WAR PAR
DYŃ TNE
SKI+ RS•

Pharmaceutical Package

Compromise following the Polish Presidency of the EU Council

AUGUST 2025

INNOVATION ◆ ACCESS TO MEDICINE ◆ ENVIRONMENTAL IMPACT

Contents

1 Introduction

On 4 June 2025, the Council of the European Union announced that it has adopted a position on the **Pharma Package**, the biggest reform of EU pharmaceutical law in over 20 years. Agreeing on a common mandate was one of the priorities of the Polish Presidency of the Council of the EU. This consensus is the result of intense negotiations over many months and brings the EU closer to ensuring better access to safe and affordable treatments, as well as strengthening innovation and resilience in the European pharmaceutical sector.

The Pharma Package includes the following drafts:

- **A new Pharmaceutical Directive**—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
- **A new Pharmaceutical Regulation**—Regulation 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.

The new regulation is to include updated rules on orphan drugs (previously included in Regulation 141/2000). Rules on paediatric medicines (previously in Regulation 1901/2006) will be included in both the new regulation and the new directive.

In what is known as a "mandate for negotiations with the European Parliament," the Council of the EU:

- Proposed to maintain the current eight-year data protection period for innovative medicines, with the possibility of extending it if certain conditions are met
- Shortened the basic market protection period for new medicines from two years to one year, with the possibility of extension to two years if certain pre-defined targets are met
- Strengthened the "Bolar exemption," which allows for accelerated availability of cheaper equivalents of innovative medicines, and extended its scope to include tenders
- Provided for introduction of a supply obligation, under which member states can require holders of drug authorisations to make products available in sufficient quantities to meet the needs of patients in a given EU country
- Modified the proposal of the "voucher" for transferable data exclusivity.

The position of the Council is for the time being a proposal of amendments to new legal acts, and is not yet binding law. Next, formal negotiations will begin with the participation of the European Parliament, the Council of the EU and the European Commission, a procedure known as "trilogues." Their aim is to agree on a common text of the provisions. During the further legislative path (see diagram in Appendix 1), the Pharma Package may be subject to further changes.

In this report, we examine selected significant changes compared to the original wording of the package (which we discussed in our report two years ago "Pharmaceutical Package: The biggest reform in EU pharmaceutical law in 20 years"). Now, as we did then, we focus on the three declared objectives of the new legislation: fostering innovation of medicines, increasing access to medicines, and environmental concerns.

2 Fostering innovation of medicines

2.1 Data exclusivity and market protection

Changing the duration of regulatory data protection for medicines is one of the most commented-on proposals in the Pharma Package. In the original proposal, the European Commission envisaged a reduction in the overall period of data exclusivity from eight years to six years. However, the current version maintains the eight-year period and includes additional possibilities for extending it.

Regulatory data protection, alongside patent protection, is a mechanism for supporting and stimulating innovation in the pharmaceutical sector which has been in place for years. The Pharma Package proposes a new compromise on how protection periods are calculated. This compromise is an attempt to reconcile many conflicting interests, in particular the interests of patients (who want to have faster access to cheaper treatment with generic products, as well as access to innovative medicines) and the interests of pharma companies (which make significant financial outlays on research into new drugs in the hope of recouping their investment at the commercialisation stage).

Data exclusivity and market protection

Regulatory data protection, also known as data exclusivity or the data protection period, is the period when an applicant for marketing authorisation of a medicine cannot use the results of clinical trials of someone else's original product to obtain registration of its own generic product in a simplified procedure (i.e. by citing protected studies of the reference product). This period is currently eight years from the date of the first marketing authorisation of the reference medicinal product in any of the countries of the European Economic Area.

Data exclusivity is complemented by market protection, also known as the market protection period. Market protection means that a generic medicine registered using the simplified procedure (i.e. based on the data of someone else's original product) cannot be placed on the market. Market protection lasts 10 years, which is two years longer than data exclusivity. During the two years between the end of data exclusivity and the end of market protection, a generic equivalent of the original medicine may not be placed on the market,

but may undergo registration procedures aimed at placing the product on the market as soon as the market protection period ends.

Data exclusivity and market protection—referred to together as "regulatory protection"—constitute a separate legal regime, parallel to patent protection.

Change in the duration of regulatory protection

The current periods of regulatory protection are referred to as the "8+2+1" rule:
- Eight years of regulatory data protection
- Plus two years of market protection
- Plus one year of market protection (for a new indication).

Regulatory data protection lasts eight years. After that, the holder of market authorisation for the original medicine can still count on two years of market protection, with the possibility of an extension by an additional year if it registers a new indication for which significant clinical benefits are expected compared to existing therapies.

