# THE EU PHARMACEUTICAL PACKAGE: WILL IT STRIKE A BALANCE BETWEEN STIMULATING RESEARCH AND FACILITATING EQUAL ACCESS?

Tomislav Sokol *

*Abstract: Through the revision of EU pharmaceutical legislation, the Commission has tried to solve the problem of unequal access to medicines within the EU, while also making Europe more competitive in the global pharmaceutical market. Even though there are some positive aspects in the Commission proposal, such as cutting the deadlines for conducting the marketing authorisation procedure, there are also issues which can be seen as problematic and representing a step backwards in terms of promoting innovation within Europe. The Parliament is taking a more realistic and balanced approach between the need to stimulate research and innovation on one hand, and to facilitate equal access to medicines on the other. In relation to the issue of antimicrobials, the Parliament is combining a number of push and pull incentives, thereby motivating the industry to create new antimicrobials, but also ensuring these antimicrobials are finally developed and made accessible for European patients. All this means that the final text aiming at striking a balance between stimulating innovation and enabling equal access should follow, as far as possible, the balanced approach of Parliament. The revision of the pharmaceutical legislation is not a silver bullet to resolve all the problems relating to equal access. The revision of the Transparency Directive, which would at least accelerate national pricing and reimbursement decisions and set a strong enforcement mechanism, would definitely improve patients' equality and make new medicines more accessible for them. Finally, the revision of the cross-border healthcare legislation, which would simplify the legal framework and make it more understandable for patients, would provide all European citizens with the same, or at least a similar, opportunity to avail themselves of best-quality treatments and medicines anywhere in the EU.*

*Keywords: cross-border healthcare, equal access to medicines, innovation, pharmaceutical legislation, regulatory data protection, research, transferable exclusivity voucher.*

* Assistant Professor at the Catholic University of Croatia; Member of the European Parliament. Email: tsokol@zsem.hr; ORCID: 0000-0002-3592-2967. DOI: 10.3935/cyelp.21.2025.594.

## 1 Introduction

Healthcare primarily belongs to the competences of the Member States of the European Union. It is prescribed in Article 168 of the Treaty on the Functioning of the European Union (TFEU) that the organisation and financing of healthcare is a national prerogative, while European actions in this field are to be limited to supporting and complementing national activities and policies.

One area which represents an exception to the described situation concerns the regulation of medicines (medicinal products, pharmaceuticals). According to Article 168 TFEU, the European Parliament and the Council, acting via the ordinary legislative procedure, may adopt 'measures setting high standards of quality and safety for medicinal products and devices for medical use'. The precursor of Article 168, Article 152 of the Treaty Establishing the European Community (EC Treaty), was used, along with Article 95 of the EC Treaty (the current Article 114 TFEU) on harmonising the internal market, as the legal basis for the adoption of existing pharmaceutical legislation.[1] This legislation represents the legal framework for the authorisation and placing on the market of certain categories of priority innovative medicines, evaluation being conducted by the European Medicines Agency (EMA) with the final decision being made by the European Commission, through the centralised Union procedure.[2]

---

[1] European Parliament and Council Regulation (EC) 726/2004 of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency [2004] OJ L136/1. See also European Parliament and Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67 and European Parliament and Council Regulation (EU) 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC [2014] OJ L158/1. See also J Borg and others, 'Strengthening and Rationalizing Pharmacovigilance in the EU: Where Is Europe Heading to?' (2011) 34 Drug Safety 187, 193; G Permanand, E Mossialos and M McKee, 'Regulating Medicines in Europe: The European Medicines Agency, Marketing Authorisation, Transparency and Pharmacovigilance' (2006) 6 Clinical Medicine 87, 88; J Regnstrom and others, 'Factors Associated with Success of Market Authorisation Applications for Pharmaceutical Drugs Submitted to the European Medicines Agency' (2010) 66 European Journal of Clinical Pharmacology 39, 40; S Vogler and others, 'Pharmaceutical Policies in European Countries in Response to the Global Financial Crisis' (2011) 4 Southern Med Review 69.

[2] Medicines which are subject to the centralised procedure include: medicinal products which have been developed by means of 'recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, hybridoma and monoclonal antibody method'; 'advanced therapy medicinal products'; medicinal products containing a new active substance for treating 'acquired immune deficiency syndrome, cancer, neurodegenerative disorder, diabetes, auto-immune diseases and other immune dysfunctions, viral diseases'; orphan medicinal products. See Regulation 726/2004 (n 1) Annex I.

According to the Commission, the said legislation has resulted in the authorisation of 'safe, efficacious and high-quality medicinal products'.[3] However it has not resolved the problem of unequal access to medicines for patients across the European Union. To tackle this problem, the Commission has proposed a major revision of the legal framework, with two legislative proposals, a directive and a regulation.[4] Among others, two specific objectives of the reform have been stated: making sure 'all patients across the EU have timely and equitable access to safe, effective, and affordable medicines' and offering 'an attractive innovation and competitiveness friendly environment for research, development, and production of medicines in Europe'.[5] The aim of this paper is to determine whether the said reform is fit for achieving the mentioned objectives and which improvements should be undertaken to strike the right balance between them.

The paper starts with an analysis of the current situation in the EU relating to access to medicines on one hand and facilitating innovation on the other. It then analyses the reform proposed by the Commission and the position adopted by the European Parliament in the first reading aiming to improve the proposal. The paper then compares the two approaches and tries to determine how to achieve the right balance between innovation and access at the Union level.

## 2 State of play

Throughout its existence, EU pharmaceutical legislation, regulating conditions for authorising medicines and placing them on the European market, has been successful in terms of ensuring the safety and efficacy of medicines available for patients in the European Union.[6] According to

[3] Commission, 'Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC' COM (2023) 192 final, 26 April 2023 (Directive Proposal) Explanatory Memorandum.

[4] Commission, 'Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006' COM (2023) 193 final, 26 April 2023 (Regulation Proposal).

[5] See Regulation Proposal (n 4) Explanatory Memorandum.

