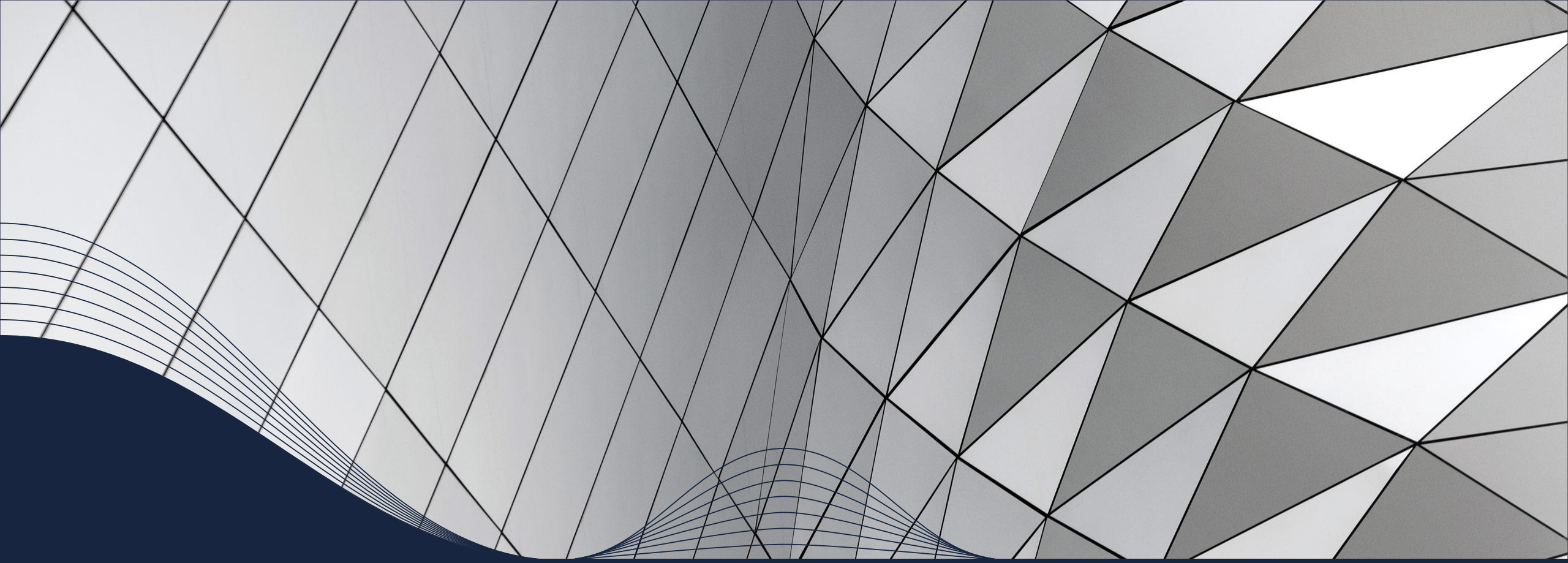
Stefano Marino

DLA Piper



EU Pharmaceutical Law Reform: where are we (heading to)?
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Stefano Marino, Senior Consultant

DLA PIPER

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The Commission's Proposed Reform – 26 April 2023

6 key political objectives pursued through two legislative acts (a Directive and a Regulation)

1. ACCESS - Patients' access to safe and effective medicinal products in the whole Union (excessive variance amongst Northern/Western vs. Southern/Eastern Member States)
2. AFFORDABILITY - Financial sustainability for national health systems
3. AVAILABILITY - Shortage prevention and continued supply of "critical medicines"
4. Streamlining approval procedures
5. Environmental sustainability and stricter risk assessment, to better fight AntiMicrobialResistance (AMR)
6. Combatting AMR: prudent use of antibiotics and incentives for new ones

Regulatory Data Protection (RDP) and Market Exclusivity (ME): EU and other countries

Source: European Commission

- As is

Country	Protection	Duration
Canada	New Chemical Entity+ Market Protection	6+2 years
EU	New Chemical Entity+ Market Protection	8+2+1 years
Switzerland	New Chemical Entity	10 years
USA	New Chemical Entity (small molecule)	5 years
USA	Biosimilar Application Approval Exclusivity (biologic)	4+8 years
Israel	Market Protection	6 or 6.5 years
China	New Chemical Entity	6 years
Japan	New Chemical Entity	8 years

1. Access and incentives: Council Proposal of 04.06.2025

RDP and ME (8+1+1+1 = 11 max.)