Under the recent agreement on the position of the Council, the Pharma Package introduces a rule that can be described as "8+1+1":
- Eight years of regulatory data protection
- Plus a possible extension of data protection by one year
- Plus one year of market protection.

The possible extension of data protection by one year involves the use of a **voucher** (data exclusivity voucher) obtained for developing a new antibiotic (referred to as a "priority antimicrobial") designed to combat severe or life-threatening infections, when the data confirm that it has a significant clinical benefit and it also has a new mechanism of action or a new active substance, either alone or in combination with other active substances.

The Council mandate upholds the position that the voucher is to be transferable: a company that obtains a voucher can transfer it at any time before it is used to another medicine or even to another company. However, the use of the voucher for another drug would only be possible for a centrally registered medicinal product, and—crucially—**not until the fifth year** of regulatory data protection, and if the marketing authorisation holder (MAH) demonstrates that the annual gross sales of this medicinal product in the EU **did not exceed EUR 490 million** in any of the preceding four years.

The current version of the Pharma Package also maintains the introduction of a special case of granting a separate data protection period of four years for a medicine containing an active substance or substances not previously authorised in the EU for a new therapeutic indication (known as "repurposed medicinal products"), provided that:

- The medicine has been registered as a generic product and has not yet benefited from data protection (or 25 years has passed since the first authorisation), and
- The drug has gained a new indication that has not yet been approved in the EU, thus providing a significant clinical benefit, which is confirmed by studies.

The general period of market protection provided for in the Pharma Package is to be one year, but this period could be extended if certain conditions are met (see diagram in Appendix 2):

- **By an additional 12 months** for meeting the "unmet medical needs" criterion at the time of the initial marketing authorisation application. This criterion is met if there is no authorised medicine for the disease in question in the EU, or the use of a new medicine for the treatment of the disease in question results in a marked improvement in efficacy or safety (while maintaining at least comparable efficacy to other medicines or other available medicines or treatments, diagnosis or prevention approved in the EU); **or**
- **By an additional 12 months** for meeting the criterion of a new active substance. This criterion is met if the medicine contains a new active substance and its clinical trials have been carried out in more than one member state using an appropriate comparator (i.e. an effective and commercially available comparable medicine, used in a clinical trial for comparison with the investigational medicine), in accordance with scientific guidelines provided by the European Medicines Agency, and the marketing authorisation application was first submitted in the EU (or within 90 days after such an application was filed outside the EU); **and**
- **By an additional one year** for meeting the criterion of a new indication, which will be met if the MAH obtains registration of a new indication during the regulatory data protection period, and the data show a significant clinical benefit compared to existing therapies (this extension can be used only once).

Under the Pharma Package, the overall period of market protection shall not exceed **two years** from the end of regulatory data protection, except where one additional year of market protection is granted for fulfilling the criterion of a new indication. The period of market protection can therefore last from one year to a maximum of three years.

Exemption from the protection of intellectual property rights

In its agreed position, the Council of the EU proposed to support the earlier marketing of generics and biosimilars by clarifying the scope of the so-called Bolar exemption and extending it to include tenders.

Under the current wording of the Pharma Package, the protection provided by patent rights or a supplementary protection certificate for medicines is not considered to be infringed if the necessary research, trials and other activities are carried out in order to:

- Obtain marketing authorisation, in particular for generic, biosimilar, hybrid or biohybrid medicines, and for subsequent amendments
- Conduct a medical technology assessment
- Obtain approval of prices or reimbursements, or
- Submit applications in public procurement tenders under EU or national law, so long as this does not involve the sale (or offering) of the medicine in question during the period of protection under a patent or a supplementary protection certificate.

Activities undertaken solely for these purposes may include, in special cases, e.g. filing an application for marketing authorisation, and offering, manufacturing or supply, including by external suppliers and service providers. However, the exemption will not extend to introduction of a drug onto the market as a result of such activities.

2.2 Orphan drugs—designations and period of market exclusivity

The Pharma Package is intended to adjust the criteria for regarding a medicinal product as an orphan drug and the procedure for granting such status. The updated version of the package also provides for changes in the period of market exclusivity for orphan drugs. The overall period of market exclusivity would still be 10 years, but with a possibility of extending it. The Council also supported changing the rules on the scope of protection for the last two years of its duration. At the same time, the proposal of a separate, five-year period of market exclusivity for drugs with a well-established use remains in place.

Orphan drug designation

The current proposal for the Pharma Package retains the existing criteria for labelling a drug as an "orphan medicinal product."

A medicine is regarded as an orphan if:

- The condition affects not more than five in 10,000 persons in the EU, **and**
- There exists no satisfactory method of diagnosis, prevention or treatment of the condition that has been authorised in the Union (or, where such method exists, the medicinal product would be of significant benefit to those affected by the condition).

