Joint ESIP-MEDEV Position Paper

on

The Revision of the EU Pharmaceutical Legislation

European Social Insurance Platform (ESIP)
Medicine Evaluation Committee (MEDEV)

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About the European Social Insurance Platform (ESIP)

The European Social Insurance Platform (ESIP) represents 45 national statutory social insurance organisations in 17 EU Member States and Switzerland, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

About the Medicine Evaluation Committee (MEDEV)

The Medicine Evaluation Committee (MEDEV) was established in 1998 by representatives of the social health insurance organisations in Austria, Finland, Germany, Luxembourg, The Netherlands, and Switzerland to facilitate informed discussions and exchanges on pharmaceutical policy developments in the EU. MEDEV is a network of 22 national authorities from 18 Member States and Norway bringing together all the relevant institutions (national HTA agencies and social health insurers-payers) responsible for the assessment, pricing and reimbursement of medicines in Europe. The overarching mission of MEDEV is to further the sustainable provision of medicines to patients who are publicly insured. The European Social Insurance Platform (ESIP) in Brussels was commissioned with the role of coordinating the activities of the Committee.

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Executive Summary

High pharmaceutical prices coupled with low level of evidence on patient-relevant outcomes and solid comparative data affect national pricing & reimbursement decisions and consequently access to affordable treatment. ESIP and MEDEV welcome the revision of the EU pharmaceutical legislation insofar as it builds a pharmaceutical ecosystem that preserves the sustainability of healthcare systems, emphasises the corporate social responsibility of pharmaceutical companies, and prioritises societal needs.

This document presents a set of common recommendations from public bodies responsible for health technology assessment (HTA), pricing and reimbursement (P&R) and public health insurers, towards producing solid evidence across the product lifecycle and promoting affordable and sustainable access to treatment.

- **Strengthen evidentiary requirements across the product life cycle**: stronger sets of evidence are crucial for informed decision-making. Data requirements of different decision-makers across the product life cycle should be considered from the early stages. Solid evidence must be produced already at the time of marketing authorisation, aligning the EU pharmaceutical legislation with Regulation (EU) 2021/2282 on health technology assessment, strengthening the requirement to conduct randomised controlled trials (RCTs) with active comparators and clarifying the timelines for post-launch evidence generation as well as penalties for non-compliance. Accelerated and adapted pathways, such as phased reviews outside health crises and sandboxes, are viewed with concern as inherently linked to uncertainties.

- **Finetune the proposal to reduce regulatory data protection**: shorter periods of regulatory data protection (RDP) contribute to faster access to more affordable generic and biosimilar products. The proposal to reduce RDP is viewed positively, provided that the cumulative duration of RDP does not exceed eight years from the original marketing authorisation. Among the criteria for additional RDP, unmet medical need (UMN) and market launch in all Member States are to be supported, the latter linked to stronger conditions on supply continuity. Instead, no further incentives should be provided for conducting RCTs with active comparators, considered the gold standard.

- **Better define unmet medical and societal needs**: the proposed categorisation of UMN is supported, provided that the definitions of UMN, high unmet medical needs (HUMN) and criteria for orphan designation are made clear and consistent throughout the legislation. Permanent clinically relevant increase of quality of life could be considered as an additional parameter. The consultation process involving HTA and P&R bodies for establishing guidelines on UMN is strongly supported, as a way to steer research and incentives towards areas of real unmet medical and societal needs. While it is imperative to address antimicrobial resistance (AMR), transferrable exclusivity vouchers are rejected as highly unpredictable and costly. Alternative push and pull incentives mechanisms should be considered instead.

- **Ensure that the legal framework for orphan medicinal products (OMPs) prevents evergreening and focuses on ultra-rare diseases**: the pharmaceutical expenditure for orphan medicinal products is steadily increasing. In this context, it is vital to target incentives on truly and ultra-rare diseases, reducing the prevalence threshold, reintroducing regular re-evaluations of market exclusivity also based on return on investment and supporting provisions limiting evergreening and facilitating the market launch of generic and biosimilar products.

