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Pharmaceutical Package

The biggest reform in EU pharmaceutical law in 20 years

SEPTEMBER 2023

INNOVATION • ACCESS TO MEDICINE • ENVIRONMENTAL IMPACT

Contents

1 Introduction

On 26 April 2023, the European Commission officially announced plans for a major revision of EU pharmaceutical law, known as the Pharmaceutical Package. Draft amendments to EU legislation of key importance to the pharmaceutical sector have now been released.

The Pharmaceutical Package includes proposals for:

- A new Pharmaceutical Directive to supersede Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use
- A new Pharmaceutical Regulation to supersede Regulation 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

The new regulation is also to include updated provisions on orphan drugs (previously included in Regulation 141/2000). Provisions on paediatric medicines (previously included in Regulation 1901/2006) will be found in both the new regulation and the new directive. With this repositioning, Regulation 141/2000 and Regulation 1901/2006 are to be repealed.

For now, the Commission's proposal from April 2023 is only a draft of two new acts, not adopted law. The package is just starting its legislative journey (see diagram in Appendix 1), during which it may undergo changes.

The Commission submitted its proposal to the European Parliament on 26 April 2023 for a first reading. The Commission is now receiving comments on the proposal, which it will forward to the EP and the Council of the European Union (the comment period ends 8 November 2023).

Voting in the EP as part of the first reading is planned for April 2024. Then the EP's position will be forwarded to the Council for a first reading. If the Council does not accept the EP's position, the bill will return to the EP for a second reading.

The declared aims of the reform are:

- Creation of a single market for medicines
- Reducing administrative burdens so medicines can reach patients faster
- Better access to affordable medicines
- Addressing shortages of medicines and ensuring security of supply
- Fostering innovation and competitiveness
- Producing more environment-friendly medicines and reducing antimicrobial resistance
- Better communication on public funding of pharmaceutical research.

In our report, we present some of the significant changes that the package is to introduce to EU pharmaceutical law. We have focused on three categories which are also declared objectives of the new legislation: fostering innovation of medicines, increasing access to medicines, and concern for the environment.

2 Fostering innovation of medicines

2.1 Regulatory data protection (data exclusivity)

Modifying the duration of regulatory data protection for medicines is a key proposal in the Pharmaceutical Package and has received the most comment. The proposal provides for a reduction of the overall period of data exclusivity from eight years to six years. However, this general period may be extended if additional conditions are met.

The protection of registration data, in addition to patent protection, is a mechanism that has been known for many years to support and stimulate innovation in the pharmaceutical sector. The Pharmaceutical Package proposes a new compromise on how protection periods are calculated. This compromise is an attempt to reconcile a number of conflicting interests, in particular the interests of patients (who want faster access to cheaper treatment with generic products, as well as access to innovative medicines) and the interests of innovative pharma companies (which make significant financial outlays in research on new drugs in the hope of recouping their investment when the product is commercialised).

Data exclusivity and market protection

Regulatory data protection, also known as "data exclusivity," is the period when an applicant for marketing authorisation of a medicine may not 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 the period of "market protection." Market protection means that a generic medicine registered using a simplified procedure (i.e. based on someone else's original product) cannot be placed on the market during that period. Market protection lasts for 10 years, which is two years longer than data exclusivity. During the two years between expiry of data exclusivity and expiry of market protection, generic medicine may not be placed on the market, but may be subject to registration procedures aimed at placing the product on the market immediately after the market protection period ends.

Data exclusivity and market protection (collectively referred to as "regulatory protection") constitute a separate legal regime parallel to patent protection.

Modifying 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 (new indication).

Regulatory data protection (data exclusivity) lasts for eight years. After that, the marketing authorisation holder (MAH) for the original medicine can still count on two years of market protection, with the possibility of extending it by an additional year if a new indication is registered for which significant clinical benefit is expected compared with existing therapies.

The pharmaceutical package, on the other hand, introduces a rule that can be described as "6+x+2":
- Six years of regulatory data protection
- Plus a possible extension of the data exclusivity period (x)
- Plus two years of market protection.

