

Uneasy Compromises: 100 Amendments to the EU's Pharmaceutical Review

March 20, 2024

The Pharmaceutical Review (the Review), leaked on January 31, 2023, and published by the European Commission (Commission) on [April 26, 2023](#), was always going to be a complex and ambitious project, not least because it was founded on the unsupported idea that by reducing intellectual property (IP) protection overall, investment could be steered into “unmet medical need” (UMN) markets where IP reductions would be smaller (see our previous blog posts [Six Surprises](#) and [Missing Numbers](#)). After reviewing different reports and over 3,500 amendments demonstrating divergent views on IP and innovation, the Parliament's lead committee on the Review (Committee on the Environment, Public Health, and Food Safety, or ENVI Committee) voted on March 19, 2024, on a set of 100 Compromise Amendments that bring some improvements but several new risks as well.

Regulatory data protection: two down + one up = down 0.5, with a cap

The Commission's initial proposal included a two-year *reduction* of baseline RDP (regulatory data protection, i.e., the exclusive right of innovators to use the results of preclinical tests and clinical trials placed in their product dossier) from eight to six years, with three opportunities to limit the loss: (i) two years of RDP for placing the product on the market “in a sufficient quantity” in all EU Member States within two or three years (“launch conditionality”, generally considered unachievable); (ii) six months RDP for a product that “addresses an unmet medical need” (generally considered unpredictable); and (iii) six months for doing comparative clinical trials (with difficulties to predict feasibility and the acceptability of the comparators chosen). The difficulties to obtain these extensions were discussed in our previous blogpost ([The Pharma Review needs to remain grounded in economic reality](#)).

The ENVI Committee's [Weiss Report](#) of October 3, 2023 took a different approach — *to increase* baseline RDP from eight to nine years and to scrap launch conditionality — in order to increase predictability and attract innovation to the EU. The Parliament's ENVI Committee ended up with a mathematical “split the difference” compromise on baseline RDP: 7.5 years (i.e., $6 + 9 = 15$, divided by 2). Launch conditionality was replaced by an obligation to file nationally for pricing and reimbursement (P&R; see below). The chance to obtain a UMN increase was maintained (with 12 months to be gained instead of 6 months). The chance to get 6 months additional RDP for “comparative trials” was maintained, too. A new incentive of six months RDP is now proposed for doing “a significant share” of research and development (R&D) within the EU, working with public entities. However, RDP is proposed to be capped at 8.5 years overall, thereby cutting the total of the three incentives (12 + 6 + 6 months) by up to 50%. Thus, applicants could not obtain more than one or two of these incentives, making all of

them uncertain.

Like for the Commission's original proposal (see the [Missing Numbers](#) blog post), there has been no assessment of the impact of the Compromise Amendments on the competitiveness of the EU industry. Reducing the baseline RDP level, even by 6 months, from 8 to 7.5 years, is still a signal that the European Parliament (like the Commission) is seeking to decrease baseline IP protection. The proposed incentives are unpredictable, in particular the test for obtaining UMN status: The definition of UMN is focused on "remaining high morbidity," but this concept will be defined only in future Commission guidelines. At any rate, at the time companies take go/no-go decisions on product development, they cannot predict whether, 10 or 12 years later, the need will still be unmet. Furthermore, products that do not get UMN status may face extra hurdles at the national P&R stage, notwithstanding a proposed recital that this negative effect need not be "automatic." Combined with the "cap" of RDP at 8.5 years, the net overall effect of the package on innovation or investment is uncertain at best.

Obligation to file for P&R — With a catch

The Compromise Amendments propose an obligation for the marketing authorization holder (MAH) to file for pricing and reimbursement in each Member State that requests it and "to negotiate." In case of a "positive decision to permit the marketing of the medicinal product according to Directive 89/105/EEC" (the Transparency Directive), the MAH will be subject to an "obligation ... to ensure appropriate and continued supply to cover the needs of patients in that Member State." But the proposal is silent on what happens if the decision is "positive" for the Member State but negative for the MAH (e.g., because the reimbursement level is too low to cover the risks and costs of bringing the product to market). The risk is greater still because failure to supply can attract significant fines. No risk assessment has been made.

Orphan medicinal products (OMPs): protection down for most products

For OMPs, the Compromise Amendments maintain the Commission's proposal to reduce the baseline orphan market exclusivity (OME) protection from about 11 years currently (10 years + the time taken to process a generic or biosimilar MA application) to a baseline of nine years. For products addressing high UMN (HUMN, which includes the requirement for an "exceptional therapeutic advancement"), the OME would be set at 11 years. In accordance with the suggestion of the [Wölken Report](#) of October 20, 2023, the Commission's proposal for an extra 12 months OME for an all-EU launch has been removed. For products based on bibliographic data, OME is proposed to be 4 years (non-extendable). The Compromise Amendments also maintain the Commission's proposal to abandon the current system whereby each new orphan indication can obtain its own market exclusivity periods ($\approx 11 + \approx 11 + \approx 11$), to a system with a single OME, allowing a one-year extension for the first two new indications (i.e., nine years (extendable as above) +1 +1) – thus creating a new concept akin to a global orphan MA ("GOMA").

