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ALERT

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EU Commission publishes its much-anticipated proposals to reform pharmaceutical regulations

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On April 26, 2023, the EU Commission published its long-awaited proposals to revise the EU's pharmaceutical legislation. The proposals, the largest reform in over 20 years, have been controversial ever since they were originally leaked to and published by Politico. The officially released draft is similar to the leaked document. The stated purposes of the proposals are to:

- create a single market for medicines,
- address the growing issue of antimicrobial resistance,
- move to a more environmentally sustainable position on medicines and
- address medicine shortages, amongst other goals.

The key area of controversy has been the reduction of the regulatory data protection ("**RDP**") period from eight years to six years. Drug manufacturers are able to increase this up to a maximum of 12 years of protection in certain defined circumstances:

- Developing products for an unmet medical need ("**UMN**") will add **six months** exclusivity at the point of obtaining Marketing Authorization ("**MA**");
- If the MA holder obtains authorisation for a new therapeutic indication, an **additional year** will be added to the RDP period;
- **Two additional years** will be added for products "*released and continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorization is valid*" within two years of obtaining the MA; and
- Six months will be added for products containing a new active substance where comparative clinical trials take place.

A medicinal product will be determined to be a UMN if:

- At minimum, one of its indications relates to a life-threatening or debilitating condition and no medicinal product within the EU is authorised for that particular condition; or
- Where there are existing medicinal products authorised for such use but the condition in question has a high morbidity or mortality rate and the product will have meaningful reduction to the relevant patient population; or
- It is an Orphan Medicinal Product ("**OMP**"), which are designated as UMN by default;

For OMPs, the default duration of Orphan Market Exclusivity ("**OME**") is set to nine years, and 10 years for OMPs addressing a "high unmet medical need" which is similar to the concept of "significant benefit" currently set out in the Orphan Medicinal Products Regulation. These periods can be extended by a year where the product is released and continuously supplied within two years of obtaining a marketing authorisation. Finally, the default OME duration can be increased by another year for new indications in new orphan conditions which are authorized before the final two years of the OME period.

The Commission attempts to tackle the problem of medicinal shortages in its new proposal through a new notification requirement for marketing authorisation holders – they will need to notify the national competent authority or the European Medicines Agency ("**EMA**") of real or potential shortages and also:

- Intention to temporarily suspend marketing (notification is required six months beforehand);
- Intention to permanently stop marketing (notification is required 12 months before last supply);
- The request to permanently withdraw marketing authorisation (notification is required 12 months before last supply);
- Temporary disruption in supply (notification should be made immediately and in any case no less than six months before expected disruption).

Additionally, marketing authorisation holders who intend to permanently withdraw an MA for a "critical" medicine will be required to, in the first instance, offer to transfer this authorisation on reasonable terms to a third party. Alternatively, the marketing authorisation holder can allow a third party which has already declared an intention to place the critical medicine on the market to use documentation contained in the product file for the purposes of submitting its own application for an MA.

We can expect further guidance from the EMA in the form of a list of these critical medicines which will require a pan-EU response and common methods of shortage-reporting. This list will also include further requirements which will bolster security of the supply chain for these medicines in particular.

Transferable data exclusivity vouchers (TEVs) have been introduced in an effort to encourage the development of new antimicrobials capable of combating antimicrobial resistance. These vouchers will be made available to "priority antimicrobials". These are antimicrobials that are backed by preclinical and clinical data that demonstrate significant clinical benefits against antimicrobial resistance, in addition to possessing one of the following attributes:

- It belongs to a new class of antimicrobials;
- Its mechanism of action is fundamentally different from any authorised antimicrobial in the EU; or
- It contains an active substance that has not previously been authorised in the EU and addresses a serious, life-threatening infection or multi-drug resistant infection.

The TEV will provide an additional year of RDP to the developer, which would be in addition to any existing RDP, and which can be used to promote any centralised product within their own product line or sold to another marketing authorisation holder. Additionally:

- This voucher can only be used once and must be utilised within the first four years of RDP;
- It is valid for a period of five years;
- A maximum of 10 vouchers will be issued by the Commission over a 15-year span, at which point all TEV provisions will end unless they are extended; and
- The sale of TEVs must be reported to the EMA and made public.

What comes next?

The above are just a few of the key salient points from the Commission's proposals – the whole package is extensive, affecting the entire lifecycle of medicines. The package will now make its way to the European Parliament and Council for consideration and adoption. In the EU system, nothing is finalised until everything is finalised. Given the upcoming elections in European Union member states for representation in the European Parliament as well as the end of current

European Commission's term of office in October 2024, it is possible that changes will be made to the legislative proposal before it is enacted into law.

This alert was authored by Lincoln Tsang and Azim Rahman, a trainee solicitor, in the European Life Sciences Practice.