The general period of data exclusivity would therefore be reduced from eight to six years, but this period could be extended if certain conditions are met (see diagram in Appendix 2):
- **An additional two years** for meeting the release and continuous supply criterion, where within **two years** of obtaining the authorisation (three years if the MAH is an SME, nonprofit, or entity holding fewer than five centrally registered medicines within its corporate group) for all markets of the member states where the authorisation is in force (in the case of central registration, in all 27 member states), the medicine has been released on the market and is continuously supplied in quantities and presentations to meet the needs of patients in these markets
- **An additional six months** for meeting the criterion of responding to unmet medical needs, i.e. that at least one indication of a medicine relates to a severely debilitating or life-threatening disease and there is no registered medicine for that disease in the EU (or there is a registered medicine for the disease but morbidity or mortality is still high), and the use of the medicine benefiting from the extension results in a significant reduction in morbidity or mortality

- **An additional six months** for meeting the new active substance criterion, which is that the medicine contains a new active substance and its clinical trials have been carried out using an appropriate comparator (i.e. an effective and commercially available comparator used in a clinical trial to compare with the investigational medicine), in accordance with the scientific advice provided by the European Medicines Agency
- **An additional one year** for meeting the criterion of a new indication, where the MAH obtains registration of a new indication and the data presented indicate a significant clinical benefit in comparison with existing therapies (this extension can be used only once)
- **An additional one year** for use of a "data exclusivity voucher," obtained for development of a new antibiotic ("priority antimicrobial drug" of a new category, with a new mechanism of action, containing a previously unregistered active substance that addresses a multi-drug resistant organism and serious or life threatening infection). Interestingly, the voucher is to be transferable, i.e. a company that obtains a voucher for its drug will not have to exercise the privilege of longer regulatory protection in relation to the drug for which it received the voucher, but will be able to shift it to another of its medicines or even transfer it to another company (for a fee or free of charge). The voucher would be available only for a centrally registered medicine and only during the first four years of its regulatory data protection period. The institution of the voucher is to be limited—it is to operate for no longer than 15 years or until a total of 10 vouchers are issued (whichever comes first).

Under the Pharmaceutical Package, the general period of regulatory data protection can therefore last from 6 to 10 years (or up to 11 years when using a voucher).

The Pharmaceutical Package also provides for a special case for granting a separate period of regulatory data protection of four years. This applies to drugs already on the market that are proved to be effective for a new indication (known as "repurposed medicinal products") as a result of new research. The four-year registration data protection period would be available to a medicine that:

- Has been registered as a generic product and has not yet benefited from data protection (or 25 years have passed since the first authorisation), and
- Will receive a new indication not yet registered in the EU, thus providing a significant clinical benefit, confirmed by studies.

2.2 Market exclusivity period for orphan drugs

The Pharmaceutical Package would also modify the duration of market exclusivity for orphan drugs. The overall period of market exclusivity is to be reduced from 10 years to 9 years, but it is possible to extend it to a maximum of 13 years. It is also planned to amend the rules on the scope of protection for the last two years of its duration. In addition, a separate five-year period of market exclusivity is proposed for well-established medicines.

Duration of protection

Currently, the standard market exclusivity period for orphan medicinal products (i.e. drugs for rare diseases) is 10 years from the date of authorisation. During this period, authorities are not allowed to register generic orphan drugs or accept applications for registration of generic orphan drugs. If at the end of the fifth year of market exclusivity for orphan drugs, it is determined that the criteria for 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, in a situation where the orphan drug also meets paediatric requirements. The aim is to obtain confirmation from the authority that the application for authorisation is consistent with an agreed paediatric investigation plan.

The Pharmaceutical Package plans to shorten the overall period of market exclusivity for orphan drugs from ten years to nine years. But it will be possible to extend this period if certain conditions are met (see diagram in Appendix 3):

- **By one year** for meeting the criterion of responding to "high unmet medical needs," i.e. that there is no registered drug for the disease in the EU (or a drug exists, but it is demonstrated that in addition to significant benefits, the orphan drug will also bring exceptional therapeutic advancement), and use of the orphan drug in question significantly reduces morbidity or mortality
- **By one year** (up to twice) for meeting the criterion of a new indication, i.e. that at least two years before expiry of the market exclusivity period for the orphan drug, the MAH obtains registration of a new indication for another orphan disease
- **An additional one year** for meeting the release and continuous supply criterion, meaning that within two years of obtaining authorisation (three years if the MAH is an SME, nonprofit organisation or entity holding fewer than five centrally registered medicines within its capital group) for the markets of all 27 EU member states, the medicine has been released on the market and is continuously supplied in quantities and presentations (SKUs) that meet the needs of patients in these markets.

Under the Pharmaceutical Package, the market exclusivity period of an orphan drug can therefore last from 9 to 13 years.