[6] See Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Reform of the pharmaceutical legislation and measures addressing antimicrobial resistance' (2024) 1. On the different stages of development and marketing of new medicines, called the 'cycle of innovation', see G Bache, M Flear and T Hervey, 'The Defining Features of the European Union's Approach to Regulating New Health Technologies' in M Flear and others (eds), *European Law and New Health Technologies* (OUP 2013) 11–12.

the European Federation of Pharmaceutical Industries and Associations (EFPIA), EMA has, since it was founded in 1995, given recommendations to the European Commission to authorise more than 1,500 new medicines, and the Union regulatory framework has helped attract more than EUR 41 billion in annual investments in research and development by the pharmaceutical industry in the EU.[7] EU regulations can be a powerful stimulus for innovation in general,[8] and there are arguments that with pharmaceutical legislation this has generally been the case, with 1,160 medicines being authorised from 2005 to 2020 through the centralised procedure (through EMA and the European Commission) and more than 17,000 medicines, primarily generic ones, being authorised via mutual recognition and decentralised procedures during the said period.[9]

There is also special legislation in two priority areas, namely rare diseases and children's diseases.[10] These rules have been developed to

---

[7] See EFPIA, 'Regulatory Road to Innovation' <www.efpia.eu/about-medicines/development-of-medicines/regulations-safety-supply/regulatory-road-to-innovation/#> accessed 24 July 2024.

[8] See J Pelkmans and A Renda, 'How Can EU Legislation Enable and/or Disable Innovation' (2014) European Commission (July) 1. Support for the competitiveness of the European pharmaceutical industry and securing a high level of innovation have been acknowledged as some of the main policy objectives of the EU in the pharmaceutical sector also in the literature. See L Hancher, 'The EU Pharmaceuticals Market: Parameters and Pathways' in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (CUP 2010) 635–636.

[9] See Commission, 'Commission Staff Working Document Impact Assessment Report Accompanying the documents Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006' (2024) 17. This procedure can be summarised as follows: 'Pharmaceutical companies that wish to follow the centralised procedure submit a dossier to the European Medicines Agency (EMA). The dossier is assessed by the Committee for Medicinal Products for Human Use (CHMP), the EMA's medicines assessment committee. The CHMP has in principle 210 days to reach a final decision. This period may be suspended to allow the company to answer questions. Companies can also give verbal explanations relating to the dossier they have submitted. The CHMP produces an opinion which is sent to the European Commission and used in reaching the final decision. The European Commission usually adopts the CHMP's opinion in all respects. Once a favourable decision has been made, the Summary of Product Characteristics (SmPC) and the package leaflet are determined. A European Public Assessment Report (EPAR) is produced. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. The EPAR can be found on the EMA website'. See to that effect Medicines Evaluation Board, 'Centralised Procedure' <https://english.cbg-meb.nl/topics/mah-centralised-procedure> accessed 24 July 2024. On the approval process, see, also, I Abed, 'The Approval Process of Medicines in Europe' (2014) 23 Medical Writing 117.

[10] European Parliament and Council Regulation (EC) 141/2000 of 16 December 1999 on orphan medicinal products [2000] OJ L18/1 (Orphan Drugs Regulation). See also Euro-

direct investments into research and the development of orphan medicinal products and medicinal products for paediatric use. According to the Commission, the said regulatory framework led to redirecting investments into previously neglected areas through a combination of rewards, incentives and obligations. This is something Member States could not have done by themselves due to the small number of patients affected, as well as market fragmentation.[11] The EU has, until now, authorised more than 200 orphan medicines for patients suffering from rare diseases which have become available faster and more broadly for EU patients and has facilitated the creation of a 'paediatric research environment' in the Union.[12]

The main regulatory tools for stimulating innovation and the development of medicines in the EU are market exclusivity and regulatory data protection. Regulatory data protection means that an applicant who wants to obtain marketing authorisation cannot rely on the data from the file concerning previously authorised medicines during the protection period. This represents an important incentive for the companies developing innovative medicines, enabling them to have an essentially privileged market position within the said time. According to Regulation

---

pean Parliament and Council Regulation 1901/2006 (EC) 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 [2006] OJ L378/1 (Paediatric Regulation). Rare diseases include life-threatening or very serious conditions which affect no more than five in 10,000 people in the EU. See Regulation 141/2000 Art 3 and Commission, 'Orphan Medicinal Products' <https://health.ec.europa.eu/medicinal-products/orphan-medicinal-products_en> accessed 24 July 2024. According to the paediatric medicines legislation, applications for marketing authorisation have to include paediatric investigation plans (PIPs), unless a waiver or a deferral has been granted. See to that effect Regulation 1901/2006 Art 7.

[11] See Commission, 'Commission Staff Working Document Executive Summary of the Evaluation Joint Evaluation of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use, and Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products' (2020) 2. On the other hand, there are also some differing views arguing that progress has not been satisfactory, especially at the very beginning. See to that effect R Joppi, V Bertele and S Garattini, 'Orphan Drugs, Orphan Diseases. The First Decade of Orphan Drug Legislation in the EU' (2013) 69 European Journal of Clinical Pharmacology 1009, 1014. The paediatric medicines legislation has had minor impact on the development of orphan medicinal products for children, resulting in longer time to market authorisation, but has enabled the further paediatric development of medicines still off-label to children. See to that effect A R Kreeftmeijer-Vegter and others, 'The Influence of the European Paediatric Regulation on Marketing Authorisation of Orphan Drugs for Children' (2014) 9 Orphanet Journal of Rare Diseases 1, 15. In the first ten years of the paediatric medicines legislation, 273 new medicines appropriate for use in children were authorised in the European Union. See to that effect P A Tomasi and others, 'Enabling Development of Paediatric Medicines in Europe: 10 Years of the EU Paediatric Regulation' (2017) 19 Paediatric Drugs 505.

[12] See Commission (n 10) and Commission (n 11) 2.

726/2004, authorised medicines can benefit from an eight-year period of data protection and a ten-year period of marketing protection which may be extended to eleven years if there is a new therapeutic indication bringing significant clinical benefit when compared to existing therapies.[13]

Furthermore, it is prescribed by Directive 2001/83 that a medicine does not have to undergo pre-clinical tests and clinical trials if the applicant company is able to prove that the pharmaceutical in question is a generic or an authorised reference medicine. Such a generic medicine may not be placed on the market for ten years from the initial authorisation of the reference product, which may be extended to a maximum of eleven years if there is a new indication bringing significant clinical benefit.[14] In addition, according to the Orphan Drugs Regulation, when a medicine has been authorised with an orphan designation, the EU and the Member States may not grant marketing authorisation or extend an existing marketing authorisation, for the same therapeutic indication, relating to a similar medicine, for a period of ten years.[15] This period may be extended to twelve years when the results of studies carried out are reflected in the summary of the product characteristics addressing the paediatric population and completed in accordance with an agreed paediatric investigation plan.[16]

It can be seen that an elaborate system of incentives for the development of new medicines has been established in the EU, with significant success. The described EU legal framework has generally contributed to stimulating innovation and the development of new medicines in the European Union and generally resulted in an increased number of marketing authorisations in the Union territory. This sounds pretty positive, but, if one looks at global developments and the competitiveness of the

---

[13] See Regulation 726/2004 (n 1) Art 14.

