The following sections offer examples of such actions that may have the potential to be scaled up. The list of identified actions is non-exhaustive, and no further analysis of individual actions was conducted. As such, this chapter aims to be inspirational rather than comprehensive. The identified actions have been structured along the same main themes as covered by the previous chapters.

9.1. Patient

A 2017 academic study reviews current initiatives to increase patient involvement in R&D but finds that, while these initiatives exist, they lack consistency and a structured approach[191]. The authors set up a practical guideline for how patients can be involved in various stages of R&D level.

In 2020 the European Patients' Academy on Therapeutic Innovation (EUPATI) was established as an independent non-profit foundation, based in the Netherlands[192]. It originated as a project supported under IMI2. EUPATI offers a Patient Expert Training Programme to train so-called patient experts, enabling them to impactfully participate in research programming and discussions with decision-makers. It has established National Platforms in most EU Member States[193]. These platforms are used to raise awareness about the role of patients and to identify opportunities for joint action.

In 2017, EUnetHTA established a task group on the involvement of Patients & Consumers and Health Care Providers. Resulting from this, the task group published a document detailing "Patient Input in Relative Effectiveness Assessments"[194], outlining how patients can be involved in the HTA process. It is not known if or how any of the Member States have incorporated this guidance into national HTA procedures.

The rational prescription and use of medicines, in particular antibiotics, has been an increasingly relevant topic in academic literature. A 2020 study across 13 European countries found that all investigated EU Member States had multiple strategies in place to support the rational prescription of medicines both at the micro- (targeted approaches) and macro- (system approaches) level but that there were differences between Member States. At the micro-level, all Member States used seminars, workshops, clinical literature and newsletters, treatment guidelines and medicine formularies, illustrated materials and educational outreach. Common strategies at the macro-level included international reference pricing, prescription fill limits, caps of number of pills per month, prescriptions per month, prescribing restricted to specialists and dispensing timeframes[195].

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[191] Geissler, J., Ryll, B., di Priolo, S. L., & Uhlenhopp, 'Improving Patient Involvement in Medicines Research and Development: A Practical Roadmap.', *Therapeutic Innovation & Regulatory Science*, 51(5), May 2017, pp. 612–619), available at: https://journals-sagepub-com.vu-nl.idm.oclc.org/doi/full/10.1177/2168479017706405, accessed on 03/06/2021.

[192] EUPATI – About Us. European Patients' Academy on Therapeutic Innovation), available at: https://eupati.eu/about-us/, accessed on 03/06/2021.

[193] EUPATI National Platforms have been established in Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovakia, Spain and Sweden), available at: https://eupati.eu/national-platforms/, accessed on 03/06/2021.

[194] See: Patient Input in Relative Effectiveness Assessments, EUnetHTA, May 2019), available at: https://eunethta.eu/wp-content/uploads/2019/06/Final_290519_Patient-Input-in-REAs.pdf, accessed on 03/06/2021.

[195] Rotar, A. M., van den Berg, M. J., & Klazinga, N. S., 'An expert-based mapping of healthcare system strategies to support rational drug prescribing in primary care across 13 European countries'. *Health Research Policy and Systems*, *18*(1), 102, September 2020), available at: https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-020-00605-w, accessed on 03/06/2021.

9.2. Market

All Member States have national authorities to monitor anti-competitive behaviour and, where necessary, take action against this. The degree to which these authorities intervene in the pharmaceutical sector was here not further explored, as it is assumed that the procedures for doing so are sufficiently well-established and offer no new insights for additional action. However, alongside such authorities, other actors may also bring forward action if they consider that national authorities do not sufficiently take their responsibility. One such example is the Dutch Pharmaceutical Accountability Foundation, established in 2018 in the Netherlands to draw attention to pharmaceutical companies that demand excessive prices for medicines [196]. In addition to bringing legal action against pharmaceutical companies or the national government, the Foundation aims to foster better access to medicines by highlighting pathways for stakeholders to take action.

9.3. Research, development & innovation

Alongside their contribution to the research programmes of the Commission, all Member States have well-established programmes and subsidies of their own to support medical research and pharmaceutical product development. These measures vary in their size and scope but many are complementary to the work of the Commission in the areas of unmet need identified in the Resolution.

For instance, in 2020, Orphanet – a consortium of 40 academic institutions from within Europe and globally – published a list of research infrastructures useful to rare diseases in Europe by country of location. It shows that many Member States are host to and support valuable infrastructures needed to support research into rare diseases [197]. Whilst some infrastructures are (partially) funded by the Commission, others are not and operate mainly from national funding.

Many Member States independently offer funding opportunities for research into novel antibiotics. At a more global scale, a noteworthy development is the creation of the CARB-X non-profit partnership. This partnership is investing up to USD 480 million from 2016-2022 to accelerate the development of innovative antibiotics and other therapeutics, vaccines, and rapid diagnostics to address drug-resistant bacteria. While the consortium includes multiple government bodies and large philanthropic foundations, Germany is currently the only participating Member State.

9.4. Health system

The COVID-19 pandemic has shown the potential benefits of joint procurement. However, it has also shown that coordinating such actions at the level of all Member States can pose challenges. On a smaller scale, bi- and multilateral purchasing agreements between Member States already existed prior to this. Table 8 outlines the main initiatives that have been in place since 2012. Due to their scale and expressed interest from Member States, the BeNeLuxA and Valletta initiatives are of particular relevance.