The net effect of the Compromise Amendments on OMPs is reduced OME for almost all products (except the uncertain category obtaining HUMN status) and significantly reduced OME for second and third orphan indications (up to a decade less for each). There has been no assessment of the impact of this reduction on the competitiveness of the orphan industry in the EU nor of the P&R impact for products that do not succeed in getting HUMN status.

Paediatrics: more flexibility but more burdens and less protection

For paediatric medicines, the Compromise Amendments maintain the Commission's welcome proposal to introduce "evolutionary and simplified" paediatric investigation plans (PIPs), introducing much-needed flexibility. However, there are new burdens as well. Currently, the standard obligation to carry out a PIP can be waived if the disease occurs only in adults. But the waiver would not apply "when the product is directed at a molecular target or due to its mechanism of action [MoA] ... is responsible for a different disease or condition in the same therapeutic area in children." There would be no additional reward for conducting such a "MoA PIP." The obligation to place the product with the paediatric indication on the market in all Member States where the "adult" version is on the market is maintained as proposed by the Commission. For OMPs, the current possibility to obtain a two-year OME extension for completing a PIP is removed.

Antimicrobial resistance

The Wölken report had proposed to delete the Commission's proposal to introduce a Transferable Exclusivity Voucher (TEV) to use the extension of RDP for a successful product as a source of funding for new antimicrobials (for which there is currently no market). The Compromise Amendments maintain the Commission's TEV proposal in restricted form, as an alternative to "milestone payments" and a subscription model for joint procurement of new antimicrobials. The conditions for a TEV have been made stricter, for example, by stating that a TEV cannot be applied to a successful product if that extends its RDP beyond the 8.5 year RDP cap discussed above. There is no assessment of the impact of these changes.

General IP exemptions: Bolar, "pharmacy compounding," and ATMPs

The Compromise Amendments provide for several general exemptions to IP rights likely to generate concern. First, the amendments largely maintain the Commission's proposal to extend the "Bolar" provision, which currently exempts from patent infringement all activities by generic/biosimilar applicants to obtain a generic or biosimilar marketing authorization (MA). The Bolar exemption would extend to conducting health technology assessments and obtaining P&R approval (directly or using third-party suppliers and service providers) as well as the associated "subsequent practical requirements."

Second, the amendments state that pharmacists have an important role "to compound" medicinal products. The amendments open the door, even more widely than the Commission had proposed, to allow pharmacy compounding (e.g., a stock of medicinal products prepared in advance using the "official formula"), not only for patients served by the pharmacy but also to supply the patients of "another pharmacy," without specifying (as is required under European Pharmacopoeia rules) that such compounding should not replace suitable comparable authorized medicinal products. Replacement compounding can have serious implications, bypassing IP rights and blocking market access to compoundable authorized medicinal products (as has happened already in several Member States). No assessments have been made of the potentially serious impact of this. A separate exemption is now proposed for "hospital formula" compounding for the supply of hospital patients — without a manufacturing authorization. Furthermore, in the context of OMPs, the Amendments state that medicinal products prepared for an individual patient in a pharmacy using the magistral or official formula could be considered as "satisfactory treatments," potentially blocking orphan designation for that product.

For the manufacturing of advanced therapy medicinal products (ATMPs) without an MA in a hospital, the Compromise Amendments require the existence of "special needs" of a patient, but they do not maintain

the protection proposed in the Weiss Report (which explicitly restricted such production to situations where “no [ATMP] is authorized within the Union”). The Compromise Amendments even envisage “cross-border exchange” of ATMPs in case of “absence of other solutions for the individual patient.”

Remaining questions

This Sidley Update did not discuss other risks introduced by the Compromise Amendments, such as new rules on disclosure of R&D funding by any public entity; strict new rules on shortages; environmental risk assessments for new and legacy products; and harmonized standards for “the design of scientific studies” and for advertising on social media. These will be discussed separately.

With regard to IP, despite the proposal to include helpful recitals stating that the aim of the Pharma Review includes creating “an attractive environment for research, development and manufacturing of medicines in the Union,” the overall direction of IP/regulatory protection, as proposed in the Compromise Amendments, is clearly downward, and several new exemptions bypassing IP are being proposed. If the Parliament adopts the ENVI Compromise Amendments in its Plenary Session on April 11, 2024, the next stages will include the Commission, which will consider the amendments proposed by the Parliament, and the Council (the Member States), which has not taken a position.

The entry into force of the new rules is still several years off, but company pipelines may already be affected.

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