The EU Pharmaceutical Legislation Reform: What's in for Patients

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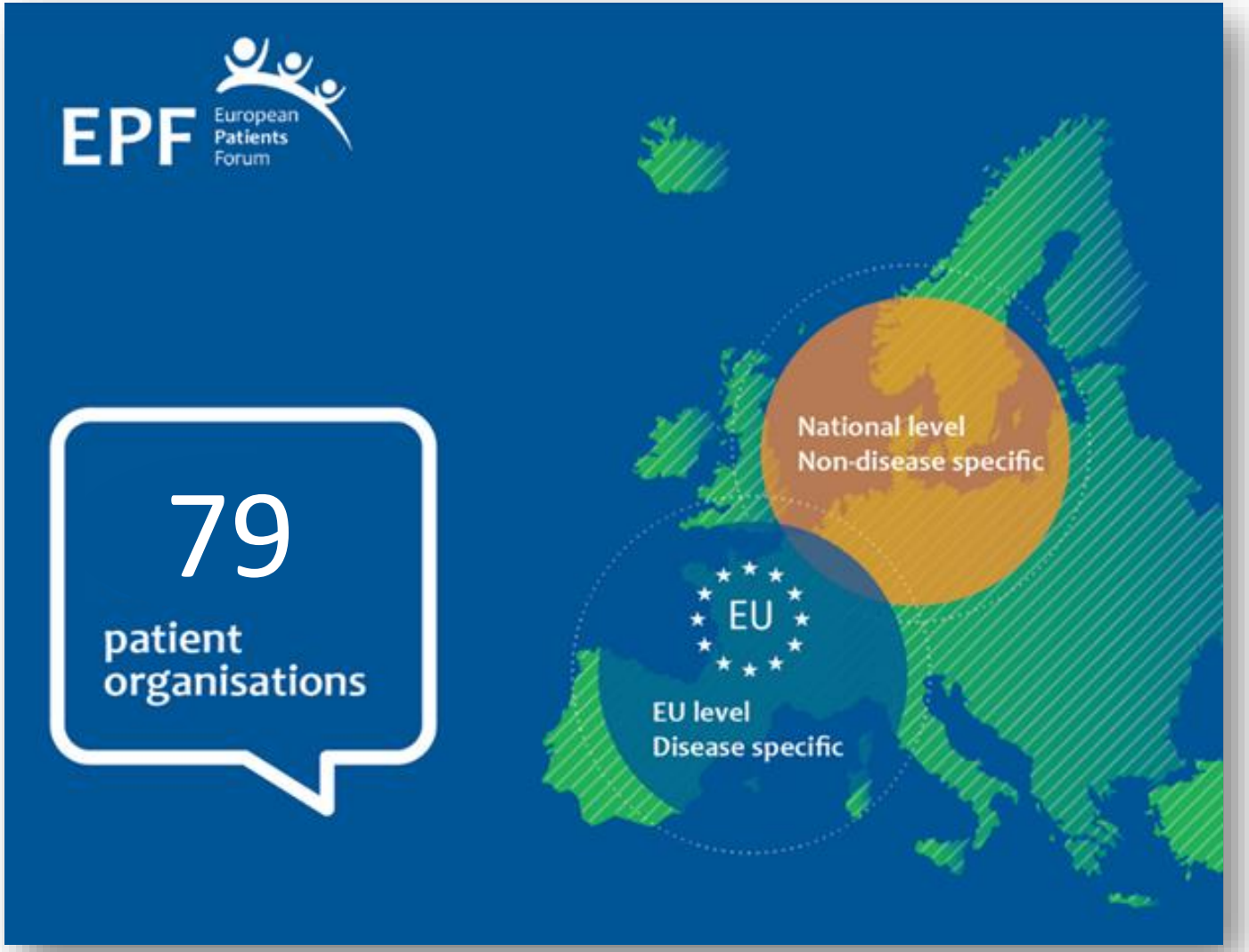
About EPF – European Patients' Forum

Our Vision

A Europe where patient organisations are valued partners in creating equitable, person-centered, accessible, and sustainable healthcare systems, based on patients' unique expertise



Why does it matter to the patient community?

This is an opportunity to:

- **Boost the development of medicines** that better address unmet medical needs
- **Foster patient access to medicines** (e.g., addressing shortages, access to generics and biosimilars)
- **Improve patient involvement** in the regulatory process

EPF's recommendations

1. Medicines targeting unmet medical needs

2. Increased patient access to medicines and treatments

3. A patient-centred regulatory process

1. Medicines targeting patients needs

Recommendations to ensure the added therapeutic value of medicines

1. Applicants for marketing authorisation should be encouraged to include **data on therapeutic value for patients** in the application dossier.

2. **Definition of "added therapeutic value"** in co-creation with patients.

