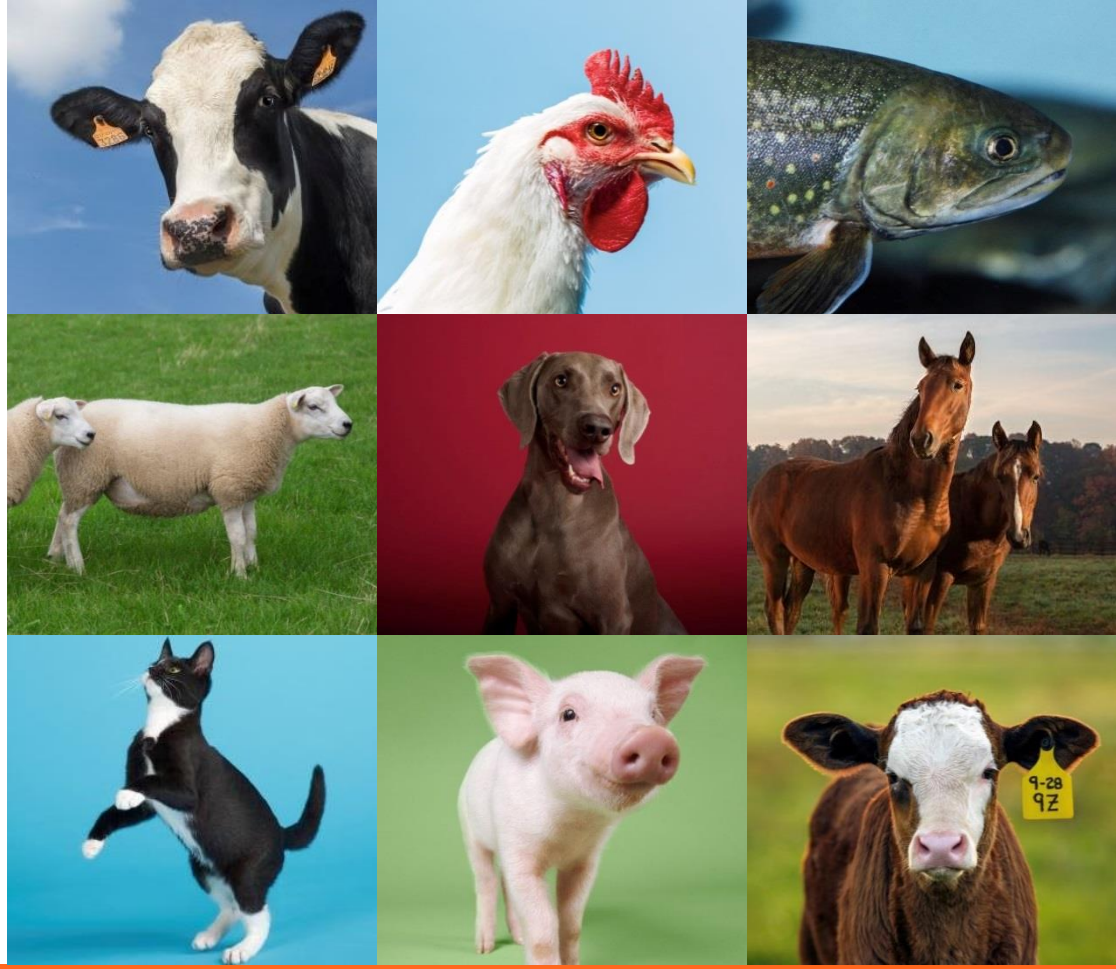
Data Protection for Veterinary Medicinal Products



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Agenda

- What is Data Protection?
- Patents
- Generics
- Data Protection Periods in the EU
- Benefits of Data Protection

What is Data Protection?

- **Data Protection is the mechanism used by Regulatory Authorities to temporarily prevent a “generics” company from referring to data generated and submitted by an “innovator” company**

- Data Protection may also be known as:
  - Protection of Technical Documentation
  - Market Exclusivity

- Data Protection delays the introduction of generic products in a market, even in the absence of a Patent
- Data Protection and Patents are separate, unrelated devices, although they may achieve a similar result

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Reasons for Lack of Patent Protection (examples)

Patent: A title granted by public authorities that confers a temporary monopoly for the exploitation of an invention upon the person who reveals it, furnishes a sufficiently clear and full description of it, and claims this monopoly (WHO)

- A patent is **temporary** and granted to the person/company who **first** reveals the invention
  - Drug discovery, development and registration takes a long time; patent applications must be made as early in the process as possible
  - A patent may already be close to expiry when the product is first launched in the market
  - Narrow window of opportunity to extend the patent validity at product registration (Supplementary Protection Certificate; SPC)
- A patent is only granted for an invention, i.e. something **novel**. The patent could be for a molecule, formulation, manufacturing process, therapeutic claim, etc, but it must always be proven to be new
  - If an existing molecule is formulated and/or used in a different way it may not qualify for a patent
  - Product registration may still require submission of complete quality, safety and efficacy data
  - There is no correlation between eligibility for a patent and registration dossier requirements

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What is a Generic?