In addition, the Pharmaceutical Package provides for a separate new five-year period of market exclusivity for orphan drugs registered on the basis of bibliographic data. This is a case where there is no reference product with the active substance in question, but the active substance has a well-established medicinal use confirmed by the scientific literature, allowing 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 market exclusivity period, but it could not be extended under the criteria outlined above.

Scope of protection

In the context of market exclusivity of orphan drugs, a significant change is proposed concerning the scope of protection of the entity benefiting from the market exclusivity period.

Under current law it is not allowed for the authority to accept and consider an application for authorisation of a competitive (generic) drug for the entire market exclusivity period of orphan drugs. The proposal would only prohibit the issuance of an authorisation for a generic orphan drug during the market exclusivity period, but would allow for acceptance and consideration of an application for authorisation within the last two years before the end of the market exclusivity period.

This means that competing orphan products will be able to undergo the registration procedure during the market exclusivity period, so that authorisation and marketing of the drug can take place immediately after market exclusivity ends.

2.3 Advanced therapy medicinal products—hospital exemption

As part of the Pharmaceutical Package, there are changes in the regulation of advanced therapy medicinal products—hospital exemption. The planned changes are intended to clarify the rules of operation of this institution and to accumulate data on the use, safety and efficacy of these products.

Scope of changes

An "advanced therapy medicinal product" 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 a marketing authorisation. This is the hospital exemption. In principle, the definition of ATMPs (hospital exemption) would remain unchanged. It is intended to be an advanced therapy medicine prepared in a non-systematic manner in accordance with specific requirements and used in the same member state in a hospital, under the sole professional responsibility of a practising physician, to fill an individual prescription for a custom-made product for a specific patient.

However, the Pharmaceutical Package sets forth specific requirements 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, Polish regulations already provide for such approval by the Chief Pharmaceutical Inspector (GIF).

Under the proposal, the recipient of the approval for manufacture of an ATMP-hospital exemption would collect information on the use, safety and efficacy of the ATMP-hospital exemption and submit it at least once a year to the national authority (in Poland, probably GIF), which will then analyse the information in light of the detailed requirements. This information would 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 European Medicines Agency and the national authorities of other member states of the withdrawal of authorisation for safety or efficacy reasons.

Meanwhile, the Commission would adopt implementing acts specifying:

- Details of the application for authorisation of an ATMP-hospital exemption (including evidence on quality, safety and efficacy)
- The method of collecting and reporting information on the use, safety and efficacy of an ATMP-hospital exemption
- Rules for exchange of knowledge between recipients of approvals for ATMP-hospital exemption within one or more member states
- Conditions for non-systematic preparation and use of an ATMP-hospital exemption.

Under the Pharmaceutical Package, the EMA would prepare a report summarising the experience with the authorisation system for ATMP-hospital exemption, based on information obtained from member states. The first report would be due three years after entry into force of the new directive, with further reports to be published every five years.

3 Increasing access to medicines

3.1 Combating medicine shortages

One of the key objectives of the Pharmaceutical Package is to combat shortages of medicines. Among other measures, it is planned to create special monitoring lists at the EU level and to impose additional obligations on marketing authorisation holders.

The fight against drug shortages began in earnest during the COVID-19 pandemic. Indeed, Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices was adopted in January 2022. This regulation establishes a list of critical medicines in the event of a crisis. The Pharmaceutical Package includes further mechanisms to address shortages.

System-wide perspective

To combat shortages and unavailability of medicines, the Pharmaceutical Package proposes the introduction of:
- Union List of Critical Medicinal Products
- List of Critical Shortages.

The Union List of Critical Medicinal Products would include medicines which, if not available in sufficient supply, could threaten or cause serious harm to the health of patients.

When a medicine is added to the Union List of Critical Medicinal Products:
- Recommendations for appropriate security of supply measures could be developed at the EU level for marketing authorisation holders, member states, the European Commission or others, e.g. on supplier diversification or stock management
- Taking these recommendations into account, the Commission could implement appropriate countermeasures to improve security of supply, *inter alia* by introducing requirements for stockpiling of active ingredients or finished products by MAHs and wholesalers
- MAHs would be required to comply with these measures.

The List of Critical Shortages would include medicines whose supply is lower than the demand in a given member state, where there is a lack of alternative medicines, and addressing this problem requires coordinated action at the EU level.