[196] Solutions for better access to medicines, Pharmaceutical Accountability Foundation website), available at: https://www.farmaterverantwoording.nl/en/solutions/, accessed on 03/06/2021.

[197] List of Research Infrastructures useful to Rare Diseases in Europe. Orphanet (2020), available at: https://www.orpha.net/orphacom/cahiers/docs/GB/Research_Infrastructures_for_rare_diseases_in_Europe.pdf, accessed on 03/06/2021.

Table 8: Member state collaborations on pricing and access

Collaboration name	Scope	Collaboration start and interested Parties	Key focus areas/activities
Baltic Procurement Initiative	Medicines & medical devices (lending) & vaccines (joint procurement)	2012 - Estonia, Latvia & Lithuania	Joint procurement & information sharing of vaccines and medicines Sharing of medicines across countries in time of shortage
BeNeLuxA Initiative	Mainly new & costly Medicines	2015 - Belgium, Luxembourg, Netherlands 2016 - Austria 2018 - Ireland Interested Parties: France, Italy, Switzerland, Czech Republic, Romania, Slovenia	Horizon scanning HTA Pricing & reimbursement negotiations Exchange of strategic information
Nordic Pharmaceutical Forum and FiNoSe	Old & new medicines	2015 – Denmark, Iceland, Norway, Sweden, Finland (Observer)	Horizon scanning Price negotiations Information sharing
Visegrad – "Fair & Affordable Pricing" (FAAP)	High-priced Medicines	2017 – Hungary, Lithuania, Poland, Slovakia 2019 – Czech Republic Interested Party: Ukraine	HTA reports Price negotiations Information sharing
Valetta Declaration	New and innovative medicines and therapies	2017 – Cyprus, Greece, Ireland, Italy, Malta, Portugal, Romania, Spain 2018 – Slovenia, Croatia Interested Parties: France (Observer), Estonia	Horizon scanning HTA Pricing & reimbursement negotiations Exchange of strategic information

Source: Rauland M (2020)[198].

[198] Cross Country Collaborations in Europe: The Future of Pricing & Access Negotiations? Rauland M (24 November 2000) Pharma Boardroom), available at: https://pharmaboardroom.com/articles/cross-country-collaborations-in-europe-the-future-of-pricing-access-negotiations/, accessed on 03/06/2021.

In 2018, the Expert Panel on effective ways of investing in Health (EXPH) published a report on innovative payment models for high-cost innovative medicines[199]. In this report, the EXPH describes new payment models, such as value-based pricing and managed entry agreements, and points towards further literature describing countries' experiences with these models. The report offers recommendations about how and under what conditions such models could be introduced but also notes that "no single model of payment can be reported as 'the solution' to achieve all intended objectives (financial sustainability of health systems, access of patients to innovation and ensuring conditions for innovation that matters to take place)".

Regardless of what methods national authorities use to decide on pricing and reimbursement of medicines, they should be able to communicate this to the public. When an authority decides against reimbursement or postpones a decision, thus preventing access to the medicine for patients, it is imperative that it can properly explain the grounds for doing so and indicate under what circumstances it could change its position (for instance, if a company reduces its price or if more evidence of effectiveness becomes available). A 2018 report the WHO Regional Office for Europe published a review of medicines reimbursement policies in Europe and observed that "in most countries different stakeholders are involved in pharmaceutical reimbursement but groups of patients and citizens are rarely represented"[200]. It thus recommended greater consultation and involvement of patients as this could help to communicate sensitive decisions to the public.

9.5. Regulatory framework

Most innovative medicines are nowadays authorised through the centralised procedure and assessed by the EMA. This means that the EMA's role as a regulatory standard-setter has grown and that Member States are more focused on incorporating the guidance offered by the EMA into their own regulatory frameworks. Nonetheless, through their direct participation in the EMA, Member States play key roles in the EMA's standard-setting and decision-making processes.

National authorities also have an important responsibility for communicating and explaining regulatory processes to their citizens, including those pertaining to pharmacovigilance. The COVID-19 situation, in particular the introduction of COVID-19 vaccines, has brought such issues to the attention of much wider audiences than before. To support policy makers, the OECD recently offered governments guidance on what to communicate and how to promote public trust in COVID-19 vaccination, through use of the 'OECD Trust Framework'[201]. This includes communication about how the approval of the vaccines has come about and what systems there are for ongoing surveillance to monitor adverse events.

9.6. Developing countries

Across the Union, countries engage in bilateral cooperation with developing countries on access to medicines. Additionally, many Member States are significant contributors to multilateral health organisations that work to improve access to medicines and vaccines for people in developing

[199] Innovative payment models for high-cost innovative medicines. Report of the Expert Panel on effective ways of investing in Health (EXPH) (2020)), available at: https://ec.europa.eu/health/sites/default/files/expert_panel/docs/opinion_innovative_medicines_en.pdf, accessed on 03/06/2021.

[200] Medicines reimbursement policies in Europe. WHO Regional Office for Europe (2018)), available at: https://www.euro.who.int/__data/assets/pdf_file/0011/376625/pharmaceutical-reimbursement-eng.pdf, accessed on 03/06/2021.