[14] See Directive 2001/83 (n 1) Art 10. See on this issue, for example, EFM 't Hoen and others, 'Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation' (2017) 10 Journal of Pharmaceutical Policy and Practice 1, 3; and C Schoonderbeek and B Jong, 'Regulatory Exclusivities for Medicinal Products for Human Use in the EU' (2015) 5 Pharmaceutical Patent Analyst 5, 5–6.

[15] This period may be cut to six years 'if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, inter alia, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity'. See Orphan Drugs Regulation (n 10) Art 8. On this topic, see, for example, E Brosset and A Mahalatchimy, 'EU Law and Policy on New Health Technologies' in T Hervey, C Young and L Bishop (eds), *Research Handbook on EU Health Law and Policy* (Edward Elgar 2017) 213–214.

[16] See Paediatric Regulation (n 10) Art 37. A paediatric-use marketing authorisation can also be obtained for medicines developed specifically for children. If it is granted, the same eight years' data protection and 10 years' market protection periods under Regulation 726/2004 (n 1) Art 14 will apply. See Paediatric Regulation (n 10) Arts 1, 30, 38.

EU in that setting, the picture looks slightly different. According to a report prepared for EFPIA in 2002, the amount of investment made by pharmaceutical companies in the development of new medicines in the United States and Europe differed by only EUR 2 billion in favour of the US, while in 2020 that difference extended to EUR 25 billion. China has also become very active in this area and narrowed the enormous gap which had existed before, by increasing production capacity and focusing on investments in research hubs and clinical trials. Private expenditure for R&D in China grew fivefold between 2010 and 2020. Of the total R&D investments made in the United States, Europe, Japan and China in 2020, 31% took place in Europe, while the figure was 41% in 2001. During the same period, China increased its share from 1% to 8%. This means that, even though the expenditure in Europe is increasing, the rate of that increase is much slower than it is for the main global competitors.[17]

Furthermore, rapidly advancing new developments in the pharmaceutical sector, including, for example, personalised medicines, have set new challenges for the ever more complex system run by EMA. The review time of marketing authorisation by EMA has been significantly longer than by the Food and Drug Administration (FDA) in the United States. For anticancer medicines undergoing the standard regulatory approval procedure, the review time was 304 days (median) by the FDA and 343 days (median) by the EMA, while the difference was even bigger (123 days) for expedited regulatory approval procedures.[18]

Obtaining marketing authorisation at the EU or national level does not mean that a medicine is already available for patients within the Union. Most medicines become available after they have been placed on the list of medicines covered by the national social security system (health insurance or a national health service)[19] in a given Member State. These decisions fall solely within the powers of the Member States, ac-

[17] See T Wildson and others, 'Factors Affecting the Location of Biopharmaceutical Investments and Implications for European Policy Priorities' (2022) 1, 2, 11. On the emergence of China as a major global competitor, see A C Santos Akkari and others, 'Pharmaceutical Innovation: Differences between Europe, USA and "Pharmerging" Countries' (2016) 23 Gestão & Produção 365, 377.

[18] See F da Costa Gonçalves, E Demirci and A Zwiers, 'A Detailed Analysis of Expedited Regulatory Review Time of Marketing Authorization Applications for New Anticancer Drugs in the US and EU' (2022) 15 Clinical and Translational Science 1959, 1962.

[19] Social security means a statutory system based on the principle of solidarity, providing protection against a lack of earnings, or against particular costs in the event of the occurrence of a recognised social risk, such as needing healthcare. See Danny Pieters, *Social Security: An Introduction to the Basic Principles* (2nd edn, Kluwer Law International 2006) 2–3, 87–88. Social security coverage has different dimensions: breadth relates to the extent of the population covered; depth concerns the number and character of the covered services; height means the extent (percentage) of the costs of the covered services. See to that effect

cording to Article 168 TFEU, while Union legislation sets some basic principles and procedural requirements on how the national procedures on making such decisions are to be carried out.[20]

Data show that there are huge gaps in terms of the availability of medicines between different Member States, the situation generally being worse in smaller eastern countries of the EU. For instance, according to the European Commission, 152 new medicines were authorised between 2016 and 2019 through the centralised EU procedure and 133 of them were accessible in Germany, while in Member States like Romania or the Baltic countries, fewer than 50 of these were available to patients in 2020. The average time of access after marketing authorisation, for example, was four months in Germany, compared to two years or more in Romania.[21] According to EFPIA's latest data from the beginning of 2024, the access gap between the highest and lowest Member State is 84% in the four-year period. According to the same data, the total number of medicines (authorised by the EU from 2019 to 2022) available to patients in EU Member States varies from 147 out of 167 in Germany to only six in Malta. The second-worst performing Member State is Lithuania with 14.[22] The situation is even worse for cancer medicines where in Germany the rate of availability is 46 out of 48 centrally approved oncology medicines, while in Lithuania there are only three, and none in Malta.[23] For orphan medicines, 56 out of 63 centrally authorised medicines are available in Germany, and only one in Lithuania, three in Malta, etc.[24] Thus, it can be seen that inequality of access to innovative medicines in the European Union is quite severe, creating essentially first- and second-class citizens in terms of healthcare protection. The background to this is very complex, as are the potential solutions, which will be further explained in the following sections as part of the discussion on the potential actions that can be taken at the EU level on the said issue.

---

S Smith, 'The Irish "Health Basket": A Basket Case?' (2010) 11 European Journal of Health Economics 343, 344.

[20] On the Member States' approval process for the coverage of medicines, see Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems [1989] OJ L40/8 (Transparency Directive).

[21] See Commission (n 9) 17–18.

[22] See M Newton and others, 'EFPIA Patients WAIT Indicator 2023 Survey' (2024) 2, 9–10.

[23] For example, in the non-EU country of North Macedonia, seven oncology medicines, authorised between 2019 and 2022, are available. This is two times more than in Lithuania. See Newton and others (n 22) 18–19.

[24] See Newton and others (n 22) 26–27. In general, patients in Germany, France and the Scandinavian countries are able to access larger numbers of medicines in a shorter period than in other Member States. See to that effect A Detiček and others, 'Patient Access to Medicines for Rare Diseases in European Countries' (2018) 21 Value in Health 553, 559.

