

PHARMA DEUTSCHLAND POSITION PAPER ON THE EU PHARMACEUTICAL LEGISLATION

TRILOGUE AGREEMENT

- Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use - COM/2023/192
- Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency - COM/2023/193

date: 09. September 2025

About us

Pharma Deutschland e.V. represents the interests of the pharmaceutical and medical device industry at both federal and state levels to politics, authorities, and institutions in the healthcare sector. With around 400 member companies, it is the pharmaceutical industry association with the largest number of members in Germany. The political advocacy and member support extend to the area of prescription and non-prescription medicines as well as medical devices, including medical apps and digital health applications.

Introduction

The legislative package to revise EU pharmaceutical legislation aims to foster innovation and streamline regulatory processes. However, key elements under discussion in the current trilogue fall short of delivering on these goals. For the pharmaceutical industry – especially small and medium-sized enterprises (SMEs) – planning reliability is essential for long-term investments in research, development, and manufacturing.

As it stands, certain aspects of the Parliament and Council positions still require improvement to create a stable and predictable framework. Instead of reducing uncertainty, the current proposals risk introducing further complexity – both in terms of regulatory requirements and economic sustainability.

Importantly, well-functioning regulatory mechanisms should be preserved. The European Commission has rightly proposed not to modify certain areas such as advertising, homeopathy, and falsified medicines. These frameworks – along with others like the requirements for fixed-dose combinations, well-established use and regulatory data protection – have proven their practical value and should not be changed without a compelling justification. Why alter what already works well? Unnecessary revisions risk destabilizing established systems that offer legal clarity and operational efficiency for both authorities and the pharmaceutical industry.

Against the backdrop of persistent medicine shortages, what is needed now is a clear commitment to strengthening European production capacity and securing resilient supply chains. Yet companies are being confronted with additional reporting obligations, increasingly complex procedures, and new bureaucratic burdens – all of which disproportionately affect SMEs and undermine their competitiveness.

Push for more digital transformation! Moreover, digitalization must be fully leveraged to future-proof EU pharmaceutical legislation. For example, a smart introduction of electronic package leaflets (ePIL) presents a clear opportunity to reduce administrative burden, improve access to up-to-date product information, and support sustainability goals while increasing flexibility of distribution of goods between different EU-markets. A future-oriented framework should create the flexibility to implement such digital solutions across the EU in a harmonized manner.

Pharma Deutschland therefore calls on trilogue negotiators to ensure:

- Reliable regulatory frameworks that support long-term investment
- A meaningful reduction in administrative burden
- A coherent European strategy for supply security that acknowledges the economic realities of the industry,
- And forward-looking legislation that embraces digitalization and strengthens Europe's position as an attractive hub for pharmaceutical innovation and manufacturing.

Only a balanced and industry-conscious approach can make the pharmaceutical package a true driver of innovation, support EU being competitive with other regions – and ensure the safe and reliable supply of medicines for patients across Europe.



10 Key Recommendations

1. Regulatory Data Protection / Market Exclusivity D. 81-85

Position: Support Council's position as the most pragmatic basis, maintaining the eight-year baseline while introducing transparent and predictable modulation of market protection. Elements of the Parliament's proposal may complement this, but any further erosion of RDP would weaken Europe's competitiveness and innovation capacity. The European Commission's proposal to reduce regulatory data protection (RDP) to a six-year baseline is unacceptable, as it undermines investment security and disregards the realities of pharmaceutical R&D.

2. Shortages and Supply Resilience R. 116-127, 130-134

Position: Limit Shortage Prevention Plans (SPPs) to critical medicines only. Reject overly long (6-month) notification periods; keep 3 months with flexibility. Support standardized, electronic reporting and proportional transparency tools while avoiding double notifications. Caution against mandatory data sharing that breaches commercial confidentiality.

3. Antimicrobials Accessibility D. 17, 51

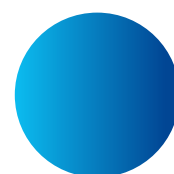
Position: Remove blanket prescription requirement for all antimicrobials and limit it to antibiotics for systemic use (with proven AMR risk). There's no evidence that non-prescription antifungals or antivirals contribute to AMR and doing so would overburden health systems.

4. Environmental Risk Assessment (ERA) D. 22, 23, 24, 47, 51 R. 15, 16, 104

Position: Support ERA and appreciate introduction of commitments and post-approval measures (e.g. for data from environmental studies) as suggested by Council, i.e. considering the same requirements as for other parts of the dossier. ERA should not block authorisations unnecessarily; PBT/PMT hazard criteria must not trigger automatic restrictions.