[201] Enhancing public trust in COVID-19 vaccination: The role of governments. OECD (10 May 2021)), available at: https://www.oecd.org/coronavirus/policy-responses/enhancing-public-trust-in-covid-19-vaccination-the-role-of-governments-eae0ec5a/, accessed on 03/06/2021.

countries. This includes support for, among many others, UNICEF, GAVI, Unitaid and the Global Fund to fight against AIDS, tuberculosis and malaria. Product Development Partnerships, such as the Drugs for Neglected Diseases Initiative (DNDi) and the Medicines for Malaria Venture, also receive significant amounts of funding from various Member States. Funding commitments for basic research and product development R&D for global health priorities are tracked and reported by the think tank Policy Cures Research[202].

Along with the contribution the Commission is making to the COVAX facility, for facilitating the distribution of COVID-19 vaccines to developing countries, individual Member States have also stepped forward. For instance, together with the Commissions announcement that it was doubling its contribution to a total of EUR 1 billion, Germany pledged a separate EUR 900 million[183]. This makes it the second largest contribution by an individual government, after the United States. Smaller, but nonetheless significant pledges have been made also by other individual Member States.

9.7. Monitoring, evaluation & reporting

The WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (PPRI) is a network of pharmaceutical pricing and reimbursement authorities of 47 - mostly European – countries (as of December 2019) as well as international and European institutions (e.g. European Commission, OECD, World Health Organization). The members publish factsheets on their health and reimbursement system as well as recent developments in the countries. These factsheets vary in frequency between countries - for some, only one factsheet is available while others have recently updated theirs. More frequent and uniform reporting across Member States could offer a basis for comparison and highlight structural differences for consideration in the planning of future actions.

[202] Policy Cures Research), available at: https://www.policycuresresearch.org/, accessed on 03/06/2021.

10. CONCLUSION

Since the European Parliament adopted the Resolution on options for improving access to medicinal products in 2017, there have been many changes in both the policy landscape and in the broader context that have impacted access to medicines for patients in the Union or that have the potential to do so. Challenges have grown further as health budgets are under pressure, whilst the frequency of medicine shortages is increasing. The UK's withdrawal from the European Union and the COVID-19 pandemic meanwhile have created new problems that could jeopardise the continuity of supply of medicine for EU citizens.

Against this backdrop, the Commission has proposed, initiated or even fully implemented noteworthy actions in all main thematic areas considered. Many of these can be linked in some form to the new **Pharmaceutical Strategy for Europe** that the Commission adopted in 2020 and which offers the blueprint for ongoing and expected action by the Commission. They are also support by the Commission's newly adopted **EU4Health Programme**.

Key actions taken to date within the EU legislative framework are:

- An SPC manufacturing waiver was introduced by the adoption of Amending Regulation 2019/933 (2020).
- An IP Action Plan was adopted (2020).
- The EMA received an extended mandate to facilitate a coordinated EU level response to health threats and to help prevent and mitigate shortages of critical medicines (2020).
- Negotiations have started on a legislative proposal for joint HTA (2021).
- An impact assessment is being conducted for the introduction of the European Health Data Space (2021).
- An impact assessment is being conducted for revision of the legislations for medicines for rare diseases and children (2021).
- A back-to-back evaluation and impact assessment for the revision of the general EU pharmaceutical legislation will be conducted (2021-2022).
- An evaluation of the Cross-Border Healthcare Directive 2011/24/EU will be conducted (2021).

No action was found in response to the call from the Parliament to revise or replace the EU Transparency Directive 89/105/EEC. Whilst not yet at the stage of legislative action, the Commission is currently also conducting a study on medicine shortages that is expected to result in the recommendation of concrete policy solutions. In parallel to this, it is organising high-level strategic dialogue with stakeholders on security of medicines supply. Further policy actions are expected to flow from this as well.

Alongside such changes to the legislative framework, access to medicines is expected to be supported by further investment in research and innovation under Horizon Europe. Under this new framework programme, the Commission will support a number of European Partnerships, including the Innovative Health Initiative and the EDCTP3 programme, that are specifically aimed at improving and accelerating access to innovative medicine. Improved access to cancer care will be covered under the high-level Cancer Mission.

In response to the COVID-19 pandemic, the Commission has developed the EU Vaccines Strategy. Under this strategy, it has concluded Advance Purchasing Agreements with pharmaceutical companies

to fund the development of vaccines and secure supply thereof for EU citizens. The Commission and Member States are also supporting the COVAX facility for providing access to COVID-19 vaccines globally. Most recently, it announced a separate Strategy to support the development, manufacturing and procurement of COVID-19 therapeutics.

The areas that appear to have been least addressed so far by specific actions of the Commission relate to the expectation of public return on public investment. The Parliament had asked the Commission to place conditions on projects funded with EU public money, based on non-exclusive and voluntary licensing or by asking for affordable pricing guarantees. Beyond a 2020 call under Horizon Europe for projects for COVID-19 related health technologies which required any goods or services developed to be made available through non-exclusive licences, no other examples were found where similar conditions have been built in to call texts. The inception impact assessment for the proposed revision of the legislation for medicines for rare diseases includes policy options with the possibility to link the duration of market exclusivity to the number of EU markets where the product is made available, but not to conditions on pricing or non-exclusive licensing. Also with regards to compulsory licensing and waiving of IP rights the Commission has shown reluctance to act. In the context of COVID-19 vaccines, it has signalled that it is now open to discuss waiving of patents although it has not yet committed to doing so.

