European Commission Proposes Overhaul of Regulatory and Intellectual Property Framework Governing Pharmaceuticals

On 26 and 27 April 2023, the European Commission (the ***Commission***) adopted a comprehensive package of proposed regulatory and intellectual property (***IP***) measures that will have a profound impact on the pharmaceutical industry in Europe for years to come. The draft measures will now have to be reviewed and approved by the European Parliament and the Council of the European Union. The deliberations and negotiations required for that purpose are likely to be time-consuming and will probably not be completed before the elections for a new European Parliament in 2024.

The Commission's stated principal objectives in proposing these measures are to increase the accessibility of new medication across the EU; address unmet medical needs; contain antimicrobial resistance (***AMR***); bring down medicine shortages; and make medicines more environmentally sustainable. However, the Commission's view would appear to be that reaching these laudable objectives is the exclusive responsibility of the pharmaceutical industry and not that of other stakeholders, including national governments.

At the same time, the Commission's additional purported central goals, namely supporting innovation and boosting the competitiveness of the European pharmaceutical industry, would not fully seem to be reflected in new and incisive measures. On the contrary, some of the Commission's most eye-catching draft rules in fields involving regulatory data protection (***RDP***) and IP may yield the opposite result and will do little to stem the tide of diminishing pharmaceutical research and development efforts in Europe when compared to these in the US and China.

1. OVERVIEW

In the regulatory field, the Commission tabled the following proposals:

- A draft Directive that will establish a new code governing medicinal products for human use and will repeal Directive 2001/83/EC (***draft Medicines Code*** or ***DMC***).
- A draft Regulation that will lay down new procedures for the authorisation and supervision of medicinal products and will repeal Regulation (EC) 726/2004 (***draft Medicines Regulation*** or ***DMR***).

Both instruments make up what is referred to as the general pharmaceutical legislation containing rules broadly applicable to all medicines in areas such authorisation, post-authorisation requirements, distribution, manufacturing, supply, advertising, and supervision. They also regulate the European Medicines Agency (***EMA***). Unlike the rules which they replace, they will in future also govern orphan and paediatric medicines. This is because Regulation (EC) 1901/2006, the Paediatric Regulation, and Regulation (EC) 141/2000, the Orphan Regulation, will be folded into the new version of the general pharmaceutic legislation for reasons of simplification and increased coherence.

- A proposed Council Recommendation to combat AMR.

As regards *IP*, the Commission presented the following proposals:

- A draft Regulation regarding compulsory licensing for crisis management. Compulsory licensing of patents allows a government to authorise the use of a patented invention without the consent of the patent holder. The Commission's draft Regulation establishes rules for compulsory licensing of patents in relation to crisis-relevant products and technologies, including medicines, whenever voluntary initiatives prove insufficient in times of a public health emergency. There is at present a patchwork of 27 national compulsory licensing regimes which the Commission wants to overcome. While compulsory licensing has been a hot topic in recent years, particularly with regard to medicines, it is doubtful whether this initiative will bring any tangible public health benefit. It will at best serve as a symbolic assault on patent law but may accelerate a patent eroding trend as well. Compulsory licences will also give rise to a suspension of the RDP and market protection discussed below (Article 80(4), DMC).
- A major overhaul of the existing system of Supplementary Protection Certificates (***SPCs***). An SPC is an IP right that extends the term of a patent by up to five years for a human or veterinary medicinal product, or a plant protection product, that was authorised by regulatory authorities. SPCs have existed for many years, but the Commission's proposed system contains four proposed Regulations:
  - Two draft Regulations introduce a centralised procedure for the grant of national SPCs, by recasting and repealing the existing EU Regulations (one for medicinal products and the other for plant protection products), and
  - Two completely new Regulations will create a unitary SPC (with the same centralised examination procedure), one for medicinal products and one for plant protection products. The unitary SPC complements the EU's Unitary Patent System that will enter into force on 1 June 2023.

