December 2024

**INDUSTRY PROPOSAL TO IMPROVE PATIENT ACCESS**

## Background concerns

Europe is lagging behind other regions of the world, with only one-fifth of innovative medicines being discovered here. To prevent further erosion of Europe's competitiveness, we need at the very least the maintenance of the existing baseline of eight years of RDP.

Industry shares the objective to improve access to medicines for European patients. Respectfully, the Commission's proposal will not achieve this. The widely divergent setup of national health systems and priorities means that it is not feasible for any company to release and continuously supply their products into the supply chain in a sufficient quantity and in the presentations necessary to cover local patient needs or to obtain positive pricing and reimbursement decisions in accordance with Articles 2 and 6 of Council Directive 89/105/EEC within two years from receiving marketing authorisation, including for many reasons beyond the marketing authorization holder's sole control.

The Hungarian Presidency's October 2024 proposed patchwork quilt of various incentives capped at eight years (some of which appear to infringe fundamental WTO principles), introduces significant additional complexity and legal uncertainty that will lead to litigation and delays. In addition, the proposal to make market protection (and, where available, orphan market exclusivity) incentives dependent on marketing authorization holders releasing and continuously supplying their products within four years of marketing authorisation does not serve the broader policy objectives of improved European competitiveness and improved patient access to innovative medicines, and gravely undermines the internal market.

Specifically, the proposed power of Member States to declare a loss of two years of market protection at national level for failure to continuously supply is highly discretionary and would distort competition in the internal market by allowing generic or biosimilar competitor products to launch earlier in some Member States than in others. This is contrary to the legal basis of the proposal, Article 114 TFEU (the instrument to harmonise conditions and improve the functioning of the EU internal market), to the general EU law principle of legal certainty, and to Article 16 of the Charter of Fundamental Rights which protects the freedom to conduct a business. Furthermore, in relation to generic/biosimilar applications that are made centrally to the EMA, there can be only one period of regulatory data protection for the whole of the EU which means that not only is the legality of the proposal highly questionable, it is also unworkable in practice.

Improved competitiveness and patient access requires at the very least:

1. the maintenance of the existing baseline of eight years of RDP without further conditionality, and
2. the safeguarding of the integrity of the internal market and compliance with international law.

## A constructive workable proposal

Patient access challenges are multiple and complex, varying widely across markets and products; they simply cannot be resolved in any single EU legislative act. Any proposal that fails to account for the multifactorial root causes for delay, the specific regulated access processes applying to vaccines versus medicines, the emergence of new and advanced technologies targeting very small patient groups, and the shared responsibility of different stakeholders in the access ecosystem, will never be a workable or adequate solution.

These complex issues require a tailored response in line with fundamental EU law principles of subsidiarity and proportionality, recognising that all stakeholders must play their role within the limits of their responsibilities. National pricing and reimbursement procedures are the exclusive competence of Member

States and, in general, already encompass assessments of estimated patient needs and the modalities to meet those needs. Once a medicinal product is placed on the market in a Member State (including following pricing/reimbursement approval), the marketing authorization holder is required, within the limits of its responsibility, to ensure appropriate and continued supplies of that product to meet local patients' needs (in accordance with Article 56(3) of the revised Directive, Article 81(2) of Directive 2001/83, and obligations under national laws and regulations).

Notwithstanding the above considerations, if there is consensus among Member States that it is appropriate for EU legislation to address access to medicines, it is necessary to consider:

- a range of alternative solutions to ensure effective access in due time to treatments that patients need, and
- which solution may be most appropriate in the circumstances.

For example, alternatives may be pursuant to a wide variety of early access schemes, or in response to a tender, or importation of packs from another EU Member State in relation to very low volume medicines conditional on authorities being flexible in relation to labelling and language requirements, or as a result of agreements between Member States to allow for cross-border patient referrals to attend specialist clinics.

Some of these alternatives may be more achievable and proportionate than others in certain markets and/or for certain products. This is why it is also indispensable to define these alternative approaches within the limits of the marketing authorisation holder's responsibility and to provide for possible exemptions for specific kinds of products which, for objective reasons, are not suited to any standardised approach.

Where, despite the best efforts of the marketing authorisation holder and the competent Member State authorities, a medicinal product is not available so as to meet the actual needs of patients in the territory four years after marketing authorisation approval, we propose a mechanism whereby the Member State concerned at its discretion can request the marketing authorisation holder to enter into a structured dialogue.

The aim of the structured dialogue is for both sides to seek to (i) better understand the reasons for the product unavailability, and (ii) where needed, identify alternative solutions to ensure effective access to treatments that patients need in due time that may be reflected in an access plan to be drawn up by the marketing authorisation holder. [1]

The proposed approach avoids the introduction of duplicative legislative duties to supply and avoids penalising companies for aspects in the external ecosystem that they do not control.