The recommendations issued in the Resolution of the Parliament were primarily directed to the Commission and the Council. Thus, this analysis has focused principally on identifying actions taken at that level. Nonetheless, useful actions were identified also that have been taken by individual Member States, groups of Member States or other organisations. These include platforms for patient involvement, joint procurement initiatives, research networks and national funding programmes for research and innovation. Such actions complement and strengthen the work of the Commission in various ways.

In conclusion, since 2017, the Commission has taken many important steps towards improving access to medicines. It has introduced or proposed legislative changes that are aimed at directing more innovation to areas of unmet need whilst placing greater obligations on product developers to ensure affordability and availability of products that benefit from innovation incentives. The regulatory framework for assessment and authorisation of medicines too is undergoing change to accelerate access. Meanwhile, efforts are ongoing to improve cooperation and coordination between Member States in areas such as joint assessment and procurement.

All of these actions can have significant impact on access to medicines for EU citizens. However, the majority of these actions were introduced only within the last 18 months or are still in preparation. For some of the proposed changes it has also not yet fully crystallised out which specific policy adoptions will be brought forward. Therefore, the true impact of these actions cannot yet be properly estimated. Nonetheless, under the Pharmaceutical Strategy for Europe, the Commission is clear in its ambitions towards improving access to medicines and has laid down concrete actions to contribute to this goal.

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ANNEX A OVERVIEW OF RECOMMENDATIONS

Chapters 4 through 10 contain a thematic description of the issues raised in the Resolution and the recommendations formulated as a result. All identified relevant actions that have been undertaken since the Resolution was adopted are described within these chapters. To guide the reader in better understanding the recommendations contained in the Resolution and how this report has been structured, Table 9 offers an overview of all recommendations and references the appropriate section of this report where the recommendation is discussed in further detail. The numbering of the recommendations is that of the corresponding paragraphs in the Resolution itself.

Table 9: Summary table of all recommendations

Paragraph of resolution	Text of paragraph	Discussed in the following chapter of this study
52	Calls for national and EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, to guarantee the sustainability of EU public healthcare systems, and to ensure future investment in pharmaceutical innovation; stresses that patient access to medicines is a shared responsibility of all actors of the healthcare system.	4.2
53	Calls on the Council and the Commission to reinforce the negotiation capacities of Member States in order to ensure affordable access to medicines across the EU.	7.2
54	Notices the report of the United Nations Secretary-General's High-Level Panel on access to medicines.	N/A
55	Notes that the repurposing of existing drugs for new indications can be accompanied by a price increase; asks the Commission to collect and analyse data on price increases in cases of drug repurposing and to report back to Parliament and to the Council on the balance and proportionality of the incentives that encourage industry to invest in drug repurposing.	3.3
56	Calls on the Member States to develop closer collaboration in order to fight such market fragmentation, in particular by developing shared HTA processes and results, and to work on shared criteria to instruct price and reimbursement decisions at national level.	7.4

Paragraph of resolution	Text of paragraph	Discussed in the following chapter of this study
57	Calls on the Commission to revise the Transparency Directive with a focus on guaranteeing timely entry into the market for generic and biosimilar medicines, ending patent linkage according to the Commission's guidelines, accelerating pricing and reimbursement decisions for generics, and precluding the multiple reassessment of the elements supporting marketing authorisation; believes that this will maximise savings for national health budgets, improve affordability, accelerate patient access and prevent administrative burdens for generic and biosimilar companies.	5.4
58	Calls on the Commission to propose a new directive on transparency of price-setting procedures and reimbursement systems, taking into account the challenges of the market.	7.3
59	Calls for a new Transparency Directive to replace Directive 89/105/EEC with the aim of ensuring effective controls and full transparency on the procedures used to determine the prices and the reimbursement of medicinal products in the Member States.	7.3
60	Calls on the Member States to implement Directive 2011/24/EU on the application of patients' rights in cross-border healthcare in a fair way, avoiding limitations to the application of the rules on reimbursement of cross-border healthcare, including the reimbursement of medicines, that could constitute a means of arbitrary discrimination or an unjustified obstacle to free movement.	4.4
61	Calls on the Commission to monitor and assess in an effective way the implementation of Directive 2011/24/EU in the Member States, and to plan and carry out a formal evaluation of this directive that includes complaints, infringements and all transposition measures.	4.4
62	Calls on the Commission and the Member States to foster R&D driven by patients' unmet needs, such as by researching new antimicrobials, coordinating public resources for healthcare research in an effective and efficient manner, and promoting the social responsibility of the pharmaceutical sector.	6.2, 6.7
63	Calls on the Member States to build on the example of existing initiatives in the EU aimed at promoting independent research in areas of interest to national health services that are insufficiently addressed by commercial research (e.g. AMR) and to patient populations normally excluded by clinical studies, such as children, pregnant women and the elderly.	6.2, 6.6, 6.7

