

Key Trends in Market Access, Pricing and Reimbursement

EU Pharmaceutical Law Forum 2019

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Context

- Patchwork of fragmented national legislations
- Continued and increased pressure on national budgets
- Growing political focus on pricing and access to medicines
- High cost of innovation; blockbuster patent expirations

First Trend: Erosion of Rules Protecting Innovation and Rewarding Risk-taking

- Questioning of pharmaceutical incentives and rewards
 - First concrete result: supplementary protection certificate (SPC) manufacturing waiver
 - Ongoing review of Regulation No 141/2000 on orphan medicinal products and Regulation No 1901/2006 on paediatric medicinal products
- Reimbursement of off-label indications
- Rise of compounding pharmaceuticals
- Compulsory licensing?

Second Trend: Increased Cooperation

- Regional cooperation among Member States in varying degrees on (i) horizon scanning; (ii) Health Technology Assessment (*HTA*); (iii) exchange of pricing information; and (iv) joint procurement/joint pricing negotiations

Example in point: Beneluxa (Belgium; The Netherlands; Luxemburg; Austria; and Ireland – Switzerland expressed an interest as well)

- Proposed Regulation on EU-level HTA
- World Health Organisation as vehicle for procurement of medicines?
- Joint Procurement Agreement

Third Trend: Clamour for Price Transparency

- Secret discounts in Managed Entry Agreements have come under increased scrutiny
- Incipient moves in countries such as Belgium to lift some of the secrecy provisions
- November 2018: UK House of Commons made unsuccessful attempt to compel Vertex to divulge prices applied across Europe for cystic fibrosis medicine Orkambi®
- Italy submits resolution on medicine cost and pricing transparency at current session of World Health Assembly
- Beneluxa Steering Committee, 15 May 2019:
“The members of the Beneluxa Initiative highly value transparency as a key contributor to achieving sustainability of access to medicines. Transparency will assist in improving insight into the inner workings of the pharmaceutical value chain. We strongly support access to data generated by clinical research, including negative and inconclusive outcomes. We welcome a wide debate on these topics and further discussion at international level. The first concrete step should be to create price transparency among countries.”

Fourth Trend: Price Containment through Competition Law Enforcement and Public Procurement

- Application of competition rules to excessive pricing (European Commission; Italy; UK; BE, NL)
- Application of competition rules to alleged collusion (e.g., February 2019 opening of case in Spain against suppliers of radiopharmaceuticals)
- Increasing use of public procurement rules and ancillary reliance on competition rules to ensure unfettered application of public procurement rules



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