A specific issue concerns the development of new antibiotics and anti-microbial resistance (AMR). Antimicrobial medicines are crucial for the protection of public health in today's world and form the backbone of modern healthcare systems. However, their timespan is limited, since, over time, mutated pathogens which survive exposure to these medicines result in the pharmaceuticals' inefficiency due to AMR.[25] Between 2016 and 2020, according to a technical report by the European Centre for Disease Prevention and Control (ECDC), AMR was responsible for a number of attributable deaths in the EU, ranging from 30,730 in 2016 to 38,710 in 2019.[26] Conversely, the pipeline for the development of new antimicrobials which could tackle the resistant pathogens is very weak, because 'an apparent market failure and the lack of market incentives has led to underinvestment by big pharma companies in new compounds'.[27]

It can be seen from the analysis presented above that the EU legal framework regulating conditions for the marketing of medicines in the common European market has generally been successful in terms of ensuring the safety and efficacy of medicines in the Union. It has also produced some results in terms of stimulating research and the development of new pharmaceuticals, through a system of incentives relating to regulatory data protection and market protection. However, the EU is increasingly lagging behind global competitors in the field of medical innovation, namely the USA, while China is accelerating and reducing the gap at an increasing rate. In terms of access to medicines, extreme inequalities persist among the Member States of the EU, with smaller countries in eastern and southern Europe particularly lagging behind larger national markets in the north and west. A special problem concerns market failure to develop new antimicrobials, making the EU unable to tackle the major public health problem of deaths attributable to AMR. The described situation sets the stage for an in-depth reform of the relevant EU legislation which will be presented next.

---

[25] See R Bonnifield and A Towse, 'Estimating the European Union's Return on Investment from an Ambitious Program to Incentivize New Antibiotics' (*Center for Global Development*, 8 December 2022) 1.

[26] See H Merk and others, 'Assessing the Health Burden of Infections with Antibiotic-Resistant Bacteria in the EU/EEA 2016–2020' (2022) European Centre for Disease Prevention and Control 4.

[27] See Commission (n 9) 17. On the issue of AMR-attributable deaths, see, for example, A Casini and others, 'Attributable Deaths and Disability-adjusted Life-years Caused by Infections with Antibiotic-resistant Bacteria in the EU and the European Economic Area in 2015: A Population-level Modelling Analysis' (2019) 19 The Lancet Infectious Diseases 56, 59.

## 3 Commission proposal

Reform of EU pharmaceutical legislation was unveiled on 26 April 2023. It consists of two intertwined legal instruments: the Directive Proposal and Regulation Proposal. It has a dual legal basis, Article 168 TFEU and Article 114 TFEU, reflecting the different general objectives the Commission is trying to accomplish: guaranteeing 'a high level of public health by ensuring the quality, safety and efficacy of medicinal products for EU patients' and harmonising 'the internal market for the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States'. Four specific objectives are stated, two of which have already been mentioned and are the focus of this paper (facilitating access and stimulating innovation), in addition to ensuring security of supply for all patients in the EU and making medicines more environmentally sustainable.[28]

The first important area which needs to be mentioned concerns regulatory data protection as one of the main tools for stimulating medical innovation and research in the European Union. Here, the Commission has proposed a major reform of the existing system of incentives. It consists of reducing the baseline period of data protection from eight to six years, with an additional two years granted for supplying the medicine in every Member State, six months for an 'unmet medical need', six months for conducting comparative clinical trials, and one year for an additional therapeutic indication where the medicine provides a significant clinical benefit in comparison with existing therapies.[29] Within the said periods, no one can refer to the same data to make a subsequent application for marketing authorisation and may not place on the market the medicine concerned by this subsequent marketing authorisation for a period of two years after the expiry of the regulatory data protection.[30]

There are two main novelties in the proposed reform. The first relates to emphasising the modulation of incentives, whereby the duration of the regulatory data protection period heavily depends on fulfilling additional conditions in the areas which are considered a policy priority. The other consists of tying these additional incentives to releasing and continuously supplying the medicine into the supply chain 'in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorisation is valid' within two years of obtaining marketing authorisation (three

[28] See Directive Proposal (n 3); and the Regulation Proposal (n 4) Explanatory Memorandum.

[29] See Directive Proposal (n 3) Arts 81–82.

[30] ibid, Art 80.

years for SMEs, not-for-profit entities, and undertakings which have received no more than five centralised marketing authorisations).[31]

To obtain the prolongation, the holder of the marketing authorisation (a pharmaceutical company) has to apply for a variation of the marketing authorisation. As part of this application, it has to submit documents from the Member State concerned showing that the mentioned condition of supplying the medicine has been met, or waiving the said requirement. The condition of supplying the medicines (market launch) is considered to have been met if a positive reimbursement decision has been made by the national social security system of the said Member State. National authorities would need to confirm within 60 days of the marketing authorisation holder's request that it complies with the prescribed condition, issue a statement of non-compliance with reasoning, or alternatively provide a statement of non-objection for the prolongation of the regulatory data protection period. If the Member State does not respond within the said deadline, it will be considered that it has provided a statement of non-objection.[32]

Another important issue concerns the concept of unmet medical need affecting the incentives provided. According to the Commission proposal, a medicine addresses an unmet medical need if at least one of its therapeutic indications concerns 'a life threatening or severely debilitating disease' and the following conditions are met: there is no authorised medicine in the EU for treating such a disease, or, even though there are authorised medicines, there is still high morbidity and mortality in the Union; the use of the medicine 'results in a meaningful reduction in disease morbidity or mortality for the relevant patient population'.[33]

In the area of rare diseases, big changes are envisaged as well. The most important one relates to the modulation of incentives and the reduction of the baseline market exclusivity period for orphan medicines, in a similar manner as with regulatory data protection. A medicine is considered an orphan medicine if it treats a life-threatening or chronically debilitating condition and the said condition does not affect more than five in 10,000 persons in the EU, if there is no satisfactory method of prevention, diagnosis, or treatment of the said condition that has been authorised in the EU or, where it does exist, the medicine in question would be of significant benefit to those affected by that condition.[34]

---

[31] ibid, Arts 81–82.

[32] ibid, Art 82.

[33] ibid, Art 83.

[34] See Regulation Proposal (n 4) Art 63.