Paragraph of resolution	Text of paragraph	Discussed in the following chapter of this study
64	Highlights the threat of growing antimicrobial resistance and the urgency of the threats of AMR recently recognised by the UN; calls on the Commission to increase its actions to combat AMR, to promote R&D in this area, and to present a new and comprehensive EU Action Plan based on the 'One Health' approach.	6.2
65	Acknowledges that the incentives put forward by the Paediatric Medicines Regulation (EC) No 1901/2006 have not proved effective in driving innovation in medicines for children, namely in the fields of oncology and neonatology; calls on the Commission to examine existing obstacles and to propose measures to promote advancement in this area.	6.4
66	Calls on the Commission to promote initiatives for guiding public and private-sector research towards bringing out innovative medicines for curing childhood illnesses.	6.4
67	Calls on the Commission to begin immediate work on the report required under Article 50 of the Paediatric Medicines Regulation, and to amend the legislation to address the lack of innovation in paediatric oncology treatments, by revising the criteria for allowing a Paediatric Investigation Plan (PIP) waiver and by ensuring that PIPs are implemented early in a drug's development, so that children are not waiting longer than necessary for access to innovative new treatments.	6.4
68	Calls on the Commission to promote public and private-sector research into medicines for female patients, to remedy gender inequality in research and development and to allow all citizens to benefit from fairer access to medicines.	6.6
69	Urges the Commission and the Member States to adopt strategic plans to ensure access to life-saving medicines; calls, in this regard, for the coordination of a plan to eradicate hepatitis C in the EU using tools such as European joint procurement.	5.5
70	Calls for the framework conditions in the areas of research and medicine policy to be established in a way that promotes innovation, particularly against diseases, such as cancer, that cannot yet be treated to a satisfactory degree.	6.7
71	Calls on the Commission to take further action to foster the development of, and patient access to, ATMPs.	6.5

Paragraph of resolution	Text of paragraph	Discussed in the following chapter of this study
72	Calls on the Commission to analyse the overall impact of IP on innovation on, and on patient access to, medicines, by means of a thorough and objective study, as requested by the Council in conclusions of 17 June 2016, and, in particular, to analyse in this study the impact of supplementary protection certificates (SPCs), data exclusivity and market exclusivity on the quality of innovation and competition.	5.2
73	Calls on the Commission to evaluate the implementation of the regulatory framework for orphan medicines (especially as regards the concept of unmet medical need, how this concept is interpreted and what criteria need to be fulfilled in order to identify unmet medical need),to provide guidance on priority unmet medical need, to evaluate existing incentive schemes to facilitate the development of effective, safe and affordable medicines for rare diseases compared to the best available alternative, to promote the European register of rare diseases and reference centres, and to ensure the legislation is correctly implemented.	6.3
74	Welcomes the pharmacovigilance legislation of 2010 and 2012; calls on the Commission, the EMA and the Member States to continue the monitoring and public reporting of the implementation of the pharmacovigilance legislation, and to guarantee post-authorisation assessments of the effectiveness and adverse effects of medicines.	8.4
75	Calls on the Commission to collaborate with the EMA, and with stakeholders, with a view to introducing a Code of Practice for mandatory reporting of adverse events and of outcomes for off-label use of medicines, and to ensuring patients' registries in order to strengthen the evidence base and mitigate risks for patients.	8.4
76	Calls on the Commission to promote open data in research on medicines where public funding is involved, and to encourage conditions such as affordable pricing and non-exclusivity, or co-ownership of IP for projects funded by EU public grants such as Horizon 2020 and IMI.	6.8 & 6.9
77	Calls on the Commission to promote ethical behaviour and transparency in the pharmaceutical sector, especially regarding clinical trials and the real cost of R&D, in the authorisation and assessment of innovation procedure.	6.9

Paragraph of resolution	Text of paragraph	Discussed in the following chapter of this study
78	Notes the use of adaptive pathways to promote faster access to medicines for patients; underlines the higher degree of uncertainty regarding the safety and effectiveness of a new medicine when it enters the market; highlights the concern expressed by healthcare professionals, civil society organisations and regulators regarding adaptive pathways; stresses the crucial importance of the proper implementation of the post-marketing surveillance system; considers that adaptive pathways should be restricted to specific cases of high unmet medical need, and calls on the Commission and the EMA to put in place guidelines to ensure patient safety.	8.2, 8.4
79	Calls on the Commission to guarantee a thorough assessment of quality, safety and efficacy in any fast-track approval process, and to ensure that such approvals are made possible by means of conditional authorisation, and only in exceptional circumstances where a clear unmet medical need has been identified, and to ensure that a transparent and accountable post-authorisation process to monitor safety, quality and efficacy is in place, as well as sanctions for non-compliance.	8.2
80	Calls on the Commission and the Member States to set up a framework to promote, guarantee and reinforce the competitiveness and use of generic and biosimilar medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 TFEU, and to present a biannual report in this regard; calls as well on the Commission to monitor patent settlement agreements between originator and generic industry that may be misused to restrict the market entry of generics.	5.4
81	Calls on the Commission to continue and, where possible, to intensify the monitoring and investigation of potential cases of market abuse, including so-called 'pay for delay', excessive pricing and other forms of market restriction specifically relevant to the pharmaceutical companies operating within the EU, in accordance with Articles 101 and 102 TFEU.	5.3
82	Calls on the Commission to introduce an SPC manufacturing waiver to Regulation (EC) No 469/2009 allowing the production of generic and biosimilar medicines in Europe, with the purpose of exporting them to countries without SPCs or where these have expired earlier, without undermining the exclusivity granted under the SPC regime in protected markets; believes that such provisions could have a positive impact on access to high-quality medicines in developing countries and LDCs, and on increasing manufacturing and R&D in the EU, creating new jobs and stimulating economic growth.	5.2, 5.4

