HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

HPRA Information Day
Regulation 2019/6 – update on implementation
Thursday, 19 May 2022
Virtual meeting

DRAFT AGENDA

10.00 Welcome and opening address

10.10 – 10.40 Session 1

1. Union Product Database - update
2. Variation procedures - update
3. Pharmacovigilance - update

10.40 – 11.00 Session 1: Q&A

11.00 – 11.10 Break

11.10 – 11.40 Session 2

1. Transitioning existing MAs to meet the requirements of Regulation 2019/6
    a. SPC/labelling format (QRD template)
    b. CVMP Q&A on describing adverse events
    c. Classification of VMPs (Article 34)
    d. Requirements for antimicrobials (Article 107)
2. Revised HPRA process for publication of SPCs
3. Revised HPRA policy on requirement for mock-ups
4. HPRA administrative procedure for renewals
5. HPRA procedure for the approval of applications for parallel trade in VMPs

11.40 – 11.55 Session 2: Q&A

11.55 – 12.00 Close and concluding remarks