The baseline market exclusivity period is set at nine years, a reduction from the currently prescribed ten years, while this has been extended to ten years for medicines addressing high unmet medical need.[35] An additional year is to be given if the market launch condition is met.[36] A medicine is considered to address a high unmet medical need if there is no medicine authorised in the EU for such a condition or where, despite medicinal products being authorised, the applicant proves that the orphan medicine, in addition to providing a significant benefit, 'will bring exceptional therapeutic advancement'; and the use of the orphan medicine 'results in a meaningful reduction in disease morbidity or mortality for the relevant patient population'.[37]

Unlike in the other areas where the baseline incentives have been reduced, the Commission has proposed additional incentives to stimulate investments into the development of new antimicrobials and to tackle the existing market failure. Tackling the problem of the lack of new antimicrobials is important in terms of stimulating innovation and bringing the new antimicrobials to European patients. The main novelty here concerns the transferable exclusivity voucher, created to incentivise innovation in developing new antimicrobials. This voucher will provide an additional year of regulatory data protection to the developer of a priority antimicrobial, which the developer can either use for its own medicines or sell it to another marketing authorisation holder. A priority antimicrobial is one which provides a significant clinical benefit concerning antimicrobial resistance and has at least one of the following characteristics:

(a) it represents a new class of antimicrobials;

(b) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;

(c) it contains an active substance not previously authorised in a medicinal product in the Union that addresses a multi-drug resistant organism and serious or life threatening infection.[38]

Finally, an important change relates to the procedural provisions of the pharmaceutical legislation with respect to the deadlines for the authorities concerned to make the relevant decisions in the process of authorising new medicines in the EU. According to the proposed reform, EMA will have 180 instead of 210 days for conducting its evaluation and, for medicines which are of major public health or therapeutic innovation

[35] ibid, Art 71.

[36] ibid, Art 72.

[37] ibid, Art 70.

[38] ibid, Art 40.

interest, only 150 days.[39] For the authorisation, the Commission should in principle make the final decision within 46 instead of 67 days.[40]

The described reform essentially means that baseline incentives for medical research and innovation have been reduced and a large part of them is tied to launching a medicine in all the Union Member States. This represents a big task for the companies developing new medicinal products, especially smaller companies, even though they have one additional year to fulfil the market launch condition in all the Member States. Besides, the wording is unclear on what happens in situations where the request for reimbursement has been made by the marketing authorisation holder but the national social security authorities have not made the relevant decision. It is prescribed that the Member State concerned can waive the condition of launching the medicine in their own territory, but there is no clear duty to do so. Thus, there is much uncertainty on whether marketing authorisation holders could be effectively penalised for reasons outside their control. The provisions on unmet medical need are not defined clearly and broadly enough and could exclude from additional incentives, for example, medicines improving the quality of life of a significant number of patients. A similar situation also exists with orphan medicines and market exclusivity. On the other hand, the introduction of the transferable exclusivity voucher and the reduction of time for making marketing authorisation decisions can be seen as steps forward in stimulating research and innovation in the EU, with some concerns, relating to the voucher's complexity and costs, which will be further addressed in the following paragraphs.

## 4 Parliament position

After several months of negotiations, the position of the European Parliament in the first reading was adopted on 10 April 2024.[41] On regulatory data protection, the Parliament proposes a baseline period of seven years and six months, which is one year and six months longer than

[39] ibid, Art 6 and Regulation 726/2004 (n 1) Art 6.

[40] See Regulation Proposal (n 4) para 49.

[41] See European Parliament legislative resolution of 10 April 2024 on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM(2023)0192 – C9-0143/2023 – 2023/0132(COD)) (Parliament Position on the Directive Proposal) and European Parliament legislative resolution of 10 April 2024 on the proposal for a regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (COM(2023)0193 – C9-0144/2023 – 2023/0131(COD)) (Parliament Position on the Regulation Proposal).

proposed by the Commission. An additional twelve months is proposed to be granted for an 'unmet medical need', six months for conducting comparative clinical trials and six months if a significant share of research and development, both preclinical and clinical, has taken place within the EU and at least partly in collaboration with public entities, such as university hospitals, located in the Union.[42] A general cap of an eight years and six months maximum period of regulatory data protection is also proposed[43] in order to prevent the accumulation of very long periods of data protection. The obligation not to place on the market the medicine concerned by the subsequent marketing authorisation for a period of two years after the expiry of the regulatory data protection is to be extended by one year if the marketing authorisation holder obtains, during the data protection period, an authorisation for an additional therapeutic indication, with a significant clinical benefit.[44]

The whole part on market launch conditionality has been deleted.[45] The deleted provision has been replaced by a duty, on the part of the marketing authorisation holders, to submit an application for pricing and reimbursement upon a request by a national social security system. This application has to be made within one year after making the request (two years for SMEs, not-for-profit entities, and undertakings which have received no more than five centralised marketing authorisations).[46] Member States have to decide on pricing and reimbursement within the deadlines set by Directive 89/105 (Transparency Directive)[47] and, if they fail to do so, the marketing authorisation holder's obligation is considered to have been fulfilled.[48] For orphan medicines and advanced therapy medicines, the marketing authorisation holder may make the application for pricing and reimbursement only in those Member States with a relevant patient population. Member States may also waive the marketing authorisation holder's obligation to make the application.[49]

Relating to rare diseases, the baseline market exclusivity period is set at nine years, as in the Commission proposal, while this has been extended to eleven years for medicines addressing high unmet medical

---

[42] See Parliament Position on the Directive Proposal (n 41) amendments 199–202.

[43] ibid, amendment 206.

[44] ibid, amendment 196.

[45] See Parliament Position on the Directive Proposal (n 41) amendment 207.

[46] This can be prolonged by six months following a reasoned notification of the marketing authorisation holder to the relevant authority. See Parliament Position on the Directive Proposal (n 41) amendment 174.

[47] Transparency Directive (n 20).

[48] See Parliament Position on the Directive Proposal (n 41) amendment 174. The Commission may also exempt certain medicines from the described obligation.

[49] See Parliament Position on the Directive Proposal (n 41) amendment 174.

need (unlike the Commission proposal, which provides for ten years for high unmet medical need).[50] The definition of what constitutes a high unmet medical need has been rearranged. According to the Parliament, an orphan medicine addresses a high unmet medical need if there is no medicine authorised in the EU for such a condition, or, where a medicine is authorised for such a condition, in addition to having a significant benefit, it will bring exceptional therapeutic advancement, and the use of the orphan medicine 'results in a meaningful reduction in disease morbidity or mortality for the relevant patient population'.[51] A provision has also been added whereby the Commission is to facilitate the joint procurement of centrally authorised medicinal products at the EU level on Member States' behalf and upon their request.[52]

When compared to the Commission proposal, the Parliament position introduces many significant changes relating to antimicrobials and the voucher. The voucher is to provide twelve, nine or six months of extra data protection for a medicine depending on the importance of the pathogen it is counteracting. Thus, the Commission is to set up the eligibility of pathogens for the said protection periods in accordance with the WHO priority pathogens list or an equivalent established at EU level, 'with 12 months of data protection for an authorised product ranked "critical", 9 months of data protection for those ranked "high" and 6 months of data protection for those ranked "medium"'.[53] Furthermore, financial pull incentives in the form of milestone payments and joint procurement with the subscription model scheme are also introduced to provide additional incentives for research and for the development of new antimicrobials. The Commission, in consultation with EMA, is to award milestone payments and support to potential priority antimicrobials addressing the priority pathogens, and to set up criteria for granting these payments 'taking into account the costs of the development of that stage and the anticipated costs of the next stage of development'. Milestone payments may not be accumulated with the vouchers.[54] The payments will have to be used for the following purposes:

> (a) to further develop the priority antimicrobial;
>
> (b) to apply for a marketing authorisation […];
>
> (c) to conduct antimicrobial stewardship and access plans […]; and
>
> (d) where relevant, to apply for the joint procurement agreement.[55]

---

50 See Parliament Position on the Regulation Proposal (n 41) amendment 204.

51 ibid, amendments 201–202.