- **Promote competition for affordable access**: the reform of the EU pharmaceutical legislation has the potential to facilitate earlier market entry of generics and biosimilars, by expanding the exemption to the protection of intellectual property rights ('Bolar' exemption) to ensure day-one competition. This objective is strongly supported and should be maintained in the final legal text. Transparency of public funding for research and development purposes is also supported since this can be reflected in further P&R negotiations.

- **Promote an environmentally sustainable pharmaceutical ecosystem**: stricter provisions on environmental risk assessment of medicinal products are supported and should be complemented with requirements for responsible disposal, such as establishing an obligation to provide therapy-appropriate package sizes for all medicinal products and requiring comprehensive shelf-life documentation on the rational use of patient-specific preparations.

General remarks

*Building a pharmaceutical ecosystem that preserves the **sustainability** of healthcare systems, prioritises **societal needs** and emphasises the **corporate social responsibility** of pharmaceutical companies.*

On 26 April 2023 the European Commission published the reform of the European pharmaceutical legislation,[1] incorporating the revision of the general pharmaceutical legislation (Regulation 726/2004 and Directive 2001/83/EC), as well as of the legislation on medicines for children and rare diseases (Regulation 1901/2006 and Regulation 141/2000).

The European Social Insurance Platform (ESIP) and the Medicine Evaluation Committee (MEDEV) welcome the proposals for a new Directive and a new Regulation as a unique opportunity to reform the mechanism for authorising medicinal products in the European Union and to promote access across Member States.

Already in the Pharmaceutical Strategy for Europe[2], the European Commission highlighted the three flagship goals of **availability**, **access** and **affordability** of medicinal products. **ESIP and MEDEV underline that a balanced approach should be promoted between competitiveness and competition, incentives for innovation and affordable access to treatment, to ensure that medicinal products effectively reach patients and healthcare systems remain sustainable.** This approach should underpin all European initiatives – legislative and non-legislative – in the field of pharmaceuticals, medical devices and health technologies.

In recent years, subsequent health crises have put healthcare systems under strain. They also triggered a solidarity response laying the foundations for a European Health Union.[3] While the provision and administration of health services remains a national competence, a common EU response has allowed crisis-relevant medical countermeasures to reach patients in a timely manner. In these contexts, a certain level of uncertainty regarding the benefit-risk ratio of medical countermeasures e.g. COVID-19 vaccines was broadly accepted, as a result of accelerated approval pathways. Nevertheless, outside health emergencies, these uncertainties should be carefully managed, as the **sustainability** of health systems relies on the combination of strong evidence for informed decisions and affordable therapeutic options.

[1] Reform of the EU pharmaceutical legislation. 26-04-2023. https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en

[2] A pharmaceutical strategy for Europe. 25-11-2020. https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en

[3] European Health Union. European Commission webpage. https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en

Instead, new medicinal products are often brought to the markets with low levels of evidence[4] combined with high prices. **The EU Pharmaceutical Revision has the potential to correct this trend, strengthening the level of evidence at time of marketing authorisation and promoting early entry to markets of generic and biosimilar products.** The **corporate social responsibility** of pharmaceutical developers should be emphasised, through binding requirements in terms of evidence generation throughout the product lifecycle, in order to authorise products whose safety, efficacy and clinical effectiveness has been duly demonstrated.

Finally, demographic changes, the climate crisis and other societal factors put further pressure on already stretched healthcare budgets. A health-in-all-policies approach, fostering disease prevention and addressing the determinants of poor health, is crucial and should be combined with a careful assessment of the highest **societal and medical needs**. Within the revision of the EU pharmaceutical legislation, national authorities responsible for health technology assessment (HTA) and pricing and reimbursement (P&R) can and should play a crucial role in identifying true unmet needs, aiming to better target research and incentives.