In line with the Parliament's text, this proposal is a constructive effort to improve access to medicines while respecting the exclusive competence of Member States in healthcare spending and without creating undue internal market distortions.

[1] It is important to recognise that any access plan is an expression of good intent based on reasonable expectations but that there are many reasons why any such plan may be subject to variations beyond the control of the marketing authorisation holder (for example, because prolonged negotiations beyond the time limits set out in the Transparency Directive 89/105/EEC may mean a later roll out than originally planned, or due to changes in expected indication, local access conditions, disease screening and diagnoses).

## Legislative proposal

**New Article 56a – Measures to improve access**

1. Upon a request to provide access to a medicinal product by a Member State in which the marketing authorisation is valid, the marketing authorisation holder shall seek to make the medicinal product available to meet the needs of the patients in that Member State within the limits of its responsibilities in accordance with applicable local laws and regulations.

2. For the purposes of paragraph (1), Member States shall make the request within one year of the granting of the marketing authorisation whereupon the marketing authorisation holder shall, within the limits of its responsibility pursuant to applicable local laws and regulations, submit an application for pricing and reimbursement for the medicinal product no later than 18 months from the date when the Member State made its request, or within 24 months from that date for any small and medium-sized enterprise within the meaning of Commission Recommendation 2003/361/EC, unless otherwise agreed between a Member State and the marketing authorization holder. The marketing authorisation holder and the Member State shall at all times act in good faith and in compliance with Directive 89/105/EEC.

3. A marketing authorisation holder shall be deemed to have discharged its obligations under paragraphs (1) and (2) of this Article where:

   (i) it has submitted an application for pricing and reimbursement approval for the medicinal product where such approval is available,

   (ii) where the marketing authorisation holder or its authorised representative has otherwise, within the limits of its responsibility, made the medicinal product available, or agreed with the Member State to make the medicinal product available, to meet the actual needs of patients in the territory in accordance with applicable local laws and regulations.

4. If, for any reason, the medicinal product has not been made available to meet the actual needs of the patients in the territory four years after the marketing authorization is granted, a Member State may request the marketing authorisation holder to engage in a structured dialogue. During the structured dialogue the Member State and the marketing authorization holder shall jointly seek:

   (i) to clarify the reasons for the unavailability of the medicinal product, and

   (ii) to identify the most appropriate and proportionate alternative access solution or solutions in the circumstances that, upon the Member State's request, shall be reflected in an access plan to be drawn up by the marketing authorisation holder.

   The structured dialogue shall be conducted in good faith within a period of six months following the Member State's request unless agreed otherwise between the parties. The process shall be clearly defined at the outset in the context of each Member State's institutional and legal framework, ensuring that due protection is afforded to the confidentiality of commercially sensitive information.

5. The obligations set out in paragraphs (1) and (2) of this Article and the process set out in paragraph (4) shall not apply to products that are to be made available in Member States under or pursuant to national immunisation programmes, or to advanced therapeutic medicinal products (ATMPS) and orphan medicinal products that have unique characteristics requiring the application of particular market access solutions.

6. The Commission shall adopt a delegated act in consultation with relevant stakeholders, including marketing authorisation holders, that extends the exemption at paragraph (5) of this Article to additional specified products or types of products based on objective and transparent criteria related to the nature of the products and/or their route to market and that provides for regular review and revision in response to the emergence of new technologies and treatments, and any relevant changes in the medicines access ecosystem.

**New article 56b - EU Access to Medicines Notification System**

1. The Commission shall set up and maintain an electronic notification system for the notification of compliance with the obligations set out in Article 56a (the 'EU Access to Medicines Notification System'). The EU Access to Medicines Notification System shall be interoperable with other relevant Union-wide data repositories for medicinal products.
2. The national competent authority of the Member States where the marketing authorization is valid shall use the EU Access to Medicines Notification System to notify their request submitted in accordance with paragraph (2) of Article 56a. The marketing authorisation holder shall use the EU Access to Medicines Notification System to notify their compliance with the obligation set out in Article 56a paragraphs (1) and (2) or their satisfaction with the criteria under Article 56a paragraph (3) (i) or (ii). In the Member States where the marketing authorisation is valid, the national competent authority shall use the EU Access to Medicines Notification System to indicate that the marketing authorisation holder has fulfilled its obligations set out in Article 56a paragraphs (1) and (2) or satisfies the criteria under Article 56a paragraph (3)(i) or (ii).
3. Before the effective use of the EU Access to Medicines Notification System, the Commission shall adopt an implementing act to establish technical and organisational requirements on its use and functioning, including on aspects ensuring data security and confidentiality of trade secrets, in accordance with the examination procedure referred to in Article 214(2).
4. Anonymised data from the EU Access to Medicines Notification System that has been aggregated at Member State level may be made public for the purpose of reporting on access in Article 86a.