52 ibid, amendment 209.

53 ibid, amendment 151.

54 ibid, amendment 147.

55 ibid, amendment 147.

Furthermore, Member States may engage in a voluntary joint procurement scheme on the basis of an agreement with the Commission. The agreement needs to be in the form of a multi-year subscription and include the following conditions:

(a) delinkage or partial delinkage of funding from the volume of sales of the antimicrobial;

(b) commitment to continuous and sufficient supply in pre-agreed quantities;

(c) commitment to the antimicrobial stewardship and access plans as referred to in Article 17(1), point (a) [of revised Directive 2001/83/EC];

(d) commitment to the environmental risk assessment as referred to in Article 22 [of revised Directive 2001/83/EC];

(e) submission of a global access plan to supply third countries in critical need, including through development partners or voluntarily licensing.[56]

It can be seen that the Parliament position tries a different approach in terms of balancing the need to stimulate research on one hand and facilitating equal access on the other. This will be evaluated against the Commission proposal in the following section.

## 5 A way forward?

In terms of balancing the need to stimulate research and the development of new medicines on one hand and the need to facilitate equal access on the other, important differences between the Commission and the Parliament can be seen. The Parliament uses a more realistic approach of providing an obligation to launch only in those Member States in which there is a need for a concrete medicine (which may not be the case for all medicines, especially those for patients suffering from rare diseases), tying it in with the Member States' fulfilling their duties (in terms of deadlines for making decisions) under the Transparency Directive. In this way, developers of new medicines are not penalised for things which are outside their control, namely the time it takes for Member States to make pricing and reimbursement decisions. The Parliament position also takes into account that there are rare diseases for which there may be no patients in certain (smaller) Member States, meaning there is no point in forcing the developers to make applications for related orphan medicines for these national markets. In such cases, there

[56] ibid, amendment 148.

will also be no interest on the part of national social security systems to make pricing and reimbursement decisions within the deadlines set by the Transparency Directive. The Commission proposal already contains the possibility to waive the said obligation, but the decision rests solely with the Member States, which creates great uncertainty for developers and is, thus, not an ideal solution. Still, according to the Parliament, if a concrete need arises, medicines will have to be provided within a certain deadline, which is definitely a step forward when compared to the current situation where there is no such obligation.

By increasing the baseline regulatory data protection period, when compared to the Commission proposal, the Parliament emphasises the importance of predictability for developers when making their investment plans for the development of new medicines. It is true, as the Commission stated in the Explanatory Memorandum to the proposal, that the reduced period of data protection is still competitive when compared to other regions.[57] On the other hand, the regulatory environment needs to be looked at holistically. Hence, the EU has to provide a comparative advantage in one area in which it can act by way of concrete legislation and that is by strengthening, or at least not reducing, the period of regulatory data protection. The fact that, despite the current system of incentives, the EU has been lagging behind the USA in the last two decades shows that reducing the existing incentives for research and innovation could hardly make the EU more competitive in the global market.

Modulation is still there in the Parliament position, which is good from the point of view of streamlining the incentives for those areas where the needs are the highest. Additionally, the introduction of a cap can be seen as a positive thing as well, because it makes sure that there cannot be a prolonged accumulation of regulatory data protection periods of more than ten years, which could result in an unreasonable burden on national budgets and could hamper access to medicines in different Member States.

One particular area in which there has been plenty of criticism of the Commission proposal, in terms of going too far in protecting the interests of developers, concerns the transferable exclusivity voucher. It has been called a 'flawed incentive', which would create a very complex system, increase costs, lead to new antibiotics not being available, and produce negative consequences for the development of biosimilars.[58] The EFPIA has since responded to these arguments by emphasising that there are solutions regarding how to make the system not overly com-

[57] See Directive Proposal Explanatory Memorandum (n 3).

[58] See, for example, C Ardal and others, 'Transferable exclusivity voucher: a flawed incentive to stimulate antibiotic innovation' (2024) 403 *The Lancet* e2.

plicated, that the voucher would decouple the incentive for the antibiotic from payment, accelerating price negotiations at the national level, that the rules can be made clearer and that the benefits generally outweigh the costs.[59] Still, the Parliament tried to streamline the voucher by providing a stronger incentive (longer data protection) in those areas where the situation is critical, but also providing additional pull incentives in the form of milestone payments and joint procurement with a subscription model. The goal is that those entities which are actually engaged in new antibiotic medicine development benefit from the new system. The conditions for granting milestone payments should ensure that the antimicrobial concerned is developed to the point of marketing authorisation and made available to patients, while multi-year subscription should increase the predictability of the system and also ensure stewardship and appropriate use. Overall, the Parliament position offers a more balanced system of push and pull incentives, making sure that the industry is incentivised to develop new antimicrobials, but also ensuring that these antimicrobials are finally developed and made accessible to European patients.

When one looks at the situation in the Council, it becomes clear that striking a balance (which is the very topic of this paper) will be one of the hardest things on which to find political agreement. The Belgian presidency addressed the question of incentives and proposed to introduce a cap of eleven years of data and market protection and to award one year of market protection instead of one year of regulatory data protection for an additional therapeutic indication. It also supported the Commission proposal on incentives for orphan medicines. The presidency emphasised that the criteria for identifying medicines addressing unmet medical needs should be objective and measurable. Finally, it submitted four different scenarios on the question of equal access in all Member States, ranging from Member States having to make a request to a company within a certain timeframe to have a medicine on its market, to decoupling incentives from access altogether (similar to the Parliament position).[60] As stated by the progress report on the pharmaceutical package that the ministers of the Employment, Social Policy, Health and Consumer Affairs Council took note of on 3 December 2024, the following remain the main outstanding issues on which there is no political agreement as of the end of 2024 (the end of the Hungarian rotating pres-

[59] See EFPIA, 'Transferable exclusivity voucher: a flawed incentive to stimulate antibiotic innovation' (*The Lancet*, 9 February 2023, EFPIA-BEAM Rejoinder) <www.efpia.eu/news-events/the-efpia-view/statements-press-releases/efpia-rejoinder-lancet-article/#_ftn1> accessed 29 August 2024.