This way the proposed reform will promote solidarity in terms of access to treatment and safeguard the welfare systems in Europe. ESIP, MEDEV and their Members are committed to contributing to this reform, building on the recommendations below, to create a pharmaceutical ecosystem that preserves the **sustainability** of healthcare systems, strengthens the **corporate social responsibility** of pharmaceutical companies, and prioritises **societal needs**.

[4] Evidence gaps for drugs and medical devices at market entry in Europe and potential solutions. KCE. 2021. https://kce.fgov.be/en/evidence-gaps-for-drugs-and-medical-devices-at-market-entry-in-europe-and-potential-solutions

Evidentiary requirements

Strong evidence for informed, timely decisions

The reform of the EU pharmaceutical legislation has the potential to strengthen the level of evidence required at time of marketing authorisation of new medicinal products. Randomised controlled trials (RCTs) are the most reliable studies to prove the (added) therapeutic value of new products and/or new indications. RCTs with an active comparator should remain the gold standard, hence turned into an obligation for pharmaceutical developers not subject to additional incentives such as extended regulatory data protection. However, ESIP & MEDEV recognise that conducting RCTs may not always be feasible, especially for products addressing an unmet medical need (UMN) and for which there is no therapeutic option available. A differentiated approach and additional incentives could be considered for RCTs conducted on products for the treatment of rare diseases, where it is more difficult to identify a relevant comparator. In any case, the developer should always be required to submit adequate scientific justification where it is not possible to conduct an RCT.

Substantial uncertainty is viewed with concern, also considering the relation with the expected health outcomes. In the absence of data proving the benefit of the product on the relevant health outcome with adequate certainty, the benefit-risk balance of the medicinal product cannot be considered favourable and the surrogate endpoint cannot be considered validated. Hence, any reference to unvalidated surrogate endpoints should be removed from the scope of this legislation.

Overall, aligning the EU pharmaceutical legislation with Regulation (EU) 2021/2282 on health technology assessment (HTAR) would be crucial to facilitate decision-making along the product life cycle, hence accelerating access to safe and effective treatments. For this reason, ESIP & MEDEV welcome and support provisions on the consultation of competent national authorities – including HTA and P&R authorities – on evidence generation. Competent national authorities should also be consulted on standards for the design of the necessary scientific studies, as a way to promote study comparability and facilitate HTA.

To complement the evidence submitted at the time of marketing authorisation, the regulatory authorities can request post-authorisation studies. Besides taking into account the evidence requirements of downstream decision-makers, timelines for the completion of these studies as well as penalties for non-compliance by the marketing authorisation holder (MAH) should be further defined in the legal text. This applies particularly to products subject to conditional marketing authorisation, under substantial uncertainties regarding the level of evidence at the time of marketing authorisation. Such penalties should include revocation of marketing authorisation, if the MAH fails to resolve existing uncertainties within the defined timeframe, unless duly substantiated with scientific reasons, or if the post-authorisation studies do not confirm that the benefit of immediate availability outweighs the risk inherent to the lack of evidence.

Finally, the COVID-19 pandemic provided a push to accelerate the assessment of necessary medical countermeasures. While bringing medical products to patients in the timeliest manner has been crucial during the health emergency, accelerated and adapted approval

pathways should by no means become the new status quo. Accelerated pathways such as phased reviews, where data packages are completed while assessment is ongoing, should remain limited to crisis contexts. In the absence of a thorough impact assessment, the concept of regulatory sandboxes is also rejected, as this tool could open yet another adapted pathway leading to marketing authorisation in the absence of solid evidence. Overall, lack of clarity on the products which would qualify for regulatory sandboxes, timelines for the evaluation and stakeholders involved in the context of a regulatory sandbox, are viewed with concern.

