EU Pharma sector developments

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Medicines for Europe

- Representing generic, biosimilar and value-added medicines industries across Europe
- Our Members supply 70% of dispensed medicines in Europe covering 80% of therapeutic areas
- Our Members employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D

EU Pharmaceutical Strategy 2020

I. Ensuring **access to affordable medicines for patients** and addressing **unmet medical need**

> *"**Generic and biosimilar medicines provide a large number of patients with accessible and affordable treatments.** They also allow health systems potential **savings** in costs through their positive effect on pricing competition. Commission will consider **targeted policies that support greater generic and biosimilar competition**, based on the sound functioning of the single market, appropriate market protection mechanisms, the **removal of barriers that delay their timely entry to market** and **increased uptake by health systems**".*

II. Supporting **competitiveness**, **innovation** & **sustainability** of EU pharma industry & high quality, safe, effective and greener medicines

III. Enhancing **crisis preparedness** & **response** mechanisms, **diversified & secure supply chains**, address **medicines shortages**

IV. Ensuring a strong EU voice **in the world**, by promoting a **high level of quality, efficacy and safety standards**

Upcoming Pharmaceutical Package

Proposal scheduled now for 26 April, to review:

- ✓ Directive 2001/83/EC (Community Code on medicines for human use)
- ✓ Regulation (EC) 726/2004 on centralised procedure and EMA
- ✓ Regulation (EC) 141/2000 on orphan products
- ✓ Regulation (EC) 1901/2006 on paediatric medicines

Leaked draft (31 January)

Incentives

- Remodulation of **regulatory exclusivities and orphan market exclusivity** to foster access in all EU countries and to address unmet medical needs
- New data exclusivity for **repurposed products**
- **Transferable exclusivity vouchers** for priority antimicrobials -> highly critical due to delayed access to generic and biosimilar and higher costs for healthcare systems
- Clarified **Bolar exemption** to allow timely generic/biosimilar entry at patent/SPC expiry

Leaked draft (31 January)

Other key provisions

- **Regulatory optimisation** (e.g. active substance master file, electronic product information, wording on generic/hybrid/biosimilar application, other regulatory simplifications, real world evidence, digitalisation of the regulatory network and processes)
- **Environmental Risk Assessment** to become a mandatory part of the assessment for all products -> risks of hampering patient access and no provision on reference to the originator ERA
- **Shortages and security of supply** -> notification for withdrawals extended to 12 months and for shortages to 6 months, MAHs to prepare shortage prevention plans

EU-India collaboration

FTA negotiations and the EU-India Trade and Technology Council

Important opportunities to:

- Facilitate open trade by addressing technical barriers & customs duties & improving customs cooperation
- Create new opportunities for EU & Indian companies through non-discriminating procurement practices
- Improve regulatory cooperation & strengthen the supply chains of medicines

Need to avoid discussions on IP and regulatory protections that would delay timely patient access to generic and biosimilar medicines