5. Well-Established Use D. 13

Position: Support position enabling use of bibliographic data and allow exemption for herbal medicinal products and for those products for which bioequivalence studies cannot be conducted.



6. Labelling and Electronic Package Information Leaflet (ePIL) D. 63, 69, 71, Ann VI.2a

Position: Support having paper and digital format as a basis but make sure the long-term goal is digital and define a transition. Favor the adoption of implementing acts to foster a harmonised implementation of the electronic leaflet. Support the adoption of a delegated act to make the electronic leaflet mandatory and to define a date when to switch to digital only to take all advantages of ePILs. Oppose the introduction of a separate document or card or a global antimicrobial resistance symbol. Oppose the introduction of a key information section on the leaflet as proposed by the EU Parliament. Ensure there is a common understanding of what a „high-quality translation“ is to avoid individual interpretation leading to additional uncertainty in planning of product launches.

7. Advertising D. 176-179, 186

Position: The European Commission deliberately excluded advertising provisions from its Impact Assessment and therefore did not evaluate potential consequences. Call for the advertising ban to comparative advertising, which was introduced by the European Commission and essentially followed by both Parliament and Council, to be deleted. Furthermore, reject the Parliament’s proposal to introduce mandatory prior advertising checks.

8. Out-of-scope provisions D. Recital 4, 125-131, 137 (1), 140 (2,3), 216

Position: Maintain established terminology and regulatory alignment within EU law, retaining effective provisions and avoiding legal uncertainty—such as unnecessary changes to homeopathy—to protect product quality, patient safety, and the accuracy of information.

9. Approval Procedures „Opt In“ D. 34, 36, 43

Position: Preserve companies’ right to determine its own business decisions. If a product is needed on an additional market, ensure there is alignment between applicant and national competent authority and respective processes in place to do so.

10. Fixed-dose combinations D. 15

Position: Keep well-established processes to introduce products which increase compliance with patients. While additional rules have been introduced to address the need of combinations to be more flexible, „classical“ fixed-dose combinations have become forgotten and respective rules are no longer included in the proposed directive. This should be changed.



Explanation

1. Regulatory Data Protection / Market Exclusivity Directive - Articles 81-85

Regulatory data protection (RDP) is a cornerstone of Europe's pharmaceutical framework, ensuring that companies are rewarded for the significant costs and risks associated with developing innovative medicines. Weakening this system would directly harm Europe's attractiveness as a location for pharmaceutical research, development, and production.

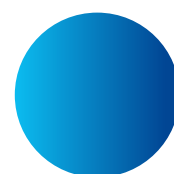
The European Commission's proposal to reduce the baseline RDP period to six years (Article 81(1)) the control of companies, such as the ability to launch a product simultaneously in all Member States (Article 81(2)(a)). Such criteria introduce unpredictability and penalize especially small and mid-sized enterprises that cannot maintain full market presence across the EU. For investors and innovators, this lack of legal certainty threatens Europe's long-term competitiveness in the global pharmaceutical landscape.

The Parliament's position provides some constructive elements, including the decoupling of access conditionality from incentives and the introduction of new research-related rewards. However, the latter should only be seen as an additional RDP option and not exchanged for another reward. However, the reduction of protection compared to the current regime risks undermining Europe's innovation capacity.

In contrast, the Council's position offers the most viable compromise. By maintaining the current eight-year baseline for data exclusivity and introducing a clear, limited modulation of market protection (Article 82 1(+1)(+1) system), it preserves planning security while allowing targeted incentives for additional innovation. This approach is transparent, predictable, and therefore the most solid foundation for a trilogue compromise.

In summary, the European Commission's proposal is not acceptable. The Council's approach is the most viable compromise, with complementary elements from the Parliament. Europe needs an RDP system that ensures predictability, stimulates innovation, and secures both industrial competitiveness and patient access in the long term.

In addition, PD supports the Council's proposal to involve the competent national authorities by requiring them to publish on their websites a list of medicinal products for which they have granted a national marketing authorisation and which remain under regulatory protection, as well as to provide hyperlinks to the relevant websites (Article 85(5a)). The amended provisions on the Bolar exemption (Article 85.), which ensure that the concerns of generic and biosimilar manufacturers are adequately considered without leading to patent infringements, are also particularly welcome and fully supported.



