EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

New Veterinary Regulation

Regulation (EU) 2019/6

PCWP/HCPWP meeting with all eligible organisations,

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REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 December 2018

on veterinary medicinal products and repealing Directive 2001/82/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.004.01.0043.01.ENG&toc=OJ:L:2019:004:TOC

Main objectives
Veterinary Medicines Regulation

- Tackling AMR
- Reduction of administrative burden
- Increase the availability of veterinary medicinal products
- Stimulate competitiveness and innovation
- Improve the functioning of the internal market for veterinary medicinal products

Innovative medicines authorised in the EU in the last few years

2016
CLYNAV - biotechnological vaccine based on a DNA plasmid that protects Atlantic salmon against pancreas disease caused by infection with salmonid alphavirus subtype 3

2017
CYTOPOINT - the first monoclonal antibody in a veterinary medicine. Intended for the treatment of dogs with atopic dermatitis. Solution for injection containing the new active substance lokivetmab

2019
Arti-Cell Forte - stem cell-based veterinary medicine intended for the reduction of mild to moderate recurrent lameness associated with non-septic joint inflammation in horses; *HorStem* – stem cell-based veterinary medicine for the reduction of lameness associated with mild to moderate degenerative joint disease (osteoarthritis) in horses

New Veterinary Regulation: opportunities provided

- Data protection periods increased
- Provides for elaboration of technical requirements for novel therapies
- Limited markets provision
- Opening up of the centralised procedure
- Obligation on MSs to assist applicants, in particular SMEs

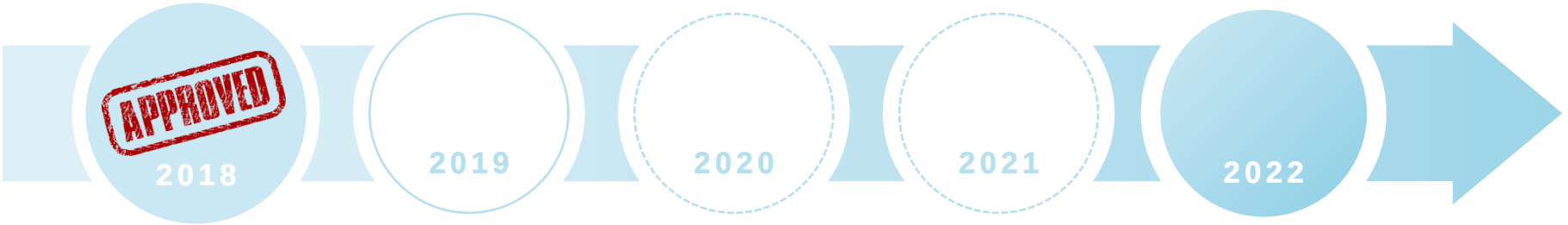
We've come a long, long way already…

- ✓ After four years of negotiations, European Parliament and Council approved the new Regulations on veterinary medicines and medicated feed on 25 October and 26 November 2018
- ✓ The new Regulation on veterinary medicinal products repeals the Directive 2001/82/EC and amendment to Regulation 726/2004

… now we're on our way…

Regulation (EU) 2019/6

- published on 7 January 2019; coming into effect on 27 January 2019
- 3 years implementation period (applicable from January 2022)
- 20 Implementing or Delegated Acts foreseen to be developed in implementation period



New Veterinary Regulation: EMA Role in implementation of NVR

- The Agency Provides scientific and technical recommendations as and when requested by the EC
- Responsible for:

➢ Revising procedures and regulatory and scientific guidance documents

➢ Leading the implementation of IT systems required by the regulation

➢ Implementing the outcomes of the implementing and delegated acts.

Mandates from the EC for scientific advice

First 7 mandates for recommendations/scientific advice from European Commission:

- Revision of Annex II (dossier requirements); esp. to introduce requirements for biologicals and novel therapies (Aug 2019)
- Variations: list of variations not requiring assessment (Aug 2019)
- Criteria for designating antimicrobials restricted to human use only (Oct 2019)
- Collection of data on antimicrobial medicinal products used in animals (Aug 2019)
- Pharmacovigilance: format and content of the Pharmacovigilance System Master File and its summary
- Good Pharmacovigilance Practice (to replace Volume 9B) (June 2020)
- Specifications for Union Product Database (going beyond master data covered by SPOR) (due Aug 2019)

Antimicrobial Resistance - Articles 36, 37

37: **Refusal**:

*"the veterinary medicinal product is an **antimicrobial veterinary medicinal product** presented for use **as performance enhancer** in order to promote the growth of treated animals or to increase yields from treated animals"*

*"the **risk for public health** in case of development **of antimicrobial resistance** or antiparasitic resistance **outweighs the benefits** of the veterinary medicinal product to animal health"*

*"A marketing authorisation for an antimicrobial veterinary medicinal product shall be refused if the **antimicrobial is reserved for treatment of certain infections in humans**"*

AMR Art. 107 - Use of antimicrobial medicinal products

*1- **Antimicrobial** medicinal products shall **not** be applied routinely nor used **to compensate for poor hygiene, inadequate animal husbandry or lack of care** or to compensate for poor farm management.*

*2. **Antimicrobial** medicinal products shall **not be used in animals for** the purpose of **promoting growth** nor to increase yield.*

Article 118 - Animals or products of animal origin imported into the Union

1. Article 107(2) shall apply, mutatis mutandis, to ***operators in third countries*** *and those operators shall not use the designated antimicrobials referred to in Article 37(5), insofar as relevant in respect of animals or products of* ***animal origin exported from such third countries to the Union****.*

REGULATION (EU) 2019/4 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 December 2018

on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.004.01.0001.01.ENG&toc=OJ:L:2019:004:TOC

New Veterinary Regulation: opportunities provided

- To fight AMR
- To support innovation and product development (flexibility to deal with the complex area of novel therapies)
- To increase efficiency of regulatory processes
- To adopt a more effective risk based approach to activities/decision making
- To foster proportionate decision making

….while promoting and protecting animal and public health, and the environment.

Any questions?

Further information

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