[60] See Council, 'Incentives system within the proposed pharma package: ways forward to achieve an agreement in the Council' (2024) 5–9.

idency): modulation of incentives; ensuring more equal market access and continuous supply of innovative medicines for all EU Member States; and the voucher.[61]

In addition to what has already been mentioned, it has to be emphasised that the EU pharmaceutical legislation, whose primary aim is ensuring the safety and efficacy of new medicines on the EU market, is not a silver bullet which can solve all the problem of inequality of access in the EU. This is the case because, as already stated in the introductory paragraphs, pricing and reimbursement of medicines is primarily a national competence and it is the last step determining when a certain medicine becomes available for patients. Hence, the EU may not harmonise national definitions of health policy and the organisation of healthcare, including the allocation of funding, as its primary objective. On the other hand, the EU may adopt measures, including harmonisation, which affect human health.[62] This possibility has been interpreted rather broadly in the past by the Court of Justice (CJEU). According to its jurisprudence, the EU legislator may adopt measures, using legal bases for the harmonisation of the internal market, even if 'public health protection is a decisive factor in the choices to be made'.[63] Therefore, any measure having some connection with the internal market and free movement may be adopted, even when its primary aim is essentially related to healthcare. As this example, as well as others like COVID-19, shows us, the possibilities of Union action in the area of healthcare primarily depend on political will, not legal limitations.[64] Very few areas of national health law remain unaffected by EU law.[65]

Of course, the financial capabilities of various Member States are very different, with Romania being at the bottom of per capita spend-

---

[61] See Council, 'Information from the Presidency on the progress achieved in the examination of the Revision of the pharmaceutical package' (2024) 8; and Council, 'Employment, Social Policy, Health and Consumer Affairs Council (Health) 3 December 2024' <www.consilium.europa.eu/en/meetings/epsco/2024/12/03/> accessed 8 January 2025.

[62] See K Purnhagen and others, 'More Competences Than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak' (2020) 11 European Journal of Risk Regulation 300.

[63] See Case C-380/03 *Federal Republic of Germany v European Parliament and Council of the European Union* ECLI:EU:C:2006:772, para 39. It has been stated in the literature that the importance of health policy for our everyday life has led to the recognition of certain related fundamental rights at the EU level, even as (formally) part of other EU policies. See A de Ruijter, *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care* (OUP 2019) 91.

[64] See Purnhagen and others (n 62) 306.

[65] See T Hervey, 'EU Law and Policy on New Health Technologies' in S Garben and L Gormley (eds), *Health Law* (OUP 2024) 9.

ing in the EU.[66] One possible solution coming from the industry could be equity-based tiered pricing, meaning that the ability to pay across countries is considered in the prices of innovative medicines. This would essentially mean that Member States with fewer resources would pay a lower price and those with more resources would pay a higher one.[67] Such a solution could only be applied in a voluntary setting, because any legal binding legislation would require a Treaty change granting more powers to the EU to introduce a centralised procedure for price setting, which does not seem to be realistic at the moment.[68] The proposal by the industry for a voluntary system, based on the confidentiality of prices,[69] could be a solution, but the lack of transparency in that system is something that would certainly be a cause for concern for national social security systems and other stakeholders.

Still, even within the existing framework, the amendment of two other pieces of EU legislation could lead to certain benefits for patients in terms of equality of access. The first is the revision of the Transparency Directive. This piece of legislation was adopted in 1989 and has never been amended, thus showing the lack of political will for a stronger EU regulation in this area. It sets certain very broadly defined principles for making pricing and reimbursement decisions, focusing primarily on the transparency of the system and making sure that all developers of new medicines (applicants for a pricing and reimbursement decision) are treated equally, without discrimination. Furthermore, it sets a deadline for a final decision, after which a medicine may be made available for patients, for a maximum of 180 days. The underlying principle of the Directive is minimum interference in the organisation of national social security systems.[70] It is also important that national decisions contain

---

66 See EUROSTAT, 'Healthcare Expenditure Statistics: Overview' <https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Healthcare_expenditure_statistics_-_overview&oldid=625409#Healthcare_expenditure> accessed 29 August 2024.

67 See EFPIA, 'A Shared Approach to Supporting Equity Based Tiered Pricing Discussion Document' <www.efpia.eu/media/636825/a-shared-approach-to-supporting-equity-based-tiered-pricing.pdf> accessed 29 August 2024. See on this issue also A Towse and others, 'European Union Pharmaceutical Markets: A Case for Differential Pricing?' (2015) 22 International Journal on the Economics of Business 263.

68 See Towse and others (n 67) 270.

69 See EFPIA (n 67) 5.

70 See Transparency Directive (n 20) Arts 1–7. See, on this piece of legislation and the principle of minimum interference, for example, Case C-20/22 *Syndicat Les Entreprises du médicament (LEEM) v Ministre des Solidarités et de la Santé* ECLI:EU:C:2022:1028, para 21. Of course, Member States still need to respect EU law, including the Transparency Directive, but other pieces of pharmaceutical legislation as well. See, to that effect, Case C-29/17 *Novartis Farma SpA v Agenzia Italiana del Farmaco (AIFA) and Others* ECLI:EU:C:2018:931, para 50.

reasoning.[71] Even though the EU does not have the power to harmonise reimbursement and price setting, it could determine some of the basic guiding principles or criteria for national social security institutions making these decisions. If this is politically not feasible, at least prescribing and enforcing concrete sanctions for Member States not complying with the set deadlines for making reimbursement decisions, and shortening those deadlines, would be a big step forward for equality of access to what we have now, where no provisions on sanctions are contained in the Directive.

Finally, revision of EU legislation on cross-border healthcare could contribute to reducing differences in access to medicines and treatment within the EU. This area is currently regulated by the EU regulation on social security coordination, the oldest piece of EU legislation on patients' rights,[72] and the directive on cross-border healthcare[73] which serves as

[71] See Joined Cases C-271/14 and C-273/14 *LFB Biomédicaments SA and Others v Ministre des Finances et des Comptes publics and Ministre des Affaires sociales et de la Santé* ECLI:EU:C: 2015:237, para 31.

[72] See Regulation (EC) 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems [2004] OJ L166/1 (Regulation 883/2004); and T Hervey and J McHale, *European Union Health Law: Themes and Implications* (CUP 2015) 189–190.

