HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

HPRA Webinar on Regulation 2019/6

Welcome | Fáilte

31st March 2021

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Objectives

- To raise awareness of upcoming changes that will impact on the regulation of VMPs.
- To focus on aspects of Regulation 2019/6 which will directly affect how MAHs engage with the regulatory system.
- To outline the next steps in the implementation pathway.
- To inform stakeholders where to find relevant information.

Outline of the webinar

- **Introduction** – J. Gabriel Beechinor
- **Union Product Database** – Elaine Hynes
- **Variations** – Mary O'Grady
- **Pharmacovigilance** – Paul McNeill
- **SPC and labelling** – Rhona McHugh
- **Manufacturing and GDP of active substances** – Paul Sexton
- **Complementary national legislation** – J. Gabriel Beechinor
- **Q & A**
- **Conclusion** – David Murphy

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Addressing your questions

- Use the Q&A function to submit questions. Indicate who the question is addressed to.
- There will be a time lapse between submitting a question and it appearing in the feed.
- Answers will be given verbally during the Q&A slot (no written responses during the webinar).
- All questions, and written responses, will be published on the HPRA website.