As the prevalence criterion is not suitable for all rare diseases, the European Commission, on behalf of the European Medicines Agency, will be able to establish specific criteria for certain conditions, such as those with short duration and high mortality. In such cases, the number of new cases over a given period of time is considered to be a better indicator of the rarity of the disease, rather than the number of current patients.

Both the original and the currently discussed version of the Pharma Package reject the existing criterion that a medicine could be granted orphan status if, without the right incentives, its introduction to the EU market would not generate a sufficient return on the necessary investment.

Modification of the procedure for obtaining an orphan designation

The Pharma Package provides for the transfer of competence to grant orphan drug designation from the Commission to the EMA. The aim of these changes is to simplify and speed up existing administrative procedures. The modifications also include the possibility of reducing the role of the EMA Committee for Orphan Medicinal Products, which currently reviews and issues opinions on all applications for orphan drug status. The reform provides for the committee to lay down specific rules under which, by way of derogation, consultations will not be required.

A new feature in the draft is the possibility for the EMA to ask sponsors to submit additional data and documents. In addition, unlike in the original proposal, sponsors will be able to request reconsideration of an application for orphan designation. The sponsor will have **15 days** from receipt of notice that its application does not meet the required criteria to take advantage of this option. In this case, the agency will have to confirm or amend its existing scientific conclusions within 30 days and issue a decision on granting orphan designation.

Importantly, the Council maintained the proposal to cut the current indefinite validity of the orphan designation down to **seven years**. The validity of the designation could be extended at the request of the sponsor if the sponsor shows that it is in the process of conducting studies to confirm the use of the product under the requested conditions, which are promising for submission of a future marketing authorisation application. This solution is intended to encourage faster introduction of orphan medicinal products to the market and thus increase their availability to patients.

Duration of protection

Currently, the standard market exclusivity period for orphan medicinal products is 10 years from the date of authorisation. During this period, the authorities cannot register generics of the orphan drug or accept applications for registration of generics. If at the end of the fifth year of market exclusivity it is determined that the criteria for benefiting from orphan drug status are no longer met, the standard period of market exclusivity for orphan drugs may be reduced to six years. It is also possible to extend the market exclusivity period to 12 years, if the orphan drug also meets paediatric requirements.

While it was originally planned to shorten the general period of market exclusivity for orphan drugs, the current version of the package restores the length of this period to **10 years**. It is also possible to extend this period (see diagram in Appendix 3):

- **By an additional 12 months** (a maximum of two times) for meeting the criterion of a new indication, which will be met if at least two years before the end of the period of market exclusivity for orphan drugs, the MAH obtains registration of a new indication for another orphan disease.

If an orphan medicinal product obtains an extension for meeting the criterion of a new indication, it will not be entitled to an additional period of market protection (see section 2.1 above).

Under the Pharma Package, the period of market exclusivity of an orphan drug could therefore last from 10 to 12 years.

The current wording of the package maintains the previous proposal of a separate **five-year period of market exclusivity** for orphan drugs registered on the basis of bibliographic data. This is a registration where there is no reference product with the active substance in question, or the reference product is not available on the EU market, but the active substance has a well-established therapeutic use, as confirmed by the scientific literature, which allows for registration without the need for clinical trials. An orphan

drug registered on the basis of such bibliographic data would benefit from a five-year period of market exclusivity, but it could not be extended as provided in the previous point.

Scope of protection

In the context of the market exclusivity of orphan drugs, we should note the agreed amendment concerning the scope of protection of the entity benefiting from the period of market exclusivity. The possibility of preparing generic drugs ready for actual entry onto the market on the first day after the innovator's monopoly ends has been strengthened.

Under the current law, for the entire duration of the market exclusivity of orphan drugs, the authority may not accept or consider an application for a competitive (generic) drug authorisation. In the agreed change, the legislation allows for acceptance and consideration of an application, or even granting marketing authorisation (or extension of an existing one for a new indication) for a similar medicine, including generics and biosimilars, if there is less than two years left until the end of the market exclusivity period.

This means that competing orphan products could undergo the registration procedure during the market exclusivity period, so that the competing products could be marketed immediately after the exclusivity period ends.

2.3 Advanced therapy medicinal products—hospital exemption

The Pharma Package provides for changes in the rules for advanced therapy medicinal products—hospital exemption. The package aims to clarify how this institution operates and guarantee the collection of data on the use, safety and efficacy of products.

