EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Revision of Good Manufacturing Practice Guidelines for Medicinal Products for Veterinary Use

Vet Info Day 13th May 2022

Presented by Brendan Cuddy

The Good Manufacturing and Distribution Practices Inspector Working Group

- The GMDP IWG is a working group of the Agency that aims to increase harmonisation amongst member states in Inspectional practices and procedures, and establish harmonised guidelines for industry operating in the environment.
- It is made up of senior inspectors from every EEA member state, and it is attended by the European Commission and observed by inspectors from MRA & other international agreement partner authorities (*CH, JPN, USA, NZ, AUS, IS, CAN, UK,*), and international partner organisations WHO and EDQM.
- It has a triple mandate to the Agency, to the European Commission and to the Heads of Medicines Agency.
- It covers the manufacture and distribution of medicines for human and for veterinary use and marketed medicines as well as investigational medicinal products as well as active substances.

The Good Manufacturing and Distribution Practices Inspector Working Group

- The GMDP IWG also serves overseeing the maintenance and development of the EUDRAGMDP database. Member states enter;
  - Manufacturing and wholesale dealer authorisations.
  - GMP and GDP Certificates and non-compliance statements.
  - Registrations manufacturers, importers and distributors of active substances.
  - 3rd country inspection planning information.

Introduction to Good Manufacturing Practice (GMP)

- Currently the principles of good manufacturing practices for medicinal products for human and veterinary use are laid down in **Commission Directive (EU) 2017/1572**, and **Commission Directive** 91/412/EEC respectively.
- Volume 4 of "The rules governing medicinal products in the European Union" contains guidance for the interpretation of these principles as detailed guidelines for medicinal products for human and veterinary use.
- Basic GMP requirements for medicinal products are described in Part I and II of Volume 4, covering basic principles and concepts for Quality management and basic requirements for manufactures of medicinal products and active substances to achieve these principles.

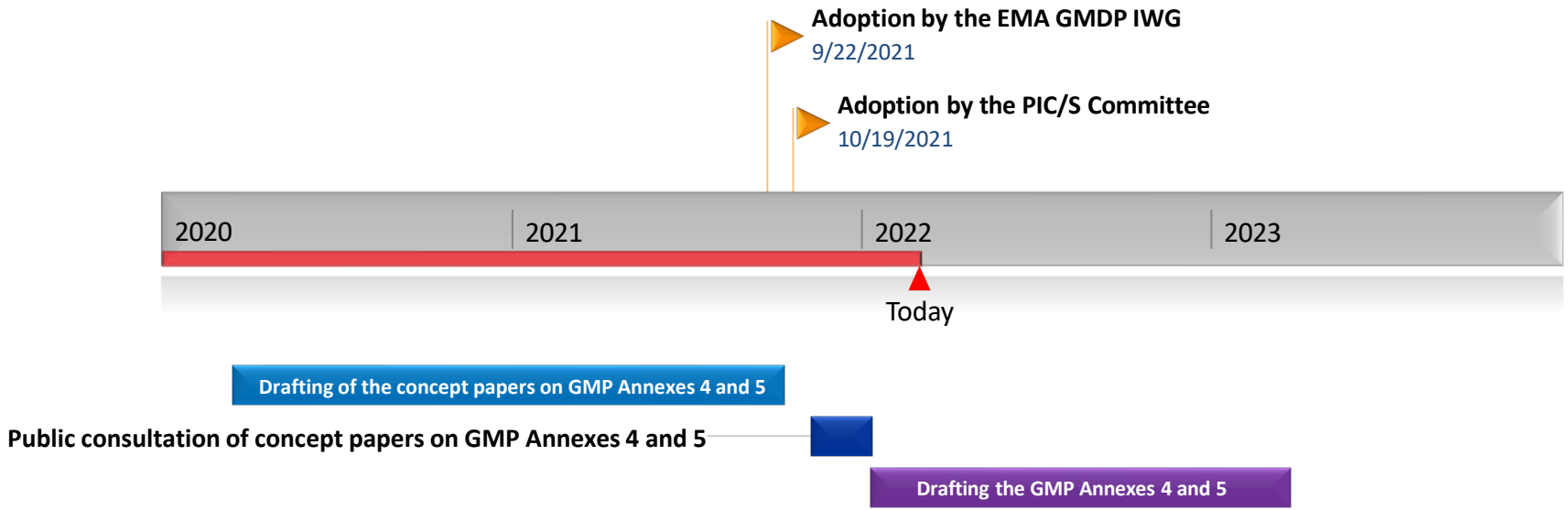
Introduction to Good Manufacturing Practice (GMP)