2. Shortages and Security of Supply Regulation – Articles 116-127, 130-134

Pharma Deutschland welcomes the Council's approach that limits shortage prevention plans (SPPs) to critical medicines only (Articles 117, 126). For instance, most non-prescription medicines have easily substitutable alternatives and should be excluded from such burdensome obligations. We further support the requirement introduced by the Council proposal on Article 119(3a) for marketing authorisation holders of non-critical medicines to carry out a regular documented risk assessment of potential supply chain risks and, where necessary, take mitigating measures. However, it should be ensured that this obligation does not generate a comparable amount of bureaucratic effort as the creation of a Shortage Prevention Plan.

The proposal for 6-month advance notice of disruptions (Article 116) is excessive and impractical, as marketing authorisation holders will tend to over-notify even for self-resolved shortages while regulatory authorities will be unnecessarily overburdened. A 3-month period, as the Council envisages, is more realistic. Pharma Deutschland supports the development of common electronic reporting templates and harmonised data formats.

Regulation Articles 120 and 138 introduce requirements for supply data sharing. Pharma Deutschland urges that any such provisions protect commercial confidentiality and avoid real-time reporting that adds complexity without improving shortage prevention.

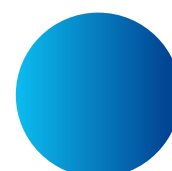
We also support a proportional approach to transparency on shortages via national and EU-level platforms, as outlined in Articles 121 and 122. It must be ensured that duplicate notifications are avoided or, if necessary, are only required for as short a transitional period as possible.

3. Ensuring access to self-care antimicrobials Directive – Articles 17, 51

Pharma Deutschland strongly opposes the blanket classification of all "antimicrobials" as prescription-only medicines in Article 51.1.(e).

This measure is unjustified, as there is no scientific evidence that non-prescription antifungals and antivirals used for self-limited conditions, and of local action, contribute meaningfully to antimicrobial resistance (e.g. athletes' foot, labial herpes, dandruff, sore throat and vaginal thrush). Still using a precautionary window, we propose limiting the scope of this article to antibiotics or any other antimicrobial for which there is an identified risk of antimicrobial resistance.

Pharma Deutschland would like to emphasize that, for non-prescription medicines, the pack size is already aligned with the recommended duration of use and daily dosage, based on



the specific indication of a product. It is impracticable to follow the Parliament proposal in Article 17.3. to fraction the medicines package, which would only be physically possible for tablets and pills but not for syrups, powders, creams, etc. Unit-dispensing incurs extraordinary professional and material resources including duplication of the materials necessary for patient safety (e.g., packaging material, patient information).

4. Environmental Risk Assessment (ERA) Directive – Articles 22, 23, 24, 47, 51 Regulation – Articles 15, 16, 104

Pharma Deutschland supports proportionate ERA requirements but urges caution against disproportionate proposals. In general, ERA must not extend to manufacturing-related environmental risks, which are already addressed under existing EU environmental legislation (e.g., Water Framework Directive).

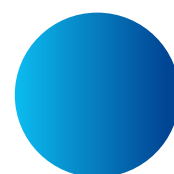
Dir. Article 22(2) introduces PBT/PMT hazard-based criteria, but such classifications should not automatically trigger prescription requirements (e.g., Dir. Article 51(1)(f)). Pharma Deutschland advocates alternative risk mitigation measures that appear to be more effective and proportionate in limiting environmental impacts than a prescription requirement!

Similarly, in the Regulation, Articles 15 and 16 (Reg.) must avoid leading to marketing authorisation refusals based on incomplete ERA submissions if post-authorisation measures can be applied. The Council's position rightly allows for such flexibility, which is essential to avoid unnecessary market access barriers.

Article 22(5) rightly assigns the European Medicines Agency (EMA) the task of developing scientific guidelines on environmental risk assessment (ERA) for medicinal products, in consultation with specialised EU agencies such as ECHA, EFSA and EEA. The Parliament's proposal to further involve environmental authorities and stakeholders such as drinking water and wastewater operators should be rejected. Such involvement risks creating conflicts of interest, as decisions on the authorisation and safe use of medicines must remain primarily guided by the protection of public health, while environmental considerations are already addressed through the established expert agencies.

In relation to Article 23, PD supports the Council's clarification, which will lead to a better interpretation of the Directive and a level playing field for market access. We also support an inclusion of Article 13 in the list, as it concerns well-established products with known active substances. Transparency measures like the ERA study register (Regulation Article 104(a)) should be limited to scientifically validated data. ERA obligations should not disproportionately delay product approvals or impose excessive administrative burdens.