Scope of changes

An "advanced therapy medicinal product" (ATMP) is a drug for gene therapy, tissue engineering or somatic cell therapy. Such products are registered under the EU's central procedure. Exceptionally, under certain conditions, some ATMPs may be placed on the market without the need for a marketing authorisation. This is known as the "hospital exemption."

Compared to the current rules, the definition of ATMP (hospital exemption) will not change. It will be defined as an advanced therapy medicinal product

prepared within a member state on a non-routine basis in accordance with specific requirements and used in the same member state in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient.

However, the Pharma Package sets forth the specific requirements that are to be met by an ATMP/hospital exemption (which in turn is to be reflected in national law). These are requirements equivalent to those in Art. 5 (good manufacturing practice) and Art. 15 (traceability) of Regulation 1394/2007, as well as requirements equivalent to those for pharmacovigilance in the new regulation (replacing Regulation 726/2004).

It is also clarified that the manufacture of an ATMP/hospital exemption is to be approved at the national level in the form of an authorisation, to be notified to the European Medicines Agency. In practice, the Polish regulations already provide for such approval by the Chief Pharmaceutical Inspector (GIF).

According to the planned changes, the recipient of approval to manufacture and use an ATMP/hospital exemption will compile and transmit aggregate information, at least once a year, on the use (such as the number of patients and product administrations), safety and efficacy of the ATMP/hospital exemption to the national authority (in Poland, most likely GIF), which will then analyse the information against the detailed requirements. This information will also be transmitted by the national authority (GIF) to the EMA (at least once a year) and stored in the EU repository.

The national authority (GIF) would inform the EMA of withdrawal of authorisation for safety or efficacy reasons. The EMA would then forward this information to the national competent authorities of the other member states.

According to the current wording of the package, it would be up to the Commission to adopt implementing acts specifying:

- Details of the application for authorisation of an ATMP/hospital exemption (including evidence of quality, safety and efficacy)
- The content and method of collecting and reporting data on the number of patients and administrations of the product, its safety and efficacy, together with a description of the data
- Rules for exchange of knowledge between recipients of approvals for an ATMP/hospital exemption within one or more member states
- Conditions for non-routine preparation and use of an ATMP/hospital exemption.

The EMA is to prepare reports summarising the experience under the system of authorisations for ATMPs/hospital exemption based on information obtained from member states. The first report will be due three years after entry into force of the new directive, with further reports to be published every five years.

2.4 Regulatory sandbox

As part of the Pharma Package, EU lawmakers have provided for the possibility of establishing regulatory sandboxes. This will make it possible to safely implement innovative pharmaceutical solutions whose unique features make it impossible to comply with the existing rules for authorisation and marketing of such products.

A regulatory sandbox is an institutional mechanism that allows innovative products, services, business models or technologies to be tested under real market conditions, but within a limited framework closely supervised by the regulator. It consists in temporarily suspending, limiting or adjusting selected legal requirements (e.g. licensing, capital, reporting). This, in turn, allows participants to test their solutions operationally while ensuring protection of the public interest, in particular consumer rights and the stability of the system.

Conditions and procedure for setting up a regulatory sandbox

Under the new regulation, a regulatory sandbox could be established if all the following conditions are met:

- A medicinal product cannot be developed and placed on the market in full compliance with the applicable requirements of EU law due to the scientific and technical characteristics of the product.
- The properties of the medicinal product that prevent compliance with the regulations may make a positive and demonstrable contribution to improving the quality, safety or efficacy of the medicinal product, at least on a par with the legal requirements, or bring a significant advantage to patients' access to prevention, diagnosis, treatment or care.
- The medicinal product is not at an advanced stage of clinical or technological development.

If these conditions are met, and the EMA deems it appropriate to set up a regulatory sandbox, it will make a recommendation to the Commission after appropriate consultation (including with the authorities of the member states). The recommendation will include a list of eligible products or product categories and a sandbox plan. Taking into account the recommendation of

the EMA and the sandbox plan, the Commission will then adopt a decision on creation of the regulatory sandbox.

The decision will specify:

- The regulatory sandbox plan, setting out in particular the technical adaptation targets and any measures to mitigate potential risks to health and the environment
- The duration of the sandbox
- The participants in the sandbox.

Products developed in the sandbox

A medicinal product developed in the regulatory sandbox could only be placed on the market after obtaining an authorisation issued in accordance with the new regulation, if the benefits associated with use of the medicinal product outweigh the risks. The maximum initial validity of such an authorisation will include the period for which the regulatory sandbox has been established, but the authorisation could be extended at the request of the holder.

In justified cases (assuming the regulatory sandbox has not been suspended or terminated), a medicinal product developed in the regulatory sandbox will continue to benefit from appropriate adjustments, but only to the extent necessary to achieve the objectives, duly justified and specified in the conditions of the marketing authorisation.

