

EU Pharmaceutical Reform: Access to medicines in all Member States

February 2024

Context:

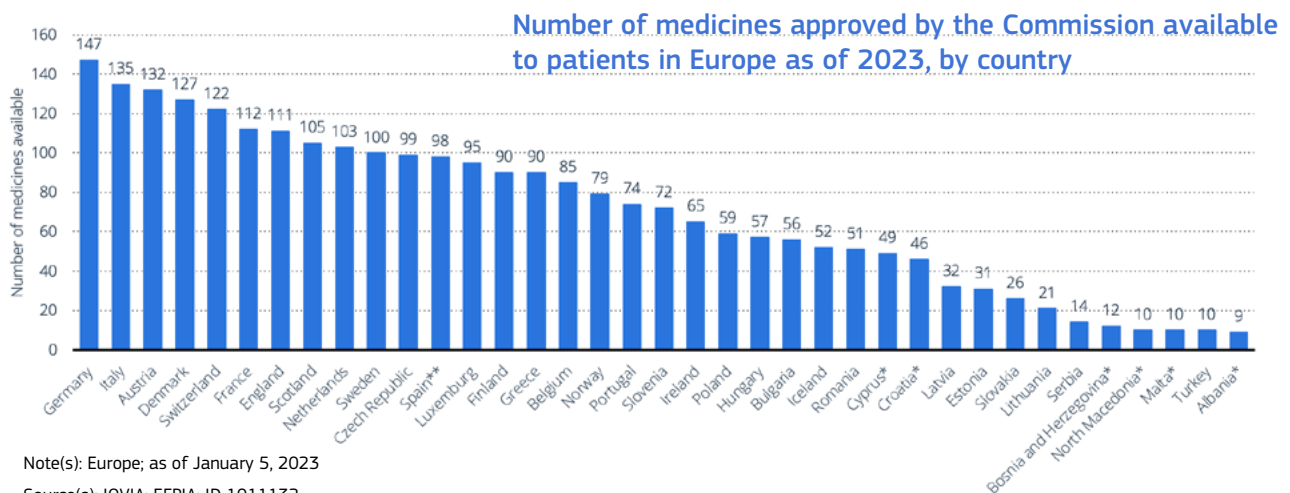
When a company receives an EU-wide Marketing Authorisation for a medicine, it can market the medicine in all EU Member States. Currently, companies are not obliged to market a medicine in all EU Member States and may decide not to market it in certain countries. After authorisation, and before a new medicine is made available to patients in a particular EU country, most medicines are subject to a Health Technology Assessment and national decisions about pricing and reimbursement or their inclusion in the national health assessments insurance scheme.

Challenges:

Medicines are currently made available to patients at different times in different Member States. In some cases, they are never marketed in some Member States, resulting in unequal patient access.

Between 2016 and 2019, out of 152 centrally authorised medicines, up to 88% were accessible to patients in bigger Member States. Patients in small or low GDP Member States had access to fewer than 32% and had to wait significantly longer to access medicines.

Since 2016, the Council and the European Parliament have repeatedly called for action to improve patient access to medicines and to ensure health system sustainability.



What changes:

The EU's pharmaceutical reform aims to ensure **access to medicines for all patients in the EU**. Companies that provide access to their medicines in all Member States where their marketing authorisation is valid will be rewarded with two extra years of data protection.

Benefits of the proposal:

- ✓ Achieves more equitable and earlier access to medicines for an additional 67 million patients in the EU (+15% increase compared to today).
- ✓ Moves from a one-size-fits-all system of incentives to a targeted approach where companies will receive +2 year of regulatory data protection, if they make the medicine available in all Member States within a certain period of time after authorisation.
- ✓ Creates a long-term, positive culture between industry and public actors to engage in earlier negotiations on supply and ensure the common objective of improving patient access to new therapies.
- ✓ It does not interfere with national pricing and reimbursement decisions as it enables the Member State to buy the medicine if and when it chooses.
- ✓ It is pragmatic: The different options available to a Member State allow it to permit the incentive and continue the pricing negotiation process smoothly and at their own pace.
- ✓ Patients stand to gain in any case:
 - If the incentive is granted, more patients will get access to the new medicine
 - If the incentive is not granted, patients will receive faster access to generics and biosimilars
- ✓ Predictability for companies (both on-patent and off patent competitors) is ensured: Companies will know whether the incentive is granted or not within the first 3 to 4 years from authorisation.

How will patients receive actual supply?

Step 1

Companies and Member States engage in good faith

- The company will reach out to Member States to gauge interest in the medicine. A Member State might not need the medicine due to lack of patients or infrastructure, or sufficient alternative therapies.
- Member States that need the medicine negotiate with the company under national rules. The medicine may undergo a Health Technology Assessment followed by the conclusion of a pricing and reimbursement agreement.
- The aim is to achieve actual supply in all EU Member States within 2 years of the Marketing Authorisation. Smaller companies will have 3 years.
- While negotiations are ongoing, a Member State can decide that actual supply can be achieved through alternative means or at a later time. The Member State and the company would achieve an agreement to this effect.

Step 2

Validation by Member States

When prompted by a company, EU Member States must certify within 60 days whether they have received actual supply of a medicine. The company's request for a prolongation of data protection must contain one of the following:

- A confirmation of supply.
- A waiver – there is not yet supply of the product in the Member State, but the Member State does not object to providing an extension of data protection.
- In case of no reaction from the Member State, a tacit waiver is triggered.
- A positive pricing and reimbursement decision under the Transparency Directive is considered equivalent to a confirmation.

Step 3

Granting prolongation of the medicine's data protection

Once a validation from all EU Member States or a waiver is secured, the company can apply for a variation of its marketing authorisation. The national competent authority/European Commission will then prolong the data protection of the relevant product by **2 years**.