ESIP-MEDEV Recommendations

- Align the EU Pharmaceutical Package with Regulation (EU) 2021/2282 on Health Technology Assessment (EU HTAR) with a view to evidence-generation along product life cycle.
- Strengthen the requirement to conduct randomised controlled trials (RCT) with standard-of-care active comparators, as the gold standard for granting marketing authorisation (MA).
- Require marketing authorisation holders (MAHs) to provide adequate scientific justification, where they claim it is not feasible to conduct an RCT.
- Consider incentives for RCTs conducted on orphan medicinal products (OMPs).
- Define binding standards for uniformly designing the necessary scientific studies, in consultation with health technology assessment (HTA) bodies and pricing and reimbursement (P&R) authorities.
- Reject unvalidated surrogate endpoints, for which there is substantial uncertainty as to the relation to the expected health outcome.
- Define timelines and the scope for the completion of post-authorisation studies, in consultation with national competent authorities (NCA) as laid down in Article 162 of the proposal for a Regulation and introduce penalties for non-compliance.
- Define a 4-year timeframe for turning conditional marketing authorisation (CMA) into full MA as well as conditions for suspending/revoking CMA.
- Support the requirement in the proposal for a Directive to turn CMA into full MA within four years from the initial CMA, for granting additional regulatory data protection (RDP) periods for medicinal products targeting UMNs.
- Limit CMA and MA granted in exceptional circumstances to the centralised authorisation procedure, to reduce uncertainties at time of HTA and P&R.
- Limit rolling reviews to health emergency context.
- Reject sandboxes as they open yet another accelerated/adapted pathway leading to marketing authorisation in the absence of solid evidence.

Regulatory incentives

Finetune the staggered proposal on regulatory data protection

One of the flagship objectives of the proposed reform of the EU pharmaceutical legislation is to promote affordability. Within this legal act, it translates into provisions fostering market entry of generic and biosimilar products as early as possible. ESIP and MEDEV welcome the reduction of the baseline for regulatory data protection (RDP) times, while highlighting that regulatory protection is the last measure of protection to expire only for a minority of originator products.[5]

Clarity on the duration of regulatory protection times, patent and supplementary protection certificates (SPCs) expiries should be established via a dedicated database, accessible to public health authorities, IP competent authorities as well as generic and biosimilar competitors. Consideration should be given to clarify, within this database, whether the validity of existing patents has been challenged in Court.

Besides reducing the baseline for RDP, the European Commission proposed a staggered approach extending protection based on certain criteria. ESIP and MEDEV are concerned that, should all these conditions be met, RDP may exceed the current time limit of 8 years of data protection and 2 years of market protection and provide up to 13 years of overall regulatory protection. To avoid further extensions delaying generic and biosimilar competition, the cumulative duration of staggered RDP periods should not exceed eight years from the date of marketing authorisation.

With a view to the different criteria for granting additional RDP, ESIP and MEDEV support rewards for products which address UMN. Incentives for the market launch in all Member States are also viewed positively, provided that stronger conditions on supply continuity are attached to the correspondent extension of RDP. Instead, ESIP and MEDEV reject incentives for conducting RCTs with active comparators, considered as the gold standard for bringing safe and effective medicines to the markets, hence not eligible for additional rewards.

In terms of RDP extension for new uses of existing products outside the scope of the original marketing authorisation (repurposed products), a balance should be found between the legal text currently in effect – 1 year of additional RDP to be granted according to Article 10(5) of Directive 2001/83/EC – and the recent proposal for a Directive – extending RDP by 4 years. Rewarding these products with two additional years of RDP is considered a suitable compromise.

[5] Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe. Copenaghen Economics. 2018. https://copenhageneconomics.com/publication/study-on-the-economic-impact-of-supplementary-protection-certificates-pharmaceutical-incentives-and-rewards-in-europe/

ESIP-MEDEV Recommendations

- Support the reduction of the baseline for regulatory data protection (RDP) times (6 years).
- Cap the cumulative duration of staggered RDP to the current timeline (8 years).
- Strengthen obligations on supply continuity for products eligible for additional RDP periods following the market launch in all EU Member States and include penalties for non-compliance.
- Reject additional RDP periods for conducting RCTs with active comparators. RCTs with an active comparator should remain the gold standard, hence turned into an obligation for pharmaceutical developers not subject to additional incentives.
- Limit the duration of RDP for repurposed products to 2 instead of 4 years.
- Establish a publicly accessible database clarifying the duration of regulatory and patent protection times.

