General Pharmaceutical Legislation

Background

The General Pharmaceutical Legislation was published by the European Commission on April 26, 2023. The proposed legislation represents a major, and timely, overhaul of EU pharmaceutical law which – at 20 years since its last revision – was not designed to regulate the current generation of medical technologies.

The Commission's stated objectives are to achieve better access, affordability, and availability of medicines, as well as to incentivize research in areas of unmet need, including anti-microbials. All while seeking to increase the competitiveness of the pharmaceutical industry in Europe.

Novartis shares these objectives. However, while there are positive elements of the draft text – we welcome efforts to build an agile, streamlined regulatory system – we believe the proposed legislation will **neither improve the stagnating competitiveness of EU life sciences, nor achieve the objective of more equitable access to medicines.**

The pharmaceutical industry in Europe

Beyond the significant value that the pharmaceutical industry delivers to patients, research-based pharmaceutical companies are an anchor for investment and a hub for wider life-science innovation. In 2022, Novartis invested 5.7 billion EUR in R&D in Europe. When a company invests in a city or town, it builds links with universities, creates opportunities for start-ups and service companies, attracts talent, and adds a creative spark that drives scientific knowledge forward.

Between 2000-2021 the innovative pharmaceutical sector more than doubled production, increased exports by a factor of six, and recorded a trade balance that puts it far ahead of other high-tech sectors in Europe. Europe's pharmaceutical sector directly employs 840,000 people, and indirectly generates about three times more employment[1]. Novartis's European workforce in 2022 numbered more than 50,000 people.

European competitiveness

The pharmaceutical footprint is a cornerstone of Europe's strategic autonomy. But we are at a crossroads. As a region, **the EU has already fallen behind global competitors in R&D and manufacturing**, with lower investment, a smaller share of global clinical trials, and longer approval times for new medicines. Of the total R&D investments made in the US, Europe, China and Japan in 2022, 31% occurred in Europe compared with 41% in 2001. Europe's relative stagnation in life science investment is evident[2].

Innovation starts with an idea; growing an idea needs funding, scientists to research it, development through clinical trials, and an effective regulatory environment. The sustainable "absorption" of innovation is the final, critical, step. Even the most promising medical innovation has no impact if not made available to patients.

Regulatory Data Protection

The most concerning measure in the draft legislation is a **two-year reduction of the period of regulatory data protection (RDP)**. The proposal would cut the current 8+2 (eight years of data protection, followed by two years of market protection) down to 6+2. Regulatory Data Protection is a type of intellectual property protection that is crucial to incentivize innovators to develop new products and/or new indications.

Further, RDP encourages ongoing research on molecules which are more advanced in their patent life by offering a period of market protection which is independent of the patent. Though it often runs concurrently to the patent, for around one third of medicines RDP is the last form of protection to expire[3].

The draft Pharmaceutical Legislation would allow, in theory, for the six-year period to be prolonged. But the **conditions of extension would be difficult – if not impossible – to meet**, and **only obtainable through uncertain and complex mechanisms**.

[1] Economic impact (efpia.eu)
[2] Europe's share of global medicines R&D shrinks by a quarter in 20 years – as sector's declining trends continue (efpia.eu)
[3] Protection Expiry and Journey into the Market - IQVIA

A company could apply for an additional two years of RDP for a medicine if it has been launched in every Member State within two years of marketing authorization, according to the draft text. For that to happen, each Member State must declare that the product is "released and continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients."

Any possibility to achieve the two additional years is an illusion. Not only would 'sufficient quantity and presentations' be difficult to define, determine and track, but launch would presumably require reimbursement. Under current Member State practices and procedures, this is **unachievable in a two-year timeframe**. As demonstrated by the Efpia WAIT indicator, only around half of EU countries reliably reach a conclusion on public reimbursement within two years of marketing authorization.

Critically, this proposal would give **every Member State a veto over a medicine's eligibility for two years of RDP**. Put simply, it would give each of the 27 Member States the singular power to determine the duration of an essential IP protection throughout the Union. This level of uncertainty, in an ecosystem that relies on a predictable IP framework, is entirely unworkable.

Similarly, two other newly proposed conditions would each offer a theoretical six additional months of RDP. But their impact is likely to be negligible:

- Unmet medical need – the concept is so narrowly defined, requiring a meaningful reduction of "high morbidity or mortality", that vanishingly few medicines would qualify. Moreover, this potentially leaves out many conditions with an actual unmet need as experienced by patients.
- Comparator trials – this would rely on the availability of a "relevant and evidence-based comparator", which depending on clinical circumstances is not always possible. It would also exclude from clinical trials any country in which the selected comparator is not the standard of care.

In practice, the uncertainties of the process would force companies to plan investments based on an assumption of 6+2 years of RDP. This would undoubtedly have an impact on decisions about which research projects to invest in, and where to make such investment. **Crucially, it will not achieve broader or faster access for patients.**

Novartis call to action for policymakers

Retain the current eight-year period of RDP, because the proposed legislation would:

- Damage Europe's life science competitiveness irreversibly.
- Not achieve more equitable access for European patients.
- Make Europe dependent on research priorities set elsewhere.

Consider EU life science competitiveness in a **context of IP erosion coupled with the need to reallocate resources to address several new obligations**:

- Provisions laid out in the draft relating to shortages, environmental risk assessments, and pediatric research and launch requirements would add considerable administrative burden.
- Other EU legislations, notably the HTA Regulation and IP Package, will also affect industry. If not carefully implemented, these could further disincentivize medicines research and launch in Europe.

De-link access and regulatory objectives:

- The EMA makes decisions at European level based on the science and clinical evidence.
- Reimbursement bodies in countries make decisions based on their local healthcare system context.
- Opportunities to understand the respective evidence expectations of both regulators and reimbursement authorities are welcomed, but the objectives of these two processes should remain distinct.

Conduct a **realistic analysis of how the legislation would affect the industry's ability to innovate** and bring medicines to market in Europe.

- In the spirit of the Competitiveness Check announced by the Commission President in Oct 2022.
- Such analysis can only be effectively conducted with input from the industry.

Engage in meaningful **dialogue with industry** to find workable, sustainable solutions to achieve our shared objectives, giving due consideration to Efpia proposals on:

- Industry commitment to file for pricing and reimbursement in all member states within two years.
- A conceptual framework for Equity Based Tiered Pricing (EBTP).