Association of Pharmaceutical Manufacturers in Estonia

Summary of Estonia's positions on EU pharmaceutical reform

1. Estonia supports the adaptation of data protection periods based on public health needs, the purpose of which is to support ensuring equal availability of medicinal products in the European Union and directing innovation to areas of unmet medical need. At the same time, we believe that, in order to ensure uniform implementation and greater legal clarity, the draft directive should set out the conditions under which the requirement of a continuous and sufficient supply of a medicinal product on the national market is deemed to be met. We propose an additional data protection period of more than 6 months (e.g. 1 year) to stimulate the conduct of clinical trials with reference medicinal products. We consider it important that information on the duration of data protection periods is public and easily accessible.
2. Estonia supports the simplification of placing generic and biosimilar medicinal products on the market, including the reduction of the administrative burden related to marketing authorisation procedures and the possibility to submit an application for a marketing authorisation for a generic medicine for rare diseases two years before the end of the marketing protection period. We also consider it important to introduce changes that will help improve the affordability of medicinal products, such as extending the possibilities for using data during the patent protection of the original medicinal products and increasing the transparency of the costs associated with developing a medicinal product.
3. We will support the changes related to the market entry of medicinal products used to treat rare conditions, including adapting the exclusivity periods for medicinal products used to treat rare conditions to public health needs and extending the exclusivity period for medicinal products used to treat rare conditions with particularly high unmet medical needs. We consider it important that criteria specific to the disease can be taken into account when granting the status of a medicinal product used to treat a rare condition and we support giving the Commission the mandate to do so.
4. We consider that the extension of the obligation to submit a paediatric investigation plan on the basis of molecular mechanism of action and more flexible conditions for the submission of a paediatric investigation plan are justified, as this will help to improve the availability of medicinal products for paediatric use. We are proposing to make the obligation to market medicinal products for paediatric use more flexible to allow for exemptions where there is no demand for a particular medicinal product, pharmaceutical form or strength of active substance.
5. We consider it important to lay down the obligations of the parties to the supply chain with the aim of ensuring uninterrupted supply of medicinal products. The division of rights and obligations between marketing authorisation holders and wholesalers in ensuring the marketing of medicinal products should be stipulated in greater detail. We support the additional possibilities for exemptions from labelling requirements provided for in the draft, where this is necessary to ensure the availability of medicinal products and in health emergencies. In addition, we propose to introduce an EU procedure for the concept and approval of a universal packaging in English, which would make it easier for medicinal products used to treat rare conditions to be placed on the market in smaller countries.
6. We support the strengthening of a coordinated monitoring and shortage management system to prevent and mitigate supply shortages, including the establishment of an EU list of critical medicinal products and the obligation for marketing authorisation holders to develop shortage prevention and mitigation plans. We consider it important that the draft introduces an obligation for marketing authorisation holders to notify of supply disruptions, temporary or permanent suspension of the marketing of a medicinal product and withdrawal of a marketing authorisation earlier than before.

7. We support increasing the efficiency of processing applications for marketing authorisation of medicinal products, including shortening the processing time for marketing authorisations and the possibility to terminate the procedure in the absence of sufficient quality data. We consider it important that it is possible to suspend the proceedings for obtaining additional information if necessary. We support the optimisation of the structure and scientific committees of the European Medicines Agency, with a view to reducing the administrative burden, and we consider it important to maintain equal representation of experts from all Member States in the scientific committees with decision-making rights. We support the possibility for Member States to join decentralised and mutual recognition marketing authorisation procedures if they so wish, in the cases where the manufacturer has included the country in the proceedings itself.
8. We support increasing regulatory flexibility for the development of innovative medicinal products, including the creation of regulatory test environments and harmonisation of the use of hospital exemption. We believe it is important that scientific advice is provided at the earliest possible stage in the development of medicinal products, in close cooperation with the health technology assessment bodies. We support the wider use of safety and efficacy data from the use of medicinal products and health care services and consider it important to continue working together at EU level to develop common standards and methodologies.
9. We will support the wider uptake of digital technologies, both in conducting the procedures related medicinal products and in the submission of the compulsory documentation accompanying medicinal products. The European Union as a whole should move towards an electronic package leaflet fasten than the 5-year deadline foreseen in the draft, e.g. 2 years after the implementation of the Directive, the Commission should consider making an electronic package leaflet mandatory across the European Union.
10. We support measures to prevent antimicrobial resistance, including a clearer definition of the prescription obligations for antimicrobial medicinal products and the introduction of information materials for healthcare professionals and patients. Estonia could only support a system of resaleable vouchers as a support measure for the development of new antimicrobials if resale rights are limited and the risks related to unforeseen costs that emergence upon the reimbursement of medicinal products are mitigated. Alternatively, we give out support to the support measures directly targeting developers of innovative antimicrobials (e.g. research and development grants, market entry fees, turnover guarantees, pre-purchase agreements) and consider it important to coordinate support measures at EU level.
11. We support stricter requirements for environmental risk assessments, but do not consider it reasonable to refuse, withdraw or suspend marketing authorisations on the grounds of environmental risk. Information on environmental risks should be part of the risk-benefit assessment of a medicinal product.
12. In ensuring the quality and safety of medicinal products, we believe it is important to strengthen inspectorates and to participate in joint inspections, although adequate resources must be provided to implement this at both EU and national level. We support allowing the decentralised manufacture of medicinal products that are patient-specific and have a short shelf-life. We believe it is necessary to clarify the wording of the draft to the effect that medicinal products serially prepared in pharmacies do not fall within the scope of the Directive.