When a medicine is added to the List of Critical Shortages:
- Recommendations for remedial measures to address or mitigate critical product shortages could be developed at the EU level for MAHs, member states, the Commission, healthcare professionals or other actors
- The Commission could take these recommendations into account and implement appropriate remedial measures
- MAHs would be required to comply with these measures.

Perspective of marketing authorisation holders

To address shortages of medicines, the Pharmaceutical Package would require MAHs to:
- Notify interruptions in supply
- Prepare a Shortage Prevention Plan
- Prepare a Shortage Mitigation Plan
- Prepare a risk assessment in relation to suspension or discontinuation of the marketing of a medicine.

As part of the disclosure obligations related to supply interruptions, the MAH would have to:
- Notify in advance of the decision to permanently cease the marketing of the drug, at least 12 months before the last delivery (Polish regulations currently require two months' notice)
- Notify in advance of the decision to permanently withdraw the marketing authorisation for the drug 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 (now two months in Poland)
- Report a temporary disruption (likely to last at least two weeks) in the supply of a medicine at least six months before the disruption (if it is forecast) or immediately after the MAH becomes aware that the disruption will occur (when for justified reasons it could not be foreseen at least six months in advance)
- Provide other information in response to requests from authorities related to the Union List of Critical Medicinal Products or the List of Critical Shortages.

A **shortage prevention plan** would have to be prepared (and updated on an ongoing basis) by the MAH for each medicinal product made available on the market. The annex to the proposed new regulation indicates that the shortage prevention plan would include product data, contact details, a risk assessment for the supply chain and, above all, measures to prevent product shortages.

A **shortage mitigation plan** and **risk assessment** in relation to suspension or discontinuation of marketing of a medicine would be prepared at the request of the national authority. The Pharmaceutical Package sets minimum requirements for these documents.

3.2 Changes in the market authorisation procedure

The Pharmaceutical Package is intended to improve access to new therapies in emergency situations, as well as speeding up the processing of applications for drug authorisations. The proposed rules provide for temporary emergency authorisation and shorter deadlines for processing authorisation applications.

Shorter processing times for drug authorisation applications

The Pharmaceutical Package would cut the time limits for processing an authorisation application under the centralised procedure. This will make the European market more accessible to marketers of new medicines. EU procedures are currently perceived as lengthy and burdensome, discouraging the introduction of new medicines to the EU market.

Currently, assessment of an application for marketing authorisation by the EMA takes 210 days. This is to be shortened to 180 days. But there will be no change to the length of the fast-track procedure (150 days, for registration of a medicine of great importance for public health and therapeutic innovation). In addition, the time for a final decision by the European Commission is to be reduced from 67 days to 46 days. The recitals in the proposal claim that this will not adversely affect the quality of the application review process.

The deadlines for obtaining marketing authorisation for a medicine are also to be shortened. According to the planned rules, national authorities would have to consider an application for drug authorisation within 180 days of submission of a complete dossier (currently 210 days).

Temporary emergency marketing authorisation

Drawing on the lessons learned in the COVID-19 pandemic, the Pharmaceutical Package proposes the implementation of "temporary emergency marketing authorisation." This is a new type of authorisation intended to respond to sudden threats to public health.

The Commission could authorise a medicine under this procedure if it is intended to diagnose, prevent or treat a serious or life-threatening disease directly related to a public health emergency. Additional conditions would also have to be met:

- The lack of an alternative treatment—or if an alternative exists, the new medicine would have to at least help avert a health crisis
- Obtaining a positive opinion from the EMA, based on existing scientific evidence.

Once these conditions are met, the medicine could receive temporary emergency marketing authorisation despite not having completed the usual studies. This type of authorisation itself would also be subject to additional conditions (e.g. heightened pharmacovigilance and a deadline for completion of studies).

A temporary emergency marketing authorisation would be granted without undue delay. As the name suggests, its validity would be limited in time. Such authorisation would automatically expire once the Commission finds that the health emergency has ceased. To gain market access after expiry, the MAH would have to submit a new application in the usual way.

4 Environmental concerns

The Pharmaceutical Package proposes amendments to the rules governing the environmental impact of medicines. The requirements for preparation of an environmental risk assessment, attached to the application for registration of a medicine, are to be extended. There are revised detailed rules for assessment of medicines containing genetically modified organisms (GMOs).

Environmental impact of pharmaceutical manufacturing

In recent years, measures aimed at the green transition of the European economy have come to the fore. Unfortunately, the growing pharmaceutical sector leaves a negative mark on the environment. Improper disposal of expired or unused medicines is a significant problem. As a result, pharmaceuticals are found in surface and groundwater, rapidly increasing the resistance to these agents.