- RDP: 8 y standard
- ME modular
- + 1 y ME standard
- + 1 y ME (not RDP) for a new significant therapeutic indication approved within the first 8 years of RDP;
- + 1 y for Unmet Medical Need («UMN»); **OR, for NEW ACTIVE SUBSTANCES**:
- + 1 y if applicant

  (i) has conducted comparative clinical trials;

  (ii) the clinical trials on efficacy have been conducted in more than one EU MS; **and**

  (iii) the marketing authorisation application is submitted in the EU first or no later than 90 days from its submission outside the EU. Generics can file after 6 years from RDP start.

1. Access and incentives: Council Proposal of 04.06.2025

(continued)

- 4 years for «*repurposed*» products (products approved for one or more therapeutic indications long ago but now clinically tested and approved for a new therapeutic indication)

- Market exclusivity for orphan products (rare diseases):

  10 y standard; 5 y for bibliographic applications);

  + 1 y market exclusivity if a new indication for a different orphan condition is granted within the first 8 years of market exclusivity, up to 2 indications = max. 12 y ME

- NO incentives for «*high unmet medical need* («HUMN»): this concept and related incentives as proposed by the Commission have been rejected by the Council as too vague and difficult to be implemented

The controversial notion of «unmet medical need» («UMN»)

Current definition (***Article 4 of Reg (EC) No 507/2006)*** relevant for : Conditional Marketing Authorisation (CMA) - Accelerated assessment - Eligibility to Priority Medicines ("PRIME") – Orphan products

Text approved by the Council on 4 June 2025

- *1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a life threatening or severely debilitating disease and* ***either of*** *the following conditions are met:*
- *(a) there is no medicinal product authorised in the Union for such disease;*
- *(b) the use of the medicinal product* ***for such a disease*** *results in* ***clinically relevant improvement in efficacy, or in safety with at least comparable efficacy, in comparison with existing medicinal products or other methods of diagnosis, prevention or treatment authorised in the Union.***
- *2. The Agency shall adopt scientific guidelines to support the application of this Article. To this end, it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004]".*
- Therefore, the Council has **made it easier to claim the ME linked to the UMN**, as **the two conditions are NOT cumulative**; has trumped all references to quantitative criteria, **focusing on the efficacy and safety instead**; and has rejected the vague concept of "High Unmet Medical Need" for orphan products. In short, this new language is **closer to the current practical interpretation of UMN in the daily practice** of EMA Scientific Committees (CHMP and COMP).

6. Fighting AntiMicrobialResistance and incentives to R & D efforts on new antibiotics

A brand new incentive: the Transferable Exclusivity Voucher (TEV)

- «One Health Action Plan against AMR»:

  proposal for a Council Recommendation on the **need of prudent use of antibiotics and of raising awareness amongst patients and doctors**, also for environmental purposes

- Need to develop novel antibiotics and **risks of immobility** (AMR; increasing hospitalisation costs)
- One of the most controversial topics of the package reform: fears for affordability and rise of costs
- If granted by the Commission, a TEV could be used or transferred to others for value, **to add 12 months of data protection for the new antibiotic or another medicinal product** (e.g. a blockbuster still under RDP)
- Similar proposal rejected by the US Congress during the “REVAMP” discussions some years ago
- Criticism expressed by Lancet and Harvard University; different “pull-type” measures implemented in Sweden and the UK