Unmet Medical Needs (UMNs)

The societal perspective

The European Commission proposal establishes criteria for the identification of UMNs and high unmet medical needs (HUMN), the latter in the field of rare diseases. ESIP and MEDEV welcome a differentiated approach to UMN based on well-identified criteria. In order to ensure legal consistency, the definitions should be clarified and aligned with the criteria for orphan designation. The conditions to define UMN – high morbidity and mortality, whether or not another therapeutic option exists – are to be supported and expanded to permanent clinically relevant increase of quality of life. Accordingly, a medicinal product shall be considered as addressing an UMN when it substantially reduces morbidity, mortality or severe adverse events for the relevant patient population.

The consultation process involving national HTA and P&R bodies for establishing guidelines on UMN is strongly supported. It is of utmost importance for national competent authorities (NCAs) to present their societal perspective, focused on patient needs and healthcare systems sustainability, in order to steer research and incentives towards areas of real unmet needs.

Regulatory incentives also include scientific advice provided by the European Medicines Agency (EMA) to pharmaceutical developers under the PRIME scheme. Regulatory and scientific support should be reflected in the application for marketing authorisation to the maximum possible extent. Where this is not possible, the reasons why marketing authorisation was nevertheless granted, especially in the absence of sufficient evidence, should be duly justified.

Antimicrobial resistance (AMR) poses a serious cross-border threat to public health and patient safety. In the absence of effective (novel) antibiotics, it generates an urgent UMN. It is therefore imperative to reduce the emergence and spread of AMR as well as to increase the development and availability of new effective antimicrobials inside and outside the EU. Nevertheless, the proposal for a transferable exclusivity voucher (TEV), extending regulatory protection for any chosen product as a reward for developing novel antimicrobials, is viewed with great concern. Studies have highlighted the limitations of such an unpredictable and costly instrument, presenting severe risks of overcompensation and jeopardizing the sustainability of EU healthcare systems.[6] Hence, the proposal for TEV as an incentive for the development of 'priority antimicrobials' is rejected altogether.

Several alternative mechanisms could be considered[7] within and outside the scope of this legislation, following guidance from the report by the European Health Emergency Preparedness and Response Authority (DG HERA) on bringing AMR medical countermeasures

[6] Antibiotic incentives in the revision of the EU pharmaceutical legislation. Joint EPHA and ReAct Europe position paper. July 2022. https://epha.org/wp-content/uploads/2022/07/antibiotic-incentives-pharma-legislation-joint-paper-2022.pdf

[7] ESIP Position Paper on Antimicrobial Resistance. 23-06-2020. https://esip.eu/publications-intranet?idf=302

to the market.[8] Consideration could be given to a push and pull incentive scheme to facilitate the development and procurement of novel and established antimicrobials, as proposed by the European Parliament in the resolution of 1 June 2023 on EU action to combat AMR.[9] Furthermore, consideration should be given also to a 'pay or play' funding scheme, establishing an antimicrobial investment charge unless the company demonstrates that investment has been made in research relevant to AMR.

ESIP-MEDEV Recommendations

- Clarify and ensure consistency among the definition of unmet medical needs (UMNs) and high unmet medical needs (HUMN); simultaneously, clarify the criteria for orphan designation.
- Where therapeutic option(s) are available, assess the reduction in diseases morbidity and mortality based on comparative evidence with standard of care.
- Include clinically relevant parameters on quality of life within the definition UMNs.
- Support consultation with NCAs as laid down in Article 162 of the proposal for a Regulation, regarding the adoption of scientific guidelines for UMN.
- Require adherence to the scientific advice provided in the form of regulatory incentives e.g. PRIME; where not possible, justify any deviation from the scientific advice offered under the PRIME scheme.
- Oppose transferrable exclusivity vouchers (TEV) as an incentive for the development of 'priority antimicrobials'.
- Consider alternatives push and pull incentive schemes, including an antibiotic investment charge, as a way to promote antimicrobial research, development and procurement.