Paragraph of resolution	Text of paragraph	Discussed in the following chapter of this study
83	Calls on the Commission to observe and reinforce the EU competition legislation and its competencies on the pharmaceutical market in order to counter abuse and promote fair prices for patients.	5.3
84	Calls on the Commission to enhance dialogue on unmet medical needs between all relevant stakeholders, patients, healthcare professionals, regulators, HTA bodies, payers and developers throughout the life spans of medicines.	6.7
85	Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, to harmonise transparent HTA criteria in order to assess the added therapeutic value of medicines compared with the best available alternative taking into account the level of innovation and value for the patients among others, to introduce compulsory relative effectiveness assessments at EU level as a first step for new medicines, and to put in place a European classification system to chart their therapeutic added value level, using an independent and transparent procedure that avoids conflicts of interests; considers that such legislation shall ensure that HTA output jointly produced at EU level is used at national level; calls, furthermore, on the Commission to strengthen early dialogues and to consider a coordination mechanism based on an independent body, which could foster cooperation between national HTA bodies while at the same time ensuring that expertise on HTA remains within national (and regional) HTA.	7.4, 8.3
86	Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order that they may share information about, in particular, negotiation agreements and good practices, and avoid unnecessary administrative requirements and delays; calls on the Commission and the Council to analyse the clinical, economic and social criteria that some national HTA agencies already apply, while respecting the competences of the Member States.	7.4, 8.3
87	Calls on the Commission and the Members States to agree on a common definition of 'added therapeutic value of medicines', with the participation of expert representatives from the Member States; notes in this regard the definition of 'added therapeutic value' used for paediatric medicines.	7.4
88	Calls on the Commission and the Member States to identify and/or develop frameworks, structures and methodologies to meaningfully incorporate patient evidence at all stages of the medicines R&D cycle, from early dialogue to regulatory approval, HTA, relative effectiveness assessments, and pricing and reimbursement decision-making, with the involvement of patients and their representative organisations.	4.3

Paragraph of resolution	Text of paragraph	Discussed in the following chapter of this study
89	Calls on the Commission and the Member States to promote major public-funded investment in research based on unmet medical needs, to ensure the public a health return on public investment, and to introduce conditional funding based on non-exclusive licencing and affordable medicines.	6.9
90	Calls on the Council to promote rational use of medicines across the EU, promoting campaigns and educational programmes aimed at making citizens aware of the rational use of medicines, with the goal of avoiding overconsumption, in particular of antibiotics, and promoting the use of prescriptions by active principles by healthcare professionals and the generic medicines administration.	4.5
91	Calls on the Member States to ensure accessibility of pharmacies, including their density in both urban and rural areas, professional staff number, appropriate opening hours, qualitative advice and counselling service.	7.5
92	Calls on the Commission and the Council to develop measures that ensure affordable patient access to medicines, and benefit to society, whilst avoiding any unacceptable impact on healthcare budgets, to employ different measures, such as horizon scanning, early dialogue, innovative pricing models, voluntary joint procurements and voluntary cooperation in price negotiations, as is the case in the initiative between the Benelux countries and Austria, and to explore the numerous tools based on delinkage mechanisms for neglected areas of research such as AMR and poverty-related diseases.	6.3, 7.3, 9.3
93	Calls on the Commission to define with all relevant stakeholders how the most advantageous economic tender (MEAT) criterion –as described in the Public Procurement Directive, and which does not imply only the lower cost criteria –could best apply to medicines tenders in hospitals at national level, in order to enable a sustainable and responsible supply of medicines; encourages the Member States to transpose into their national legislation, in the best way, the most economic advantageous tender criterion for medicinal products.	7.2

Paragraph of resolution	Text of paragraph	Discussed in the following chapter of this study
94	Calls on the Commission and the Member States to launch a high-level strategic dialogue with all the relevant stakeholders, together with representatives of the Commission, Parliament, the Member States, patient organisations, paying agencies, healthcare professionals, and representatives from the academic and scientific world as well as from industry, on current and future developments in the pharmaceutical system in the EU, with the aim of establishing short-, medium-and long-term holistic strategies for ensuring access to medicines and for the sustainability of healthcare systems and a competitive pharmaceutical industry, leading to affordable prices and faster access to medicines for patients.	7.4
95	Calls on the Commission and the Council to define clear rules on incompatibility, conflicts of interest and transparency in the EU institutions and for experts involved in issues related to medicines; calls on the experts involved in the authorisation process to publish their CVs and to sign declarations of absence of conflict of interest.	6.2
96	Calls on the Commission and national antitrust authorities to monitor unfair practices with a view to protecting consumers from artificially high prices on medicines.	5.3
97	Calls on the Commission and the Court of Justice of the European Union to clarify, in accordance with Article 102 TFEU, what constitutes an abuse of a dominant position by charging high prices.	5.3
98	Calls on the Commission and the Member States to make use of the flexibilities under the WTO TRIPS agreement and to coordinate and clarify their use when necessary.	5.2
99	Calls on the Commission to submit a report, at least every five years, to the Council and to Parliament on access to medicines in the EU, and to report more regularly in cases of exceptional problems regarding access to medicines.	10.2
100	Calls on the Commission to recommend measures to improve the rate of approval of novel therapies and the supply of these to patients.	8.2

