Windsor protocol implementation aspects

11th Industry Stakeholder Platform Meeting

Presented by Thomas Girard on 24 November 2023
Regulatory Affairs Office

Background

- The **Protocol on Ireland/Northern Ireland (IE/NI) is part of the** Withdrawal Agreement which establishes the terms of the UK's withdrawal from the EU. Based on this Protocol, EU pharmaceutical law applies to and in the UK in respect of NI only.
- Agreement between the EU and the UK to amend the Protocol in order to address some of the challenges concerning NI following the UK’s withdrawal -> EU Regulation (EU) 2023/1182 of 14 June 2023 (**the Windsor Framework**) sets new terms for the relationships with NI for different areas, including medicinal products for human use.

Regulation (EU) 2023/1182 – Aim/Principles

- With regard to the **supply** of medicinal products in NI:
  - UK to **grant** and **supervise** Marketing Authorisations **under UK law** for medicinal products for human use that are eligible to the centralised procedure that are to be placed on the market of NI

- As a consequence, to **protect** the EU Single Market:
  - Human medicinal products intended to be placed on the NI market can not be moved to any EU/EEA MSs
  - Those medicinal products must be labelled with the words "UK only"
  - Safety features required under the EU falsified Medicines Directive should be removed

Regulation (EU) 2023/1182 – Regulatory Impact on CAPs

- An EU Centralised Marketing Authorisation (CAP) will **not be valid in NI**
- **Labelling** will need to be updated where applicable (local representative in NI to be removed, multi-country packs between an EU MS and NI no longer possible)
- **Reporting of serious ADR** for CAPs in NI would be similar as for CAPs in GB
- **Parallel distribution** with NI cease to be possible for human CAPs
- It is expected that Regulation (EU) 2023/1182 will become **applicable as of 1st January 2025**. The final date will be published in the OJEU following written guarantees to be provided by the UK authorities to the Commission
- A **transitional period** is foreseen for medicinal products lawfully placed on the NI market before the date Regulation (EU) 2023/1182 becomes applicable
- **Specific guidance for CAPs** for human use is in preparation

Regulation (EU) 2023/1182 – Discussion

- Could industry feed-back on the **status of preparation/implementation** of the Windsor framework?

- Could industry feed-back on any **challenges and/or concerns** encountered or expected to face?

- Particular attention should be given to **avoid supply disruptions**, namely with regards to the supply of medicinal products to small markets historically dependent from the UK. Any permanent or temporary cessation **should be discussed forthwith with EMA and relevant NCAs**

Any questions?

Further information

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