Duties and responsibilities of sandbox participants

The supervisory and remedial powers of the competent authorities will not be affected by regulatory sandboxes. Participants will be liable for any injury to third parties resulting from the sandbox research. Participants will also be required to provide the EMA with any information that may require a change to the regulatory sandbox or relating to the quality, safety or efficacy of products developed in the sandbox.

3 Increasing the availability of medicines

3.1 Combating drug shortages

One of the key objectives of the Pharma Package is to combat shortages of medicines. There are still plans to create special monitoring lists at the EU level and to impose additional obligations on marketing authorisation holders, among other measures. The position adopted by the Council would also allow a member state to oblige marketing authorisation holders to supply a specific medicine to that country.

The fight against drug shortages began during the Covid-19 pandemic. In early 2022, an EU regulation was adopted to strengthen the role of the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. This regulation establishes a list of critical medicines in the event of a crisis. The Pharma Package includes further mechanisms to tackle shortages, and the Council of the EU has proposed additional modifications in this regard.

A system-wide perspective

To combat shortages and unavailability of medicines, the Council proposes to maintain in the Pharma Package:

- The Union List of Critical Medicinal Products, and
- The List of Critical Shortages of medicinal products of Union concern.

The European Commission will also be able (via a delegated act) to identify additional groups of medicines that require a shortage prevention plan.

In addition, it is proposed that the EMA should post information on its website about real, critical shortages of medicines of EU importance. The website should also provide links to lists of actual shortages published by the competent authorities of the member states.

Moreover, according to the current wording of the Pharma Package, an EU country may ask the marketing authorisation holder to **supply a given medicine** to the market of that country, in quantities and presentations sufficient to meet the needs of patients.

In such a case, the member state could require the MAH to:
- Submit a valid application for price determination and reimbursement
- Meet specific requirements in public procurement procedures
- Establish a marketing plan.

At the same time, the Council proposed in its agreed position that member states could exempt MAHs from a number of obligations related to the management of shortages, e.g. when medicines are supplied for military or defence purposes or to the extent that the application of such requirements entails risks to national security and defence.

The perspective of marketing authorisation holders

The current version of the Pharma Package provides that to combat drug shortages, MAHs will have to:
- Notify interruptions in supply
- Take specific action in the event of interruptions in the supply of critical medicinal products or priority antimicrobials
- Prepare a shortage prevention plan
- Prepare a shortage mitigation plan
- Prepare a risk assessment for potential threats to the supply chain, and
- Prepare a marketing plan (if a member state asks for the medicine to be supplied to that member state).

As part of the disclosure obligations related to interruptions in supply, the MAH would have to:
- Notify in advance the decision to permanently cease the marketing of a drug, at least 12 months before the last delivery
- Notify in advance the decision to withdraw their marketing authorisation, at least 12 months before the last delivery
- Notify in advance the decision to temporarily suspend marketing of a drug, at least six months before the last delivery
- Report a temporary disruption (likely to last at least two weeks) in the supply of a medicine, as soon as possible but no later than three months before the disruption (if it is forecast), or immediately after the disruption occurs, when exceptional circumstances (which must be duly determined and justified before the competent authority) have prevented the MAH from meeting the deadlines.

In addition, for critical medicines, medicines that require a shortage prevention plan, or priority antimicrobials, the MAH would have to do the following before applying for withdrawal of its authorisation:

- Publish on a dedicated website a statement of intention to offer to transfer the drug authorisation or give written consent to use the entire documentation for the purpose of processing subsequent applications for drug authorisations (and provide the link to the supervisory authority and the EMA)
- Offer, on reasonable terms, transfer of the authorisation, or written consent, to a third party that has declared its intention to place the critical medicine on the market (or permit use of the dossier for the purpose of applying for authorisation), and
- Notify the supervisory authority of the outcome of the negotiations with stakeholders.

With regard to the **shortage prevention plan**, the MAH is to be required to prepare and update such a plan on an ongoing basis for each drug recognised by the country as a medicine of critical importance, a medicine that requires a shortage prevention plan according to the Commission, and any medicine included in the list of critical shortages of medicinal products of Union concern. The MAH should implement the plan within three months. The Pharma Package indicates the minimum information that the MAH should include in the plan.

A **shortage mitigation plan** due to the suspension or cessation of marketing of a medicine is to be presented at the request of the national authority. Meanwhile, **risk assessments** for potential threats to the supply chain should be carried out regularly and properly documented. The Pharma Package sets out the minimum requirements for these documents. The current version of the package provides for an obligation to cooperate with the competent authority and to disclose to the authority at its own initiative (and update) all relevant information.

