VIEIRA DE ALMEIDA

SAÚDE

EM DESTAQUE

24. de fevereiro a 28 de fevereiro de 2025

REGULAMENTAÇÃO

INFARMED	Circular Informativa n.º 012/CD/100.20.200 | Regulamento sobre o controlo de transações de medicamentos para o exterior do país - aspetos práticos.
HMA	**CMDv** Best Practice Guide for advice from CMDv on regulatory matters Best Practice Guide for Variations Requiring Assessment
EMA	**Human Medicines / Human Regulatory** European Medicines Agency procedural advice for users of the centralised procedure for similar biological medicinal products applications [Rev.] Marketing authorisation application (MAA) - pre-submission interactions form European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure[Rev.] List of medicinal products under additional monitoring [Rev.] Addendum to the Guideline on clinical development of vaccines to address clinical trials in immunocompromised individuals Considerations regarding the implementation of ICH M13A on bioequivalence for immediate-release solid oral dosage forms **Veterinary Medicines / Veterinary Regulatory** Guideline on the conduct of efficacy studies for intramammary products for use in cattle [Rev.] Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances - Revision 2 [Rev.] Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations [Rev.]

Contactos

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