To be sure, there are a host of connections between the various proposed sets of rules. For example, the DMC and DMR are replete with rules governing AMRs, including AMR incentives. Similarly, as discussed below, the DMC also provides for statutory incursions on the RDP and IP regimes.

2. SIGNIFICANT PROPOSED REGULATORY CHANGES

- *Data exclusivity* – The draft Medicines Code reduces the default RDP from 8 to 6 years (Articles 80(1) and 81(1), DMC). The period of RDP is followed by a period of market protection of 2 years as is the case under existing rules (Article 80(2), DMC). However, the default RDP can be extended by 2 years for medicines launched in all Member States covered by the marketing authorisation, provided they are continuously supplied in a sufficient quantity and in the presentations necessary to cover patient needs (Articles 81(2)(a) and 82, DMC). Additional extensions are available for (i) medicines that address an unmet medical need (6 months – Articles 81(2)(b) and 83, DMC); (ii) medicines that form the subject of a head-to-head trial with a "*relevant and evidence-based comparator*" (6 months – Article 81(2)(c), DMC); and (iii) medicines with an additional therapeutic indication that shows a significant clinical benefit over existing therapies (12 months – Article

81(2)(d), DMC). Repurposed medicines will also benefit from RDP under the conditions laid down in Article 84, DMC.

- *Regulatory process* – A series of rules are designed to ease the regulatory burden on marketing authorisation applicants. These span documentary and procedural requirements but also provisions of a more substantive nature to facilitate the approval of novel medicines. Significantly, Articles 113 and following of the DMR provide for the possibility of establishing a regulatory sandbox, a structured context for experimentation enabling the testing of innovative technologies.
- *AMR* – Articles 40 and following, DMR contain a novel incentive for the development of "*priority antimicrobials*", a defined concept referring to new antimicrobials presenting a significant clinical benefit from the perspective of AMR. The marketing authorisation holder of a priority antimicrobial will be given the opportunity to apply for a transferable data exclusivity voucher which will confer on the holder the right to an additional 12 months of RDP for a medicine of its choice, including that of another marketing authorisation holder.
- *Shortages* – The concept of shortage is defined as a "*situation in which the supply of a* [medicine] (…) *does not meet the demand for that* [medicine] *in that Member State*" (Article 2(14), DMR). While the Commission acknowledges the "*root causes*" of medicine shortages to be "*multifactorial*" and situated "*along the entire pharmaceutical value chain*" (Recital 136, DMR), it puts the onus of addressing such shortages squarely on the pharmaceutical industry. As a result, marketing authorisation holders will have the obligation to notify authorities of shortages earlier than before (6 months' prior notice – Article 116(1)(d), DMR) and to develop shortage prevention plans per product (Article 117, DMR). EMA's Executive Steering Group on Shortages and Safety of Medicinal Products (the ***Medicines Shortages Steering Group*** or ***MSSG***) will adopt a list of critical shortages of medicinal products (Article 123(1), DMR) which will create new obligations for the marketing authorisation holder and will be subject to monitoring. Furthermore, Member State authorities will identify critical medicinal products (Article 127, DMR) which will feed into a Union list of critical medicinal products that will be established by the MSSG (Article 131, DMR). Additionally, implementing legislation will allow the Commission to impose contingency stock requirements on marketing authorisation holders, wholesale distributors and other stakeholders (Article 134(2), DMR).
- *IP* – As part of a broader effort to facilitate the market entry of biosimilars and generics, Article 85, DMC broadens the scope of the "Bolar" exemption (which allowed studies to be carried out for regulatory approval of biosimilars and generics during the protection afforded by patents to the reference medicinal product). As a result, it will also be possible to conduct studies, trials and other activities to generate data for purposes of applying for health technology assessments as defined in Regulation (EU) 2021/2282 and pricing and reimbursement decisions.
- *Transparency regarding public funding* – Pursuant to Article 57, DMC, marketing authorisation holders will be required to report on direct financial support received from public authorities or publicly funded bodies for the research and development of medicines.

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