Moreover, when a member state requests the supply of a medicine, and MAH is required to draw up a **marketing plan** for the medicine in that member state, it should include information in the plan on issues such as the supply of the medicinal product in a given period (and, at the request of the authority in the member state, update the distribution plan). If within four years of obtaining authorisation the MAH does not ensure the continuous delivery of the medicine in an EU country (in the quantities and presentations necessary to meet the needs of patients), the medicine will not enjoy market protection (or, where applicable, an extension of market exclusivity for an orphan medicine) in that EU country.

Perspective of other stakeholders

For other actors in the chain, the Pharma Package provides that suppliers and distributors of medicinal products can report a shortage of a medicine marketed in an EU country to the competent authorities of that country. Member states will be able to require distributors to report a shortage of supplied products.

The Council of the EU also proposes to give member states the power to require distributors to inform the supervisory authority of their intention to distribute a medicinal product to another member state. In such a situation, the distributor would have to notify the quantity of the drug that will be exported to the other EU country. The authority of the member state may also request additional information within a time limit set by the authority.

3.2 Changes to authorisation procedures

The Pharma Package is intended to improve access to new therapies in a crisis. The current wording maintains the earlier proposal to introduce a "temporary emergency marketing authorisation." However, the previously proposed time limits for considering applications for drug authorisation have been modified.

Consideration of an application for a drug authorisation

Currently, the process of assessing an application for marketing authorisation before the European Medicines Agency takes up to 210 days. The original wording of the Pharma Package proposed to shorten this to 180 days, but the Council of the EU proposed to abandon this change and leave the current period in place.

However, the originally proposed length of the accelerated procedure for evaluation of an application for registration of a medicine of high importance for public health and therapeutic innovation will not change. This process was supposed to last up to 150 days, and this is also the time limit in the current wording of the package. In addition, the time for the European Commission to issue a final decision is to be shortened to 46 days, in line with the original proposal.

The Council proposed to return to the existing time limit for processing applications for drug authorisations under national procedures. National authorities would have to take all appropriate measures to ensure that the

authorisation procedure is completed within a maximum of 210 days from submission of a valid application.

Temporary emergency marketing authorisation

The Pharma Package maintains the possibility of issuing a temporary emergency marketing authorisation. This is a special type of authorisation intended for situations of sudden threat to public health.

An authorisation may be granted by the Commission if the medicine is used to prevent, diagnose or treat a serious or life-threatening disease associated with a health crisis, provided there are no (sufficient) therapeutic alternatives and that the applicant obtains a favourable opinion from the EMA based on the available scientific data.

Although the drug may not have completed trials, this authorisation will be subject to additional conditions, such as the obligation to complete studies, or heightened oversight. It will be issued without undue delay, and the validity will be limited to the duration of the threat.

However, the Council proposed a change under which, as soon as sufficient data is collected, the MAH would be obliged to submit an application for drug authorisation in the usual way, to supersede the emergency authorisation.

4 Environmental concerns

The current version of the Pharma Package includes proposals for changes in the rules governing the environmental impact of medicines. The proposed expanded requirements for preparation of an environmental risk assessment, to be enclosed with the application for registration of a medicine, have been maintained. The detailed rules for these assessments in the case of medicines containing genetically modified organisms (GMOs) have been revised, however.

Environmental impact of pharmaceutical manufacturing

In recent years, initiatives toward the green transition of the European economy have increasingly come to the fore. The European Green Deal and environmental sustainability policies and strategies, in particular the Pharmaceutical Strategy for Europe of 25 November 2020 and the EU's Strategic Approach to Pharmaceuticals in the Environment, presented in 2019, are driving fundamental changes in pharmaceutical law. To prevent environmental degradation as a result of growth of the pharmaceutical sector, it was decided to strengthen the role of environmental risk assessments prepared by applicants for marketing authorisation for medicines.

The drafters define an environmental risk assessment (ERA) for a medicinal product as "the evaluation of the risks to the environment, or risks to public health, posed by the release of the medicinal product in the environment following the use and disposal of the medicinal product and the identification of risk prevention, limitation and mitigation measures. For antimicrobials, the ERA also encompasses an evaluation of the risk for antimicrobial resistance selection in the environment due to the manufacturing, use and disposal of that medicinal product."

The proposed new directive and new regulation would expand the obligations in preparing an ERA for medicines and the consequences of non-compliance.

Scope of the environmental risk assessment accompanying a drug application

An ERA report is to be enclosed with the application for marketing authorisation for a medicinal product. To counteract the negative impact of pharmaceutical substances on the environment, the existing ERA requirements

would be tightened—currently, only a limited assessment is required, and the findings are not grounds for refusing marketing authorisation.