- Detailed technical requirements are found in a set of technical annexes which cover specific process types or product types and which may apply simultaneously.
  - Annex 4 covers manufacture of veterinary medicinal products other than immunological veterinary medicinal products.
  - Annex 5 covers manufacture of immunological veterinary medicinal products.
- Annex 4 and Annex 5 are common to the member states of the European Union (EU)/European Economic Area (EEA) as well as to the participating authorities of the Pharmaceutical Inspection Co-operation Scheme (https://picscheme.org/en/members).
- Need for a coordinated approach to any revision with a drafting group drawn from EEA GMDP IWG and PIC/s Working Group on Veterinary Medicinal Products to ensure international harmonization of GMP requirements.

Reasons for Revision of current GMP Guidance

- Annex 4 & 5 were originally published in 1992 and have not been updated since publication.
- To facilitate the implementation of the principles set by international GMP guidelines;
  - The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q8, Q9, Q10 and Q11 guidelines,
  - International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines.
- To extend the underlying concepts to include new areas of technology (e.g. novel therapy products), new processing methods, new products not previously covered.
- To clarify areas that have been highlighted as ambiguous due to the age of the document.
- Extending the scope of this guideline to good manufacturing practice for the manufacture and import of investigational veterinary medicinal products used in veterinary clinical trials.

Current status



Source: IFAH and SIMV

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Global feedback on Concept Papers

Annex 4

- Access VetMed (European Group for Generic Veterinary Products)
- AnimalHealthEurope
- Association of Veterinary Consultants (AVC – clinical trials)

Annex 5

- AnimalHealthEurope
- SIMV (French association for animal health industry)
- European Manufacturers of Autogenous vaccines and Sera - EMAV

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Global feedback

- Global strong support expressed for reviewing the “old annexes”
- But some reminders of specific context of veterinary domain:
- The needs of the veterinary sector differ substantially from those of the human sector in relation to medicinal products. In particular,
  - The drivers for investment are different.
  - There are many different animal species, which creates both a fragmented market and the need for major investments in order to extend the authorisation of veterinary medicinal products existing for one animal species to another.
  - The price-setting mechanisms in the veterinary sector follow a completely different logic.
  - The size of the industry is only a small fraction of the size of the pharmaceutical industry for medicinal products for human use.

Global feedback

- Some warning about the potential negative impact on enhancing too high the level of expectations in some areas:
  - e.g. veterinary medicinal product for clinical trials
  - e.g. autogenous vaccines
  - e.g. novel therapy products

- Various suggestions on specific topic for what should be in the Annexes ("shopping lists" sent in parallel to comments of public consultation)

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Drafting the new version of Annex 4 and Annex 5

For each annex:

- Clarify the scope and the expectations
  - Type of product, dosage forms…
  - Type of process
  - "Shopping list" from industry and authorities
- Set the structure
- Elaborate a timetable
- Presentation of drafted annexes at GMDP IWG & PIC/s
- Stakeholder consultation on drafted annexes.

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GMP deliverables – Regulation (EU) 2019/6

Art. 93(2)

The Commission shall, by means of implementing acts, adopt measures on good manufacturing practice for veterinary medicinal products and active substances used as starting materials

Art. 153(4) - The implementing act to be adopted at the latest by **29 January 2025**

Conclusion

- A substantial modernisation of EU GMP guidance for medicinal products for veterinary use is underway. International harmonisation is assured through co-operation and collaboration with PIC/s.
- Stakeholder engagement through;
  - Consultation on concept papers;
  - Discussion at GMDP IWG Interested Parties Meeting;
  - Consultation on draft Annexes when published.

Any questions?

Further information

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