Emerging environmental sustainability policies and strategies, such as the Pharmaceutical Strategy for Europe of 25 November 2020, and in particular the EU's Strategic Approach to Pharmaceuticals in the Environment presented by the Commission in 2019, have spurred efforts at fundamental changes to the existing pharmaceutical law. As "an ounce of prevention is worth a pound of cure," it was decided to strengthen the role of environmental risk assessments prepared for registration of medicines by MAHs.

The proposed directives defines an environmental risk assessment 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 from the use and disposal of the medicinal product and the identification of risk prevention, limitation and mitigation measures. For medicinal product with an antimicrobial mode of action, 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 environmental risk assessment for medicines and the consequences of non-compliance.

Scope of environmental risk assessment accompanying the authorisation application

The ERA report is to be enclosed with the application for marketing authorisation for the medicinal product. To counteract the negative impact of pharmaceutical substances on the environment, the existing ERA requirements would be tightened—they are currently carried out only to a limited extent.

Under the draft directive, the EMA will draw up scientific guidelines for preparation of environmental risk assessments. Marketing authorisation holders would in principle have to comply with these guidelines, and any possible deviations would have to be duly justified.

The ERA would have to include:

- **Identification of hazards by type of product**—indication of whether the medicine or an ingredient/component is one of the substances listed in the new directive with 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 risk should take into account the entire supply chain within and outside the Union.

An inadequate ERA could result in refusal of marketing authorisation. This could occur in the case of:

- An incomplete ERA
- Insufficient substantiation of the ERA
- Environmental risks not having been sufficiently addressed.

ERAs prepared within 18 months of entry into force of the new directive would generally not need to be updated, unless the authority requests the MAH to supplement the ERA to reflect the new requirements.

The requirement to carry out an ERA will not skip certain MAHs whose medicinal products were authorised before 30 October 2005, 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 laid down in a special programme developed by the European Medicines Agency.

Further monitoring of environmental risks after obtaining a permit

Authorisation for a medicine could also be granted conditionally with an environmental reservation, meaning that an additional post-authorisation ERA may be necessary where identified or potential environmental or public health concerns, including antimicrobial resistance, require further investigation after the medicinal product has been placed on the market.

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

Special environmental risk assessment for GMO medicines

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

Under the proposed rules, an application for authorisation for a medicinal product containing GMOs should include an ERA indicating:

- Description of the GMO and the modifications introduced as well as characterisation of the finished product
- Identification and characterisation of hazards for the environment, animals and for human health
- Risk characterisation taking into account the magnitude of each possible hazard and the likelihood or probability of that adverse effect occurring
- Exposure characterisation, assessing the likelihood or probability that the identified hazards materialise
- Risk minimisation strategies proposed to address identified risks including specific containment measures to limit contact with the medicinal product.

The environmental risk assessment for a GMO medicine should also comply with the general requirements set out in Annex II to the new directive (which remains unchanged from the current version of Annex I to Directive 2001/83/EC) and Annex II to the GMO Directive.

Appendices

Appendix 1: Legislative track

26 APRIL 2023
Presentation by the European Commission of proposed new Pharmaceutical Directive and Pharmaceutical Regulation

NOVEMBER 2023
Planned deadline for submitting comments on the proposal to the Commission

APRIL 2024
Planned vote on adoption or rejection of the Commission's proposal by the European Parliament

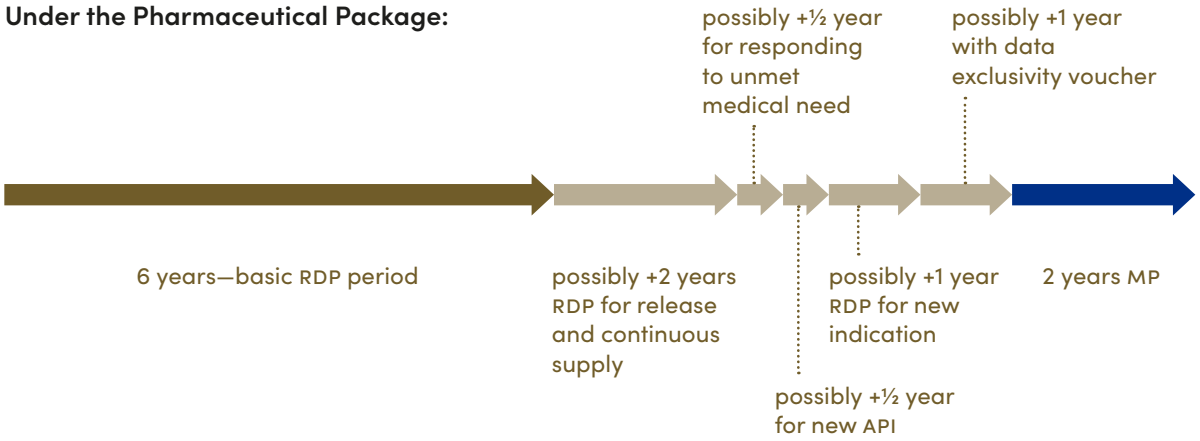
AFTER VOTING BY THE EUROPEAN PARLIAMENT
Bill forwarded to the Council of the European Union, which may ratify the EP bill or amend it and send it back to the EP for a second reading