[73] See Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare [2011] OJ L88/45 (Directive 2011/24). The Directive and the case law have been thoroughly analysed in the literature. See, for example, S de La Rosa, 'The Directive on Cross-border Healthcare or the Art of Codifying Complex Case Law' (2012) 49 CML Rev 15; M Peeters, 'Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Healthcare' (2012) 19 European Journal of Health Law 29; K Raptopoulou, 'The Directive on Cross-border Health Care: Signalling the Coordination or the Harmonisation of Public Health Systems?' (2012) European Journal of Social Law 193; G Strban, 'Patient Mobility in the European Union: Between Social Security Coordination and Free Movement of Services' (2013) 14 ERA Forum 391; J van de Gronden, E Szyszczak, U Neergaard and M Krajewski (eds), *Health Care and EU Law* (TMC Asser Press 2011). It needs to be mentioned that Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU [2021] OJ L458/1 (HTA Regulation) was adopted in 2021. It defines HTA as 'a multidisciplinary process that summarises information about the medical, patient and social aspects and the economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner'. The HTA Regulation has deleted the provisions of Directive 2011/24 on health technology assessment and created an EU system of HTA whereby Member States need to take into account European joint clinical assessments in their national HTAs. However, joint clinical assessments do not cover the economic evaluation of health technologies (the latter is subject to voluntary cooperation), which means that this system will, presumably, only have a minor impact on national pricing and reimbursement decisions. See HTA Regulation Arts 2, 13, 23, 35. On the HTA Regulation, see, for example, T Hwang and K Vokinger, 'New EU Regulation on Health Technology Assessment of Cancer Medicines' (2022) 23 The Lancet Oncology e58.

a codification of EU law on freedom to provide healthcare services.[74] The two sets of rules are rather similar, but still different in terms of the obligation to obtain prior authorisation for treatment abroad (when patients cannot obtain adequate treatment in their state of residence or affiliation), the tariffs, and the procedure under which the coverage is carried out. Under social security coordination, prior authorisation is generally required, and patients are covered on the basis of the state of treatment rules and tariffs.[75] Under the directive, patients are entitled to obtain healthcare without prior authorisation except for cases of hospital treatment, treatments involving major medical equipment and treatments or providers presenting a risk for the patient or the population and tariffs of the state of affiliation are applicable.[76] This makes it extremely complicated for patients to understand and exercise the rights which are guaranteed to them by EU law. Thus, it is not surprising that only 0.05% of EU citizens avail themselves of the possibilities prescribed by the directive on cross-border healthcare.[77]

Merging the two sets of rules, preferably in a directly applicable regulation, would help simplify things and streamline the process for patients. Furthermore, explicitly prescribing a right to a 'second opinion' for difficult or atypical cases, meaning that patients would have the right to request that specialists from one Member State seek the advice of specialists from another Member State within a single system, would also help patients from different Member States to have more equal access to the most advanced therapies and medicines anywhere in the EU. This has already been stated by the European Parliament resolution on strengthening Europe in the fight against cancer in 2022.[78] Thus, the EU legislator has additional possibilities to reduce inequalities in access within the EU, and the pharmaceutical package is certainly not an instrument which could resolve all the problems which exist today.

---

[74] See, for example, Case C-158/96 *Raymond Kohll v Union des caisses de maladie* ECLI:EU:C:1998:171; Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust* ECLI:EU:C:2006:325; Case C-777/18 *WO v Vas Megyei Kormányhivatal* ECLI:EU:C:2020:745; Case C-243/19 *A v Veselības ministrija* ECLI:EU:C:2020:872. On this case law, see, for example, V Hatzopoulos, '*Killing* National Health and Insurance Systems but *Healing* Patients? The European Market for Health Care Services After the Judgments of the ECJ in *Vanbraekel* and *Peerbooms*' (2002) 39 CML Rev 683.

[75] See Regulation 883/2004 (n 72) Art 20.

[76] See Directive 2011/24 (n 73) Arts 7–8.

[77] See European Court of Auditors, 'EU Actions for Cross-border Healthcare: Significant Ambitions but Improved Management Required' (2019) 4.

[78] See European Parliament resolution of 16 February 2022 on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy (2020/2267/INI) paras 55, 62. On the right to a second opinion, see, also, Case C-538/19 *TS and Others v Casa Națională de Asigurări de Sănătate and Casa de Asigurări de Sănătate Constanța* ECLI:EU:C:2021:809, para 58.

## 6 Conclusion

The Commission has set very ambitious goals with its proposal for the revision of EU pharmaceutical legislation. It has tried to solve the problem of unequal access to medicines within the EU, while also making Europe more competitive in the global pharmaceutical market. The crucial aspect here is how to strike the right balance between the need to stimulate research and innovation on one hand and ensure equality of access on the other. Even though there are some positive aspects in the Commission proposal, such as cutting the deadlines for conducting the marketing authorisation procedure, there are also issues which can be seen as problematic and representing a step backwards in terms of promoting innovation within Europe, such as the reduction of the baseline regulatory data protection period.

The Parliament is taking a more realistic and balanced approach by providing an obligation to launch in those Member States where there is a need for a concrete medicine. By increasing the baseline regulatory data protection period, the Parliament highlights the importance of predictability for developers when making their investment plans for the development of new medicines. The Parliament also retains the concept of modulation, which is good from the point of view of streamlining the incentives to those areas where the needs are the greatest. Furthermore, by introducing a cap, the Parliament makes sure that there cannot be a prolonged accumulation of regulatory data protection periods of more than ten years, which could result in an unreasonable burden on national budgets and hamper access to medicines in different Member States. In relation to the issue of antimicrobials, the Parliament combines a number of push and pull incentives, thereby motivating the industry to create new antimicrobials, but also ensuring these antimicrobials are finally developed and made accessible to European patients. All this means that the final text aiming at striking a balance between stimulating innovation and enabling equal access should follow, as far as possible, the balanced approach of Parliament.

Revision of the pharmaceutical legislation is not a silver bullet to resolve all the problems relating to equal access. Revision of the Transparency Directive, which would at least accelerate national pricing and reimbursement decisions and set a strong enforcement mechanism, would certainly improve the equality of patients and make new medicines more accessible to them. Finally, revision of the cross-border healthcare legislation, which would simplify the legal framework and make it more accessible to patients, would particularly help those who are unable to access adequate medical treatment in the Member State in which they live and provide all European citizens with the same, or at least a sim-

ilar, possibility to avail themselves of the best quality treatments and medicines anywhere in the EU.




**Suggested citation:** T Sokol, 'The EU Pharmaceutical Package: Will It Strike a Balance Between Stimulating Research and Facilitating Equal Access?' (2025) 21 CYELP 53.