[8] Study on bringing AMR medical countermeasures to the market – Final report. Publications Office of the European Union. 2023. https://data.europa.eu/doi/10.2925/442912

[9] European Parliament resolution on EU action to combat antimicrobial resistance (2023/2701(RSP). 1-06-2023. https://www.europarl.europa.eu/doceo/document/TA-9-2023-0220_EN.html

Orphan Medicinal Products (OMPs)

Focus on ultra-rare diseases and prevent evergreening

In 2020, the European Commission published a joint evaluation of the legislation on medicines for children and rare diseases.[10] It showed that the current regulatory framework has led to some levels of success, resulting in the increased availability of orphan medicinal products (OMPs). Nonetheless, challenges remain related to the development of effective treatments for rare diseases, where research primarily targets areas of higher commercial interest, and a vast number of rare diseases remain UMNs.

In parallel, expected low financial returns are mitigated by artificially high prices that challenge healthcare system's financial sustainability. The Council Conclusions of June 2016[11] on strengthening the balance in the EU pharmaceutical systems took note of market failures where patient access was endangered by unsustainable prices. In parallel, Member States took a stance against the misuse of incentives and rewards of the OMP regulatory framework leading to inappropriate market behaviour.

Within the reform of the EU pharmaceutical legislation, ESIP and MEDEV call to revise the legislative framework so that incentives target truly rare or ultra-rare diseases, a criterion that just over 50% of all OMPs licensed between 2000 and 2017 have fulfilled. A prevalence of 5:10,000 patients, as maintained in the European Commission proposals, equates 5,000 patients in a population of 10 million, i.e. about 220,000 patients in the entire Union. With increasing prices for OMPs, this population size seems sufficiently large to be an attractive target for a conventional marketing authorisation and could hence allow for an adequate return on investment by the developer.

ESIP and MEDEV also urge to maintain the criterion of return on investment to define whether or not a product remains eligible for orphan status. The profitability aspect from the orphan designation criteria should be reintroduced in the context of regular re-evaluations of market exclusivity, including an assessment of the volume of sales and whether it has exceeded a predefined threshold. This would reflect the initial aim of the OMP Regulation, namely to incentivise the development in disease areas where the cost of development would not be recovered by the expected sales of the medicinal product.[12] [13]

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[10] 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. European Commission Staff Working Document. 11.08.2021.
https://health.ec.europa.eu/system/files/2020-08/orphan-regulation_eval_swd_2020-163_part-1_0.pdf.

[11] Council conclusions on strengthening the balance in the pharmaceutical systems in the European Union and its Member States (2016/C 269/06)
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XG0723(03)&from=EN

[12] ESIP Position Paper on the review of Regulation (EC) 141/2000 on orphan medicinal procuts. 30.05.2019.
https://esip.eu/publications-intranet?idf=222

[13] ESIP-MEDEV position on the revision of the EU legislation on orphan medicinal products. 12.12.2022.
https://esip.eu/new/details/2/124-Rebalancing%20incentives%20for%20truly%20rare%20diseases%20

On a positive note, ESIP and MEDEV acknowledge and welcome provisions within the proposal for a new Regulation aimed at preventing inappropriate market behaviours on the one hand and facilitating market entry of generics and biosimilars on the other. We support in particular the intention to prevent evergreening practices, limiting the possibility to extend market exclusivity for new orphan indications only twice and by 12 months, and preventing separate market exclusivity periods for orphan marketing authorisation for the same active substance. Similarly, we support provisions allowing generics and biosimilars to receive marketing authorisation when similar products are still covered by market exclusivity.