POSSIBLE FURTHER TRACK
If amendments are not approved at the second reading, conciliation procedure may be held, followed by a third reading

Appendix 2: Length of general regulatory protection

Currently:

Under the Pharmaceutical Package:



Abbreviations:

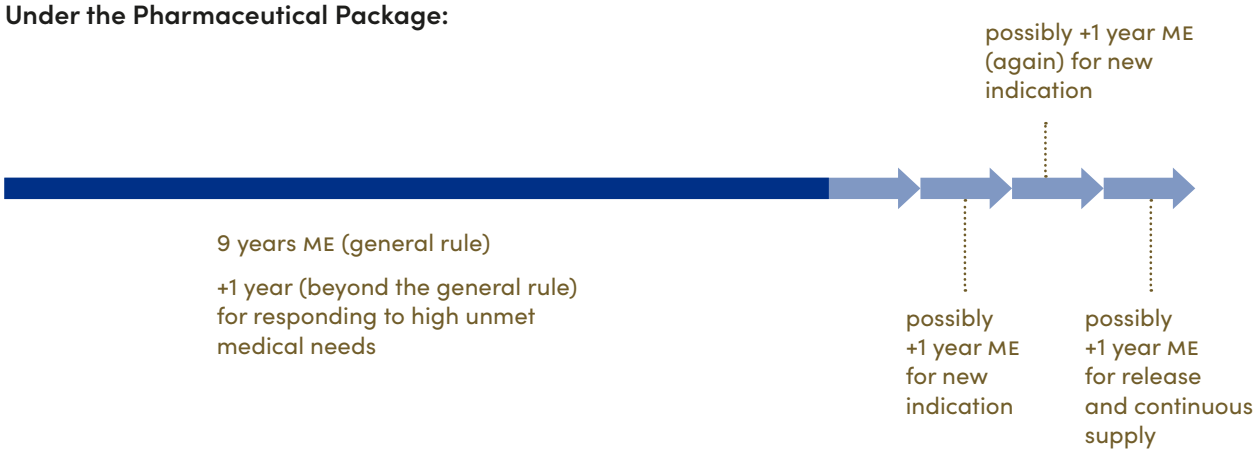
RDP – regulatory data protection (aka data exclusivity)
MP – market protection
API – active pharmaceutical ingredient

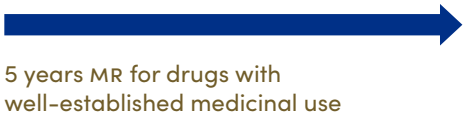
Diagram discussed in detail at p. 5.

Appendix 3: Length of market exclusivity for orphan medicines

Currently:

Under the Pharmaceutical Package:





Abbreviations

ME – market exclusivity period

Diagram discussed in detail in point 2.2.

About the Life Sciences & Healthcare practice

We offer a full range of legal services to companies from regulated industries, in particular pharmaceuticals, medical devices, biotechnology, foods and dietary supplements. We help healthcare entities and other entities that must take into account the specificity of the healthcare sector in their operations.

We develop simple, practical solutions to complex and multifaceted regulatory challenges. We identify legal risks and propose solutions to minimise them and at the same time enable the client to achieve its goals.

We take an interdisciplinary approach to our clients' cases, drawing on specialists in personal data, intellectual property, M&A, corporate law, tax, real estate, employment, administrative proceedings and dispute resolution.

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), as well as the Healthcare and Life Sciences Law Committee of the International Bar Association. Thanks to our international contacts, we can also help our clients meet their need for legal services outside of Poland.

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