3. **Inclusion of patient-relevant outcomes** in the marketing authorisation dossier

1. Medicines targeting patients needs

Recommendations to address unmet medical needs

1. Definition of **“unmet medical need” criteria with patients**.

2. Requirement to **submit a P&R application within one year** (or two years for SMEs) if the product is granted accelerated approval because it meets an unmet medical need.

2. Increased patient access to medicines and treatments

Recommendations on the incentives to develop medicines

Incentives

1. **6 years** of data protection and **8 years** of market exclusivity.
2. Additional year of data protection if a **product targets an unmet medical need.**
3. Additional year of data protection if a **P&R application is filed in all 27 Member States within 2 years.**

…which must also be accompanied by obligations

3. **Stricter rules** on granting an additional year of data protection **for one or more new therapeutic indications.**
4. Information on **planned market launch**
5. Information on **public funding received.**

2. Increased patient access to medicines and treatments

Recommendations to boost the access to and development of antibiotics

1. **Minimum annual revenue guarantee**
2. **Pay or play model**
3. Eligibility to **accelerated assessment**
4. **European guidelines on antibiotics prescribing practices**, developed with patients and healthcare professionals.
5. Leverage the creation of HERA to coordinate EU action on AMR.

The European
Health **E**mergency
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2. Increased patient access to medicines and treatments

Recommendations to promote faster market entry of generics and biosimilars

1. **Reduction from 3 to 2 years of the period for terminating the authorisation** of a product previously placed on the market and then withdrawn from the market.

2. **Retention of the sunset clause** and reduction to 2 years.

3. **Targeted revision of the regulatory and competitive frameworks** to remove barriers to generics and biosimilars.

2. Increased patient access to medicines and treatments

Recommendations to address drug shortages and supply chain vulnerabilities

1. **Extension of the notification period** for discontinuing the marketing of a product from 2 to 4 months.

2. **Transfer of the marketing authorisation** in case of discontinuation of a medicinal product.

3. Establishment of a **system for patients and patient organisations to report shortages.**

4. **EU database on shortages of medicines**, including information from national databases and legislation on falsified medicines.

5. Creation of a **list of excipients for which a sufficient production level must be maintained.**

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3. A patient-centred regulatory process

Recommendations to embed patient involvement into the legislation

1. **Legal definition of "patient organisation"**.

2. Representatives from patient organisations in the **Committee for Human Medicinal Products** (CHMP).

3. One member from patient organisations in the **Coordination Group for Mutual Recognition and Decentralised Procedures** – Human (CMDh).

3. A patient-centred regulatory process

Recommendations for streamlining procedures with high standards of evidence and patient safety

1. **Early EU-wide dialogue** between health professionals, patients, policymakers, industry, the EMA and HTA bodies, and payers.
2. **Aligned data requirements** between the marketing authorisation phase and the HTA phase.
3. NGOs, including patient organisations, should be able to **submit an application for a new indication.**

3. A patient-centred regulatory process

Recommendations to adapt to scientific progress

1. **Obligation to complete post-authorisation efficacy and safety studies** within a certain timeframe and measures in case of non-compliance.

2. **RWD and RWE should complement clinical trial data** but not replace it.

3. **Build on DARWIN EU to encourage the collection and use of real-world data to** continuously evaluate the effectiveness of authorised medicines

4. **Involvement of patient organisations** in initiatives to leverage the use and usability of RWD/RWE

3. A patient-centred regulatory process

Recommendations to improve information to patients

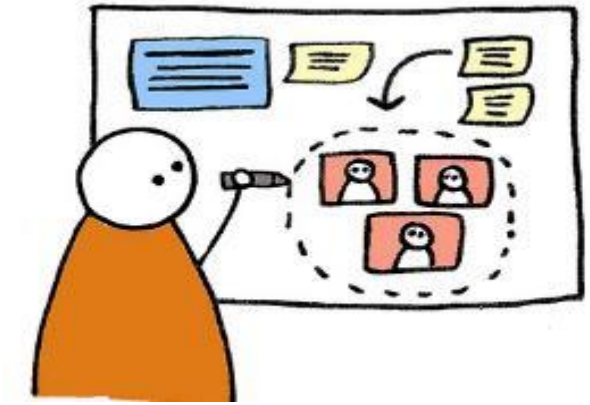
1. Inclusion of a **key information section** in the package leaflet and summary of product characteristics developed with patients.

2. Involvement of patients in the development of **the European Public Assessment Report** in the legislation

3. **Where to deposit medicinal products** after their expiry date should also be indicated.

What's next for EPF?

- Publication of EPF's position paper on the revision of the pharmaceutical legislation
- Engagement with EU co-legislators:
  - **Response to the call for feedback on the revision**
  - **Drafting amendments in consultation with members**



Any questions?