Although the new directive has not yet been adopted, in September 2024 the European Medicines Agency drew up scientific guidelines for preparation of environmental risk assessments, in accordance with the draft new directive. As a rule, MAHs will be required to comply with them, and any possible derogations will have to be duly justified.

Mandatory elements of the ERA will include:

- **Identification of hazards by type of product**—an indication of whether the medicine or an ingredient/component is one of the substances listed in the new directive as having a particular impact on the environment
- **Emission mitigation measures**—a description of the measures to avoid or limit the risk of emissions of air, water and soil pollutants, together with a justification for the appropriateness of the proposed measures
- **Evaluation of the risk for antimicrobial resistance selection in the environment (for antimicrobials)**—the determination of the risk should take into account the entire supply chain, both inside and outside the EU.

If the ERA is not properly conducted, it will result in denial of marketing authorisation for the medicinal product. Refusal could be based on:

- Incompleteness of the ERA
- Insufficient substantiation of the ERA, or
- Failure to sufficiently address the environmental risk.

An exception provided for in the proposed new directive would apply when the applicant justifies the deficiencies and also demonstrates that:

- An environmental risk assessment may be carried out after the authorisation is issued, or
- The identified risk can be effectively mitigated.

An ERA would also be required for certain medicinal products authorised before 30 October 2005 (as well as certain generic medicines if the reference product was authorised before that date), when preparation of an ERA was not yet mandatory. But this requirement would apply only to medicines identified as potentially harmful to the environment. The rules for preparing an ERA for such products would be established in a special programme developed by the European Medicines Agency.

Further monitoring of environmental risks after obtaining authorisation

Authorisation for a medicine could also be issued conditionally, with an environmental reservation. This would be possible in two cases:

- When an additional post-authorisation ERA is necessary because identified or potential environmental or public health concerns, including antimicrobial resistance, require further investigation after the medicinal product has been placed on the market, or
- If the ERA carried out contains deficiencies, or the risks identified in it have not been sufficiently addressed.

The new directive would require the MAH to immediately notify the national authorities of new information from the revised ERA relevant to the environment that could change the conclusions of the earlier assessment.

Special environmental risk assessment for GMO medicines

Notwithstanding the revised ERA requirements in the proposed new Pharmaceutical Directive, and the unchanged, specific obligations under the GMO Directive (2001/18/EC), the proposed new Pharmaceutical Regulation includes specific rules for preparation of an ERA for medicinal products containing, or consisting of, genetically modified organisms (GMOs).

Under the proposed rules, an application for authorisation of a medicinal product containing GMOs would have to include an ERA indicating:

- A description of the GMOs and their modifications
- The characteristics of the finished product
- Identification and characterisation of hazards for the environment, animals, and human health
- Exposure characterisation, assessing the likelihood that the identified hazards would materialise
- A risk characterisation taking into account the magnitude of each possible hazard and the likelihood of that adverse effect occurring
- A proposed risk minimisation strategy to address the identified risks, including specific measures to limit the spread of the medicinal product in the environment not resulting from use (i.e. inherent human contact with the medicinal product)
- The overall risk assessment and conclusions.

The environmental risk assessment for a GMO medicine would also have to meet the general requirements set out in Annex II to the new Pharmaceutical Directive (essentially unchanged from the current Annex I to Directive 2001/83/EC) and Annex II to the GMO Directive.

Appendices

Appendix 1: Overview of the legislative process

4 JUNE 2025
the Council of the EU adopted its position on the Pharma Package

SUMMER–AUTUMN 2025
launch of trilogues—informal negotiations between the Council, the European Parliament and the Commission to agree on a joint legislative text

AUTUMN–WINTER 2025
completion of trilogues and formal adoption of legislation by the European Parliament and the Council (if an agreement is reached)