6. Fighting AntiMicrobialResistance and incentives to R & D efforts on new antibiotics

(continued) – Council Proposal of 4 June 2025

- The new antibiotic shall address **a multi-drug-resistant organism causing a severe or a life-threatening infection**, and for which the preclinical and clinical data underpin **a significant clinical benefit with respect to antimicrobial resistance**
- It must have a **distinct mechanism of action** vs. other authorised antibiotics and contain a **new active substance**, whether alone or in combination with another active substance
- The applicant shall demonstrate its **capacity to supply the new AB in sufficient quantities to meet the demand in the EU**
- And show that the MAA for the new AB was **submitted to the EU first, or no later than 90 days** from its submission outside the EU
- **+ 12 months of data protection for the new AB or another medicinal product centrally approved**
- If used for another MP, a transferred voucher can only be **used in the fifth year of its regulatory data protection period**, and only if the MAH demonstrates that the annual gross EU sales of that product **have not exceeded €490 million in any of the preceding 4 years**
- The voucher shall expire if not used within 5 years from grant

A specific risk for trademark owners: Amendment 188 approved by the European Parliament

Wiping up 30 years of case-law on parallel imports and re-packaging of medicinal products?

- On 10 April 2024 the European Parliament approved Amendment 188 to the draft Directive:

Article 67(7)(a): "*For the purpose of patient safety, Member States may decide that medicinal products imported or distributed in parallel* ***shall be repackaged in new outer packaging****." (emphasis added)*

- Over 3 decades the EU Court of Justice has established several conditions to altering the product packaging. In particular**, the integrity of the originator's trademark/logo/colours and distinctive signs must be preserved**. **Re-boxing should be permitted only when it is objectively necessary to sell the product in the importing country.**
- In addition, under the Falsified Medicine Directive rules each packaging must have a unique identifier and an anti-tampering device. **Re-boxing risks altering those safety features and ends up in reducing the possibility of detecting falsified medicines**: therefore, it may facilitate counterfeiters' activities.
- On 17.11.2022 the Court of Justice ruled in Case C-224/20 that Directive 2001/83 must be interpreted as "*precluding a Member State from requiring that medicinal products imported in parallel must, in principle, be repackaged in new packaging and that recourse may be had to relabelling and to the affixing of new safety features to the original outer packaging of those medicinal products only on application and in exceptional circumstances, such as, inter alia, a risk of disruption to the supply of the medicinal product concerned*" (para. 100).
- **On 4 June 2025, the Council has not endorsed Amendment 188**. However, during the on-going "trilogue discussions" the (Danish) Presidency could raise the proposal again.
- It is hard to see how this disruptive amendment would benefit patients in the end, which should be the ultimate purpose of the EU Pharma Law reform.

Next steps: interplay with other acts and importance of “tertiary legislation”

Pharma Law Reform expected in early 2026; Health Technology Assessment (HTA) Reg., Artificial Intelligence (AI) Act and European Health Data Space (EHDS) Reg. in force as from 2025; Biotech Act and Critical Medicines Act under discussion

High administrative discretion and increased risks of judicial challenges

1. Enhanced role of EMA, patients/doctors representatives and national authorities
2. Tertiary legislation: **EMA scientific guidelines to define key aspects** in detail; **high risk of judicial challenges**
3. **Impact on the smooth functioning of EMA**
4. Impact of other legislative acts (e.g., HTA Regulation and its Implementing Acts; EHDS Reg.; AI Act; Critical Medicines Act; Biotech Act), all potentially conditioning governance and operational functioning of both applicants and regulators
5. **Risks of clashes at central and national level** (possible divergencies vs HTA bodies and payors in social security schemes)
6. **National pricing and reimbursement decisions not bound by “central” findings on UMN**
7. **CJEU likely to intervene on important parts of the new legislation: birth of a “judicial co-legislator”?**

Thank you

For comments/queries: stefano.marino@dlapiper.com