SÍNTESE SEMANAL SAÚDE

Saude@vda.pt

10 a 14 de fevereiro de 2020

LEGISLAÇÃO

NACIONAL	Resolução da Assembleia Legislativa da Região Autónoma da Madeira n.º 2/2020/M **Região Autónoma da Madeira - Assembleia Legislativa** Recomenda ao Governo da República para cumprir com a construção do Novo Hospital da Madeira

REGULAÇÃO

INFARMED	Infarmed Notícias nº 70, de fevereiro de 2020 Formulário eletrónico para avaliação da presença de nitrosamina em medicamento **Publicação para efeitos do artigo 15º-A do Decreto-Lei n.º 176/2006, de 30 de Agosto** - pedidos de autorização de introdução no mercado de medicamentos genéricos
SPMS	Boletim Informativo nº 45 Boletim Informativo nº 44 Boletim Informativo nº 43
EMA	**Medicinal Products for Human Use |** Second draft - Revision 1: Public statement on the use of herbal medicinal products containing estragole (new) **Medicinal Products for Human Use |** Overview of comments received on the draft revised Public statement on the use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005 Rev 1) (new) **Medicinal Products for Human Use |** News and press releases: Restrictions in use of cyproterone due to meningioma risk **Medicinal Products for Human Use |** News and press releases: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 10-13 February 2020 **Medicinal Products for Veterinary Use |** News and press releases: Public access to

suspected side effect reports of veterinary medicines

Medicinal Products for Human Use | Report: Applications for new human medicines under evaluation by the CHMP: February 2020 (new)

Medicinal Products for Human Use | Committee meeting report: CAT monthly report of application procedures, guidelines and related documents on advanced therapies: January 2020 (new)

Medicinal Products for Human Use | Plasma master file certificates (updated)

Medicinal Products for Human Use | Regulatory and procedural guideline: Product Management Services - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 2 (new)

Regulatory and procedural guideline: Products Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 6 (new)

Regulatory and procedural guideline: Products Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 7 (new)

Regulatory and procedural guideline: Substances, Products, Organisations, Referentials (SPOR): SPOR API v2 Specification (new)

Medicinal Products for Human and Veterinary Use | Regulatory and procedural guideline: Products Management Services - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe: Introduction - EU Implementation Guide (new)

ICH M9 on biopharmaceutics classification system based biowaivers (updated)

Medicinal Products for Human Use | Article 57 product data (updated)

Medicinal Products for Human Use | Report: List of products granted eligibility to PRIME (updated)

Medicinal Products for Human Use | Report: Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 27-30 January 2020 (new)

Medicinal Products for Human Use | Rewards and incentives for paediatric medicines (updated)

Template or form: Dossier administrative validation checklist (updated)

Medicinal Products for Human Use | programme: Committee for Medicinal Products for Human Use (CHMP): Work Plan 2020 (new)

Medicinal Products for Human Use | PRAC recommendations on signals adopted at the 13-

	16 January 2020 PRAC meeting (new) **Medicinal Products for Human Use |** Human medicines highlights - February 2020 **Medicinal Products for Veterinary Use |** Monthly report on application procedures, guidelines and related documents for veterinary medicines: December 2019 (new) **Medicinal Products for Human Use |** PRAC draft agenda of meeting 10-13 February 2020 (new) **Medicinal Products for Human Use |** PDCO minutes of the 23-26 July 2019 meeting (new) **Medicinal Products for Human Use |** PDCO minutes of the 17-20 September 2019 meeting (new) Regulatory and procedural guideline: Member states contact points for translations review (updated) Report: Final programming document 2020-2022 (new)
HMA	CMDh Minutes from the CMDh meeting with Interested parties - 13 November 2019 PSUR AR for highly refined fish oil (eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) dl-α-tocopherol), glycerol, purified egg, phosphatide); PSUFU AR for valaciclovir; Art. 46 PARs for Sandimmun/Sandimmun Neoral (ciclosporin), Infanrix-IPV/Hib (Diphtheria, Tetanus, Pertussis (acellular, component), Poliomyelitis (inactivated) and Haemophilus type b conjugate vaccine (adsorbed)) and Foradil Aerolizer (formoterol fumarate); UPDATE - Chapter 1: CMDh BPG for the allocation of the mutual recognition variation number for Type I Notifications, Type II Variations, Grouping and Worksharing; UPDATE - 'Blue-box' requirements; UPDATE - CMDh annotated QRD template for MRP/DCP;