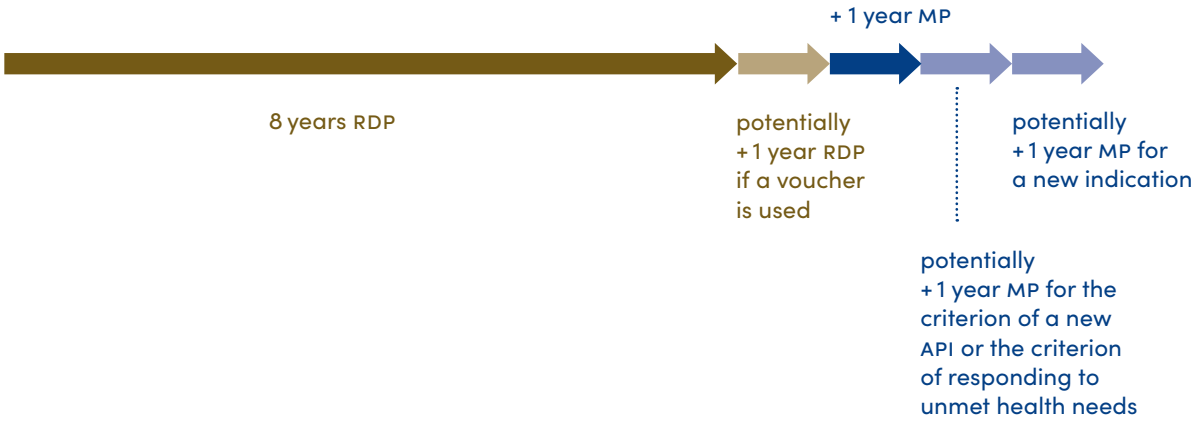
Publication in the Official Journal of the EU and entry into force of the rules after a transition period.

The new Pharmaceutical Regulation enters into force 20 days after publication, and is applicable starting about 36 months later.
The new Pharmaceutical Directive: the member states have 36 months to transpose the rules, applying them starting about 36 months after entry into force of the directive.

Appendix 2: Duration of general regulatory protection

Currently:

According to the current wording of the Pharma Package:



Abbreviations:

RDP—registration data protection, aka regulatory data protection

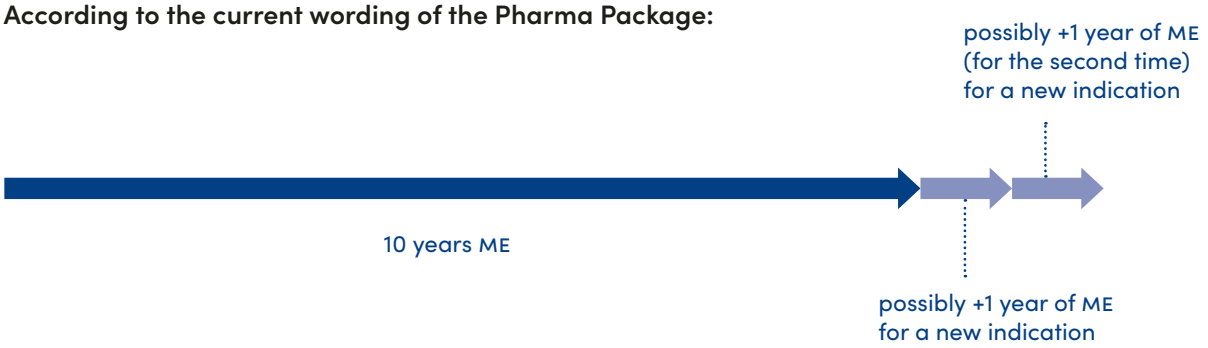
MP—market protection

API—active pharmaceutical ingredient

Appendix 3: Duration of market exclusivity for orphan drugs

Currently:

According to the current wording of the Pharma Package:



An orphan drug that benefits from an extension for fulfilling the criterion of a new indication cannot at the same time benefit from an additional period of market protection (see Appendix 2 diagram).

Abbreviations:

ME—market exclusivity

About the Life Sciences & Healthcare practice

We offer a full range of legal services for companies from regulated industries, in particular the sectors of pharmaceuticals, medical devices, biotechnology, food and dietary supplements. We advise healthcare companies and other clients whose business is impacted by special industry regulations.

We develop simple and practical solutions to complex and multifaceted regulatory challenges. We identify legal risks and propose solutions to minimise the risks, while enabling the client to achieve its business goals.

We take an interdisciplinary approach to our clients' affairs. Our team includes specialists in data protection, intellectual property, M&A, corporate law, tax, real estate, employment, administrative procedure and litigation.

We are active in industry organisations such as the European Food Law Association, the BioForum Association of Biotechnology Companies (part of EuropaBIO), the Polish Federation of Food Producers (PFPŻ), and the Healthcare and Life Sciences Law Committee of the International Bar Association. Thanks to our international contacts, we can also help clients find legal support in other jurisdictions.

Joanna Krakowiak
attorney-at-law, partner
joanna.krakowiak@wardynski.com.pl

Karolina Hryckowian
adwokat trainee
karolina.hryckowian@wardynski.com.pl

Natalia Nieróbca
associate
natalia.nierobca@wardynski.com.pl

Wardyński & Partners
Al. Ujazdowskie 10, 00-478 Warsaw
Tel.: +48 22 437 82 00, +48 22 537 82 00
Fax: +48 22 437 82 01, +48 22 537 82 01
E-mail: warsaw@wardynski.com.pl