Paragraph of resolution	Text of paragraph	Discussed in the following chapter of this study
101	Calls on the Commission and the Council to formulate a better definition of the concept –and analyse the causes –of shortages of medicines, and, in this regard, to assess the impact of parallel trade and supply quotas, to establish and update together with the Member States, the EMA and relevant stakeholders a list of essential medicines which are short of supply, using the WHO list as a reference, to monitor compliance with Article 81 of Directive 2001/83/EC on shortages of supply, to explore mechanisms to address the withdrawal of effective medicines from the market purely for commercial reasons, and to take actions to remedy these shortages.	7.5
102	Calls on the Commission and Council to establish a mechanism whereby medicine shortages across the EU can be reported upon on an annual basis.	7.5
103	Calls on the Commission and Council to review the statutory basis of the EMA, and to give consideration to enhancing its remit to coordinate pan-European activity aiming at tackling medicines shortages in the Member States.	7.5
104	Stresses that building strong surveillance and delivery systems at all levels, from community to district, provincial and national, and supported by high-quality laboratory services and strong logistical systems, could make access to medicines more feasible, while the transfer of health-related technologies (through licence agreements, and the provision of information, know-how and performance skills to technical materials and equipment) to developing countries can enable recipient countries to produce the product locally, and may result in increased access to the product and improved health.	9.2
105	Calls on the Commission and the Member States to develop a single eHealth and mHealth road map, including, in particular, the development and valorisation of pilot projects at national level, the modernisation of the reimbursement models stimulating a shift towards health outcomes-driven healthcare systems and the definition of incentives to stimulate the healthcare community to engage in this digital revolution, and to enhance education of healthcare professionals, patients and all relevant stakeholders in order to enable their empowerment.	7.6
106	Encourages the Member States to evaluate healthcare pathways and policies with a view to improving patient outcomes and the financial sustainability of the system, in particular by fostering digital solutions to improve healthcare delivery to patients and to identify waste of resources.	10.2

Paragraph of resolution	Text of paragraph	Discussed in the following chapter of this study
107	Urges the EU to step up efforts to improve developing countries' capacities and help them design working health systems that aim at improving access to services, particularly for vulnerable communities.	9.2
108	Stresses that the ongoing REFIT review of the EU Tiered Pricing Regulation(EC) No953/2003 should aim at further promoting lower prices in developing countries, and calls on the EU to open a broader and transparent discussion on pricing regulation and strategies that ensure access to quality and affordable medicines; recalls that tiered pricing does not necessarily lead to affordability, and that it is contrary to experience showing that robust generic competition and technology transfers result in lower prices.	9.3
109	Urges the EU to step up its support of global programmes and initiatives promoting access to medicines in developing countries, as these programmes have been instrumental in advancing health goals and greatly improved access to medicines and vaccines.	9.3

Source: Technopolis Group, 2021.

ANNEX B METHODOLOGY

Study objectives

To answer the main study questions, this study has gathered information on the following aspects:

- Recommendations articulated in the Resolution regarding issues of access to medicines.
- Actions undertaken or proposed by the Commission or the Member States on the issues raised in the Resolution.
- Areas where no or only partial action was undertaken and any reasons for this.
- Additional options for actions that could be undertaken at the level of the Member States.

Analytical framework

The analysis was based on existing documentation; no primary data collection was done.

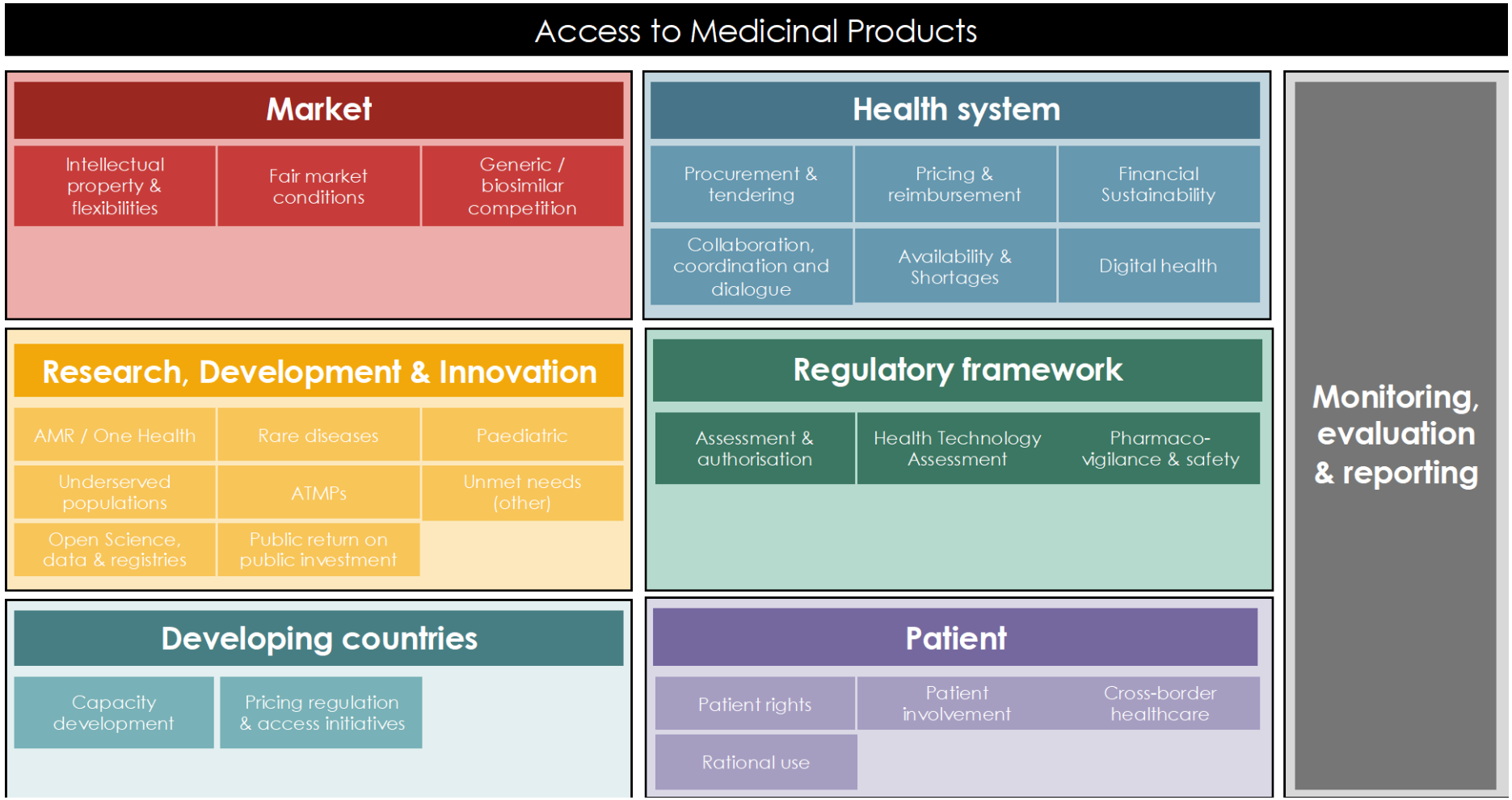
The Resolution passed by the European Parliament on 2 March 2017 on 'EU options for improving access to medicines' (2016/2057(INI)), presented the starting point for the Study. All 58 recommendations presented in the Resolution were reviewed, from which an analytical framework was developed, based on identified thematic areas and sub-themes. Six main thematic areas were developed against which each of the recommendations could be classified.