- The name and the definition varies around the world:
  - WHO: generic medicine
  - US FDA: generic new animal drug product
  - EU: generic veterinary medicinal product

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Definition of a Generic – WHO

Generic medicine:

- A pharmaceutical product usually intended to be interchangeable with the originator brand product, manufactured **without a licence from the originator** manufacturer and marketed **after the expiry of patent or other exclusivity rights** …

Originator pharmaceutical product/originator brand:

- Generally the product that was first authorized world wide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorization …

Patent:

- A title granted by public authorities that confers a temporary monopoly for the exploitation of an invention upon the person who reveals it, furnishes a sufficiently clear and full description of it, and claims this monopoly.

https://www.who.int/medicines/areas/access/NPrices_Glossary.pdf

Definition of a Generic – US FDA

- The law […] provide[s] for the approval of generic copies of new animal drug products that have been previously approved and shown to be safe and effective when used according to their approved labeling. […] a generic sponsor must demonstrate, among other things, that its proposed generic new animal drug product has the same active ingredients, in the same concentration, as the approved reference-listed new animal drug product, and that it is **bioequivalent** to the reference-listed new animal drug product.

Reference-listed new animal drug product (RLNAD)

- The approved RLNAD that the generic sponsor intends to copy must be identified.

Patent Information

- The application provides certification by the applicant that a patent does not exist, that a patent has expired …

Bioequivalence

- The application contains information to show bioequivalence between the proposed generic new animal drug product and the RLNAD …

Marketing exclusivity

- **is the period of time** [normally 3 - 5 years] **during which we** [US FDA] **will not approve a generic copy** of the approved RLNAD …

https://www.fda.gov/animal-veterinary/guidance-regulations/generic-animal-drug-and-patent-term-restoration-act-gadptra
https://www.fda.gov/media/69950/download

Definition of a Generic – EU

Art 4(8)

- 'reference veterinary medicinal product' means a veterinary medicinal product authorised in accordance with Article 44, 47, 49, 52, 53 or 54 as referred to in Article 5(1) on the basis of an application submitted in accordance with Article 8 [including documentation on quality, safety and efficacy]

Art 4(9)

- 'generic veterinary medicinal product' means a veterinary medicinal product which has the same qualitative and quantitative composition of active substances and the same pharmaceutical form as the reference veterinary medicinal product, and with regard to which **bioequivalence** with the reference veterinary medicinal product has been demonstrated

Art 18(1)(c)

- [An application for a generic veterinary medicinal product is not required to contain documentation on safety and efficacy if, inter alia] the applicant demonstrates that the application concerns a generic veterinary medicinal product of a reference veterinary medicinal product for which the **period of protection of the technical documentation** laid down in Articles 39 and 40 has elapsed ...

Art 18(6)

- … those parts of the summary of the product characteristics [SmPC] of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are still **covered by patent law** at the time when the generic veterinary medicinal product is authorised [may not be included in the SmPC of the generic]

 Regulation 2019/6: https://eur-lex.europa.eu/legal-content/AUTO/?uri=CELEX:32019R0006&qid=1642752684371&rid=1

Common Features of Generics

- There must be an originator or reference product on which to base the generic application and approval
  - Bioequivalence should be demonstrated, or its omission justified
  - Reduced data requirements (and R&D costs) are a major incentive to manufacturers
- The registration holder of the reference product is not required to give their consent for the generic applicant to refer to their registration
  - In the US and EU, the reference product must be authorised in the US or EU, respectively
- All Regulatory Authorities should respect International Patent Law and not authorise (or allow marketing of) a generic medicine that would be in breach of the applicable Patents in their market
- Some countries also apply Market Exclusivity or Data Protection rules which operate independently from Patents

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Periods of Protection of Technical Data in the EU since 28 January 2022[1]

Species	Products	Initial Period of Protection[2]	Additional Periods of Protection	
Cattle, Sheep[3], Pigs, Chickens, Dogs, Cats	All, except new antimicrobials	10 years	Plus 1 year for each new species, to a maximum of 18 years in total	Plus 4 years for certain formulation, administration route or dosage changes[5]
	New antimicrobials[4]	14 years		
Bees	All	18 years	N/A	
All other species	All	14 years	Plus 4 years for one or more new species, to a maximum of 18 years in total	

[1] Different periods of protection (10 – 13 years) apply to products registered between 30 October 2005 and 27 January 2022 (see Directive 2001/82)
[2] Periods of protection of technical data apply from the date of product registration
[3] Sheep for meat production; sheep for milk production are included in "other species"
[4] An antimicrobial active substance which has not been an active substance in a veterinary medicinal product authorised within the EU on the date of the submission of the application
[5] Changes intended to reduce antimicrobial or antiparasitic resistance, or to improve the benefit-risk balance

See Regulation 2019/6, Articles 39 and 40 for full conditions
https://eur-lex.europa.eu/legal-content/AUTO/?uri=CELEX:32019R0006&qid=1642752684371&rid=1

Benefits of Data Protection

- Guarantees a period when the innovator company can establish their new Brand in the market and recover a part of their R&D investment
  - Discovery, development and registration of a new veterinary medicinal product typically takes more than 10 years and, in the EU, costs ca. EUR 10M (rising to ca. EUR 50M for some innovative products[1])
- Can be applied to all products, regardless of Patent status, and so provides a level playing field for all innovator companies
  - Particularly important to SMEs and Biotech companies exploring new technologies
- Can be tailored to meet the specific needs of the market
  - e.g. assign longer protection periods to certain species or therapeutic areas to encourage investment in areas with unmet clinical needs
- Encourages the registration of new products in the market
  - Promotes animal health and welfare, and increases customer choice
  - Provides the substrate for the generic products of the future (Data Protection is time-limited)

[1] https://www.animalhealtheurope.eu/component/attachments/attachments.html?id=310

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