ESIP-MEDEV Recommendations

- Lower the prevalence criterion for orphan designation for single indications (from 5:10,000 to 1:10,000).
- Reintroduce the profitability criterion for the re-evaluation of market exclusivity (ME) by setting a threshold for the volume of sales (to 1 billion EUR per year) for all combined indications.
- Reintroduce and strengthen criteria for regular reviews of ME, combining profitability, prevalence and proof of a clinically meaningful benefit.
- Anticipate the review of ME criteria at the end of the second year, followed by the termination of ME if the criteria above are no longer met.
- Support provisions preventing evergreening practices and facilitating orphan generics and biosimilars market entry.

Affordability

Promote and strengthen competition

The Pharmaceutical Strategy for Europe identified affordability as one of the European Commission's flagship targets to promote patient access to treatment across the EU. In a context of subsequent demographic, health, economic and climate crises, it is of utmost importance to preserve the sustainability of healthcare systems, by containing pharmaceutical costs, discouraging abusive business strategies and ensuring that truly safe and effective treatments reach patients.

The reform of the EU pharmaceutical legislation has the potential to support this target, by fostering competition of generic and biosimilar products, as well as transparency of public funding received for research and development purposes, to be reflected and considered in further pricing strategies and negotiations.

ESIP and MEDEV strongly support an expansion of the exemption to the protection of intellectual property rights ('Bolar exemption') to ensure day one competition of generic and biosimilar products. The timely entry of these products into the Union market would increase competition, reduce prices, ensure that national healthcare systems remain sustainable and improve patient access to affordable medicines. Nevertheless, further clarification is needed in the legal text, to ensure that the Bolar exemption allows generic and biosimilar developers to obtain marketing authorisation, conduct health technology assessment and request pricing and reimbursement before the relevant patent or supplementary protection certificate (SPC) expires. Only this way, the Bolar exemption would allow the placing on the market of generic and biosimilar products right after expiration of the patent and SPC protection of the said reference medicinal product.

ESIP-MEDEV Recommendations

- Support and clarify the expansion in scope of the 'Bolar exemption' for the purpose of promoting day-one competition of generic and biosimilar medicinal products.
- Support the obligation to disclose public funding received for research and development (R&D) purposes, to increase transparency of real costs, hence supporting further pricing and reimbursement negotiations.

Environmental risk assessment

Promote an environmentally sustainable pharmaceutical ecosystem

The proposal to reform the EU pharmaceutical legislation established stricter environmental risk assessment (ERA) for medicinal products. Such provisions are welcome, as the risk-benefit balance should not only focus on the quality, safety and efficacy of the medicinal product, but should also consider and prevent undesirable effects on the environment.

ESIP and MEDEV strongly support efforts to promote more environmentally sustainable pharmaceutical ecosystems. Accordingly, the obligation to provide therapy-appropriate package sizes is welcomed and should apply not only to antimicrobial medicinal products, but to all medicinal products. Ensuring appropriate package sizes is first and foremost a measure to avoid pharmaceutical and packaging waste. Currently, package sizes sometimes prove to be inadequate, as early-onset side effects can lead to treatment discontinuation, switches or dose reductions.

Furthermore, clear obligations and timelines should be established for providing comprehensive shelf-life documentation on the rational use of patient-specific preparations, as a way to maximise shelf-life and prevent or minimise waste.

Since supply of therapy-appropriate package sizes and comprehensive shelf-life documentation respond to environmental policy concerns, their enforcement should be supported by implementing sanctions for non-compliance.

ESIP-MEDEV Recommendations

- Support stricter environmental risk assessment of medicinal products.
- Expand the obligation to use therapy-appropriate package sizes for all medicinal products, and consider sanctions for non-compliance.
- Require comprehensive shelf-life documentation on the rational use of patient-specific preparations, and consider sanctions for non-compliance.