Commentary: Maarten Meulenbelt

EU pharma reform meets US MFN pricing risks

The European Union is entering a decisive phase in the overhaul of its pharmaceutical legislation - the most extensive revision since 1965. The so-called Pharma Package, also referred to as the General Pharma Legislation (GPL), is now in trilogue negotiations between the European Commission, the European Parliament, and the Council of the EU.

The reform, consisting of a draft Pharmaceutical Directive (PR) and a Pharmaceutical Regulation (PR), has been presented as a modernisation to strengthen Europe's competitiveness and, at the same time, improve patient access, and it does include helpful attempts to streamline regulatory processes. However, some of its mechanisms – modulations of intellectual property (IP) and regulatory exclusivities, and potential obligations to launch across the EU – could have unintended negative effects, especially when viewed against the risk that the US might implement certain most-favoured nation (MFN) pricing policies. Together, these developments risk undermining both Europe's attractiveness for pharmaceutical innovation and global launch strategies.

Under current law, marketing authorisation holders are not required to launch their products in every country. They must ensure adequate supply once a product is launched, but there is no obligation to make it available across all EU markets. The Commission's proposal of April 2023 sought to change that balance through 'launch conditionality.' It proposed cutting baseline regulatory data protection (RDP) from eight to six years – a sizeable reduction – but offered companies the opportunity to regain two years by launching their product 'in sufficient quantities' in all member states within two or three years. Stakeholders pointed out that launching simultaneously across 27 member states, each with its own pricing and reimbursement regime, is unrealistic.

In response, the Parliament in April 2024 abandoned the conditionality approach but proposed an obligation to launch in member states that deliver a positive reimbursement decision. Yet the proposal fails to define positive - for example, whether a reimbursement level that is acceptable for a government but commercially unsustainable for a company would still trigger an obligation to launch.

The Council's June 2025 position went further still. It introduced a new Article 56a PD, compelling marketing authorisation holders to file pricing and reimbursement applications, to meet unspecified procurement 'requirements,' and establish a 'roll-out plan.' Failure to continuously supply a product in a member state within four years could lead to the loss of market protection, RDP, and orphan market exclusivity (OME) in that country. In addition, a new Article 5a PR would add an obligation for each company to ensure availability 'upon agreement with the respective Member State and within its responsibility.' A test of 'viability' of the company was proposed, but only in a recital to the proposed Regulation and not in the text itself; and it was not clear at what level the viability would be tested.

Such measures, without clear definitions or viability safeguards, can inject significant uncertainty into investment calculations. They risk lowering the risk-adjusted net present value (rNPV) of developing and launching innovative medicines in the EU.

The debate about obligations to launch has become more urgent by the possibility that the US might introduce MFN pricing, as proposed in the May 2025 Executive Order entitled Delivering Most-Favored Nation Prescription Drug Pricing to American Patients, aiming to align US prices with the lowest available in comparable OECD countries. Letters sent in July to 17 major pharmaceutical companies demanded substantial price reductions in the US market. The US government proposed comparisons with prices in countries with at least 60% of US GDP per capita (adjusted for purchasing power). Such a mechanism recalls the Trump administration's earlier MFN initiatives - defeated by US courts at the time - but signals renewed determination to explore linking US prices directly to foreign reference points.

If the EU were to impose obligations to launch in member states qualifying for US MFN benchmarking – which might occur either under the Trump administration, or a future administration – companies could face a difficult situation: depending on the data that would be available in the US about European prices, a discount offered in Europe could have an impact on the prices in the much larger US market.

The trilogue negotiations are not limited to launch obligations. All three EU institutions agree that baseline IP and exclusivity periods should be reduced. Under the current 8+2+1 system, products enjoy eight years of regulatory data protection and two years of market exclusivity, with an optional one-year extension for a new indication. The Commission's proposal would cut this to a 6+2+1 structure, the Parliament to 7.5+2+1, and the Council to 8+1+1. Orphan medicines would see reductions as well.

Another question relates to the robustness of protections such as RDP and OME (which are already facing baseline reductions), patents, and supplementary protection certificates (SPCs). There are several mechanisms that could erode protections, including a proposed expansion of the Bolar exemption permitting pricing and reimbursement procedures, and potentially even generic/biosimilar price listings, well before patent/SPC expiry; 'hospital exemption' rules for producing advanced therapy medicinal products (ATMPs) without an authorisation; and a proposed expansion of the possibilities to supply unauthorised pharmacy-compounded products.

The coming months will determine whether the EU's largest pharmaceutical reform in six decades strengthens competitiveness - or inadvertently weakens it.

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