These are:

- Patients.
- Market.
- Research, Development & Innovation.
- Health systems.
- Regulatory Framework.
- Developing countries.
- Monitoring, Evaluation and Reporting.

Under each of these high-level thematic areas further sub-themes were developed. The resulting analytical framework as depicted in Figure 4 of themes and sub-themes was used to categorise each of the recommendations from the Resolution. It also forms the basis of the structure of this report.

Figure 4: Analytical framework for this Study



Source: Technopolis Group, 2021.

Detailed analysis

Once the analytical framework was confirmed, each theme was assigned a code in the qualitative analysis software package Atlas.ti. The resulting code book was used to code each of the recommendations.

A review was conducted of existing documentation that could provide insight into what actions have been undertaken or proposed that have direct relevance to the recommendations issued in the Resolution. The primary source for identification of this document were European document databases including EUR-Lex for legislative documents, the EU Publications database for recent studies on access to medicines and the Commission's CHAFEA Health Programme Database[203]. In addition, the thematic websites of the European Commission and the European Parliament served as sources of information. Where relevant, documentation developed by relevant stakeholder groups, such as patient and consumer organisations and pharmaceutical interest groups, was also consulted.

All identified documents were coded in the same way as the recommendations. Once all documentation was coded, matching tables were created to juxtapose the recommendations and actions. Initial matching was done on the basis of corresponding codes only, without exploration of the content or status of the actions. Such further analysis was carried out in the next stage by reviewing the matched actions and corresponding documentation in further detail. Where available, the following points of information were extracted:

- Description and objective of action(s).
- Current status or expected timeline of action.
- Parties involved with implementation of the action.
- Expected or demonstrated results and impacts of the action.

With regards to the status of the action, a colour-coded classification scheme was developed to facilitate understanding. Table 10 contains this classification scheme.

Table 10: Classification scheme for current status of actions

Status category	Explanation
Unknown	No information on the action could be identified, or recommended action was at Member State level (out of scope).
No action	No action was taken (yet).
Proposed only	Action proposed but no further steps have been taken yet.
In preparation	The action has not yet been implemented but preparatory steps (such as an ex ante impact assessment) have been taken.

[203] For reference find EU-Lex at https://eur-lex.europa.eu/homepage.html?locale=en, EU publications database at https://op.europa.eu/en/home, CHAFEA Health Programme Database at https://webgate.ec.europa.eu/chafea_pdb/health/projects/.

Status category	Explanation
Under implementation	Preparatory steps have been completed and the action is being implemented. This also includes actions requiring continuous activity such as periodic monitoring or reporting.
Implemented	Any steps necessary to introduce the action have been completed and the action is in full effect.

Source: Technopolis Group.

Identification of additional options

In a second part, this report offers MEPs additional options to consider at the level of individual Member States or through bi- or multilateral collaboration between EU Member States based on information gathered from:

- Scopus/PubMed.
- Bibliographies of included EU policy documents.
- Websites of suitable European networks and working groups.

This report contains a high-level overview of such options, providing a basic description of the option and its potential relevance, as well as a summary of reported experiences by countries or regions that have implemented these options.

There are many factors that can prevent a patient from being able to obtain the medicine they need, ranging from selective marketing decisions by companies to products being too expensive or pharmacy stock-outs. Because of national differences in health systems and market characteristics, access to medicines is not evenly distributed across the European Union.

In response to observed problems with access to medicines, in 2017 the European Parliament adopted a resolution containing 58 recommendations for action to the European Commission and Member States. This Study reviews the main actions taken at the Union level since then that could improve access to medicines. It also includes illustrative examples of actions taken by Member States and other actors.

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