5. Well-Established Use and Data Requirements; Directive – Article 13



Pharma Deutschland endorses the Council's practical and pragmatic approach which acknowledges that limited or no availability of reference products can significantly hinder the demonstration of equivalence. We are also supportive to emphasize that bridging between literature data and the newly developed product is necessary.

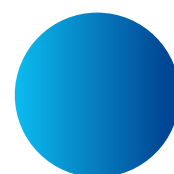
However, these two changes do not take into account that there are still products for which bioequivalence studies can practically not be conducted. This includes e.g. herbal medicinal products or endogenous substances whose levels are regulated by homeostatic mechanisms. In order to put national competent authorities in a position to allow for this legal basis for registration on a case-by-case basis, it is essential that there is in principle a mandate for this. Excluding products for which bioequivalence studies can practically not be conducted could result in a reduction of important medicines, highly valued and needed by patients. Because of this, our suggestion would be to rephrase the Council's proposal as follows:

*„In cases where, **at the time of submission of the Marketing authorisation application, no reference medicinal product is or has been authorised or if a reference medicinal product has been authorised but is not available on the market within the Union for the active substance of the medicinal product concerned or in case bioequivalence studies can not be conducted or in case of a herbal medicinal product**, the applicant shall, by way of derogation from Article 6(2), not be required to provide the results of non-clinical tests or clinical studies if the applicant can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Union for the same therapeutic use and route of administration and for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex II.“*

6. Labelling and Electronic Package Leaflets Directive – Article 63, 69, 71 + Annex VI.2a

Pharma Deutschland welcomes the Council's balanced position, maintaining the availability of both paper and electronic formats depending on national decisions. Harmonisation should preserve accessibility for all patient groups while enabling digital innovation. However, it should be kept in mind that individual countries' decisions may lead to disharmonised requirements and thus make it more difficult to re-distribute products between countries in case of shortage situations. Therefore, we suggest maintaining the possibility for the European Commission to decide when to transfer to electronic package leaflets only, as proposed by the European Commission.

Pharma Deutschland does not support the introduction of a “global antimicrobial resistance symbol” nor the creation of a separate document or card. Such measures do not provide added value for patients, as they are already comprehensively informed about the correct



use of antimicrobials by their prescribing physicians. Moreover, additional symbols, cards or documents risk adding complexity and potential confusion without improving patient safety or adherence.

Pharma Deutschland opposes the European Parliament's position on adding a Key Information Section (KIS), as this could result in patients reading only the KIS instead of all the important information in the leaflet. It is important to bear in mind: what is considered essential information varies according to the patient's condition and personal circumstances.

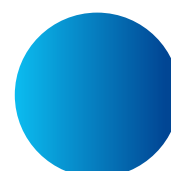
To our understanding, having the package leaflet available as an electronic version with structured content is much more effective than further lengthening a document, which is already considered being very long. In addition, only an ePIL is able to adapt to individual patients' needs when it comes to content, format and contrast of displaying.

We strongly advise ensuring there is a common understanding and definition of „high-quality translations“. Otherwise, there is too much room for individual interpretation across countries which will further impact reliable planning to put a product on the market and thus hinder the goal of better access to new medicines.

7. Advertising Directive - Articles 176, 186

Pharma Deutschland strongly opposes the restriction of comparative advertising to content contained solely in the Summary of Product Characteristics (SmPC), as proposed by the European Commission and – in slightly adapted form – taken up by both the Parliament and the Council (Article 176 (4)). The EU Commission itself excluded advertising provisions from its Impact Assessment, meaning that the consequences of this measure were never evaluated. In practice, the SmPC does not capture all relevant scientific evidence, and such a limitation would disproportionately restrict legitimate advertising opportunities. Consumer protection remains fully safeguarded, as any comparative statements must continue to be accurate, verifiable and evidence-based (Article 176 (4).)

Pharma Deutschland furthermore rejects the Parliament's proposal to introduce mandatory prior advertising checks (Article 186 (1)). We support the approach of the EU Commission and the Council, which continue to provide for prior checks only as an option for Member States. This flexible system ensures high standards in advertising without imposing disproportionate administrative burdens on companies and national authorities. This corresponds to the current legal situation. Given that no amendment to the advertising regulations was planned and there is therefore no need for change, the current legal situation should remain unchanged, as is also the view of the EU Commission and the Council.



