VIEIRA DE ALMEIDA

SAÚDE

EM DESTAQUE

+a 8 de novembro de 2024

REGULAMENTAÇÃO

EMA

Human Medicines / Human Regulatory

- European Medicines Agency post-authorisation procedural advice for users of the centralised procedure - Type IA Variations (track changes)
- European Medicines Agency post-authorisation procedural advice for users of the centralised procedure - Grouping of variations (track changes)
- European Medicines Agency post-authorisation procedural advice for users of the centralised procedure - Worksharing of variations (track changes)
- EMA Procedural Advice on Recommendations on unforeseen variations according to Article 5 of Commission Regulation (EC) nº 1234/2008 (track changes)
- Template : Letter of intent for the submission of a worksharing procedure to the European Medicines Agency
- List of centrally authorised products with safety-related changes to the product information
- European Shortages Monitoring Platform (ESMP): Implementation guide for marketing authorisation holders
- European Shortages Monitoring Platform (ESMP): Implementation guide for national competent authorities
- Applications for new human medicines under evaluation: November 2024

Veterinary Medicines / Veterinary Regulatory

- Questions and answers on Article 82 referral procedures based on Article 129(3)
- Questions and answers on Article 82 referral procedures

Contactos

saude@vda.pt