8. Out-of-scope provisions Directive – Recital 4 + Articles 125-131, 137 (1), 140 (2,3)216

The European Commission deliberately refrained from proposing any changes to the well-functioning and balanced framework for homeopathic medicinal products (HOMPs). The Council has endorsed this position. However, the European Parliament proposed changes to the current provisions. If introduced without a prior impact assessment, these changes risk undermining the core objective of safeguarding public health.

HOMPs are currently regulated under a robust legal framework that ensures access to safe high-quality products that are subject to strict labelling and advertising rules. These provisions uphold key EU principles of consumer protection and healthcare diversity. In addition, Europe is a global leader in homeopathic pharmaceutical expertise. Changes to current regulations would threaten industry integrity, regional jobs, and EU manufacturers' competitiveness. There are approx. 160 manufacturing sites for homeopathic medicinal products across 15 EU Member States.

Maintaining the term “Homeopathic medicinal product” ensures legal clarity and helps healthcare professionals and consumers distinguish between regulated and unregulated products. In addition, this change would affect packaging labelling of approx. 20,000 product licenses and create major administrative and financial efforts – both for companies and for competent authorities.

Any proposal for change should be considered in terms of its added value and potential to improve outcomes. A comprehensive review appears disproportionate in relation to the administrative and financial investment it would require with limited or no benefit to public safety, regulatory efficiency, or legal clarity.

Extensive publicly available data from the EU Member States show no evidence that suggests regulatory failure or significant safety concerns that would justify a legislative overhaul.

Similarly, also traditional herbal medicine products (THMPs) are –according to the European Commission’s proposal– out of scope. The current legislative provisions safeguard also here public safety, regulatory efficiency and legal clarity. Especially, requirements on labelling for THMPs are the same as for any other European medicines. Labelling already includes contraindications and interactions with other medications which are assessed and approved by the competent authorities. Any additional requirements will pose competitive disadvantage to herbal medicinal products compared to other (synthetic) OTC medicines with the same indications. Therefore, proposals on additional labelling for herbals as proposed in Article 140 (2,3) by the European Parliament should be rejected.



In conclusion, Pharma Deutschland fully supports the positions of the European Commission and the Council, which preserve a stable and proportionate regulatory framework for homeopathic and traditional herbal medicinal products. By contrast, we firmly reject the Parliament's proposed amendments, which lack an impact assessment, create unnecessary administrative and financial burdens, and risk undermining both patient safety and the competitiveness of the European pharmaceutical sector.

9. Approval procedure – ‚Opt-in‘; Directive – Article 34, 36, 43

Pharma Deutschland welcomes the clarification introduced in the Council's proposal for a Directive in Articles 34, 36 and 43. Still, it is important to align companies' strategies with the request of a national competent authority for the country to be included in a registration procedure in line with Articles 34 and 36. We acknowledge the need for patient needs for new and affordable medicines to be addressed, however, such decisions need to be aligned with the future marketing authorisation holder. For this reason, we suggest to amend the Council's proposal as follows:

*„If necessary to meet the needs of patients in that Member State, ~~the competent authority of a Member State may request for justified public health reasons to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure of its request within 30 days from the date of submission of the application.~~ **Following alignment with the applicant, the applicant shall provide the competent authority of those Member States entering the procedure with the application without undue delay...**“*

Pharma Deutschland also supports the deletion of Article 43 (4) in the Council's Proposal as it is important that any update to the marketing authorisation – especially the summary of product characteristics (SmPC) – must involve timely consultation with the marketing authorisation holder (MAH), preserving the principle of co-responsibility and ensuring scientific accuracy.

10. Fixed-dose combinations: Keep established regulatory pathways which increase patient compliance; Directive – Article 15

Pharma Deutschland appreciates the European Commission proposal to introduce marketing authorisations for medicinal products comprised of a fixed component and a variable component that is pre-defined. We support the Council's position to allow for this not only in exceptional circumstances but when justified by clinical purposes. However, we noted that the classical definition of a „fixed-dose combination“ comprised of two fixed components and the respective possibility to include a reference to the individual API's efficacy and safety documentation apparently got lost. While the annex still refers to these



types of products, we strongly suggest to re-include the definition of Article 10 b) of directive 2001/83/EC:

„In the case of medicinal products containing active substances used in the composition of authorised medicinal products but not hitherto used in combination for therapeutic purposes, the results of new pre-clinical tests or new clinical trials relating to that combination shall be provided in accordance with Article 8(3)(i), but it shall not be necessary to provide scientific references relating to each individual active substance.“

