POSITION PAPER

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The protection of registration data for existing and new veterinary medicinal products

IFAH, the International Federation for Animal Health, supports legislation which provides effective and adequate protection of regulatory data submitted for the market approval of new and existing veterinary medicinal products (i.e. veterinary pharmaceuticals, vaccines and other animal health products) against unfair commercialization.

Introduction

The development and bringing to market of a new veterinary medicinal product requires the originator to conduct extensive chemical, pharmacological, toxicological and clinical research and testing, at an average cost which may reach 250 million US $, and taking 6 to 12 years to complete. The data generated by such work, while proprietary to the originator, must be submitted to the regulatory authorities of countries around the world in order to obtain approval to market the medicine.

The approval process is the essential assurance to veterinarians, farmers, pet owners and the general public that veterinary medicinal products meet established regulatory requirements for safety, efficacy and quality. Such data for market approval of products is provided to regulatory authorities at the expense of the manufacturer and are developed for a product with a specific quality profile.

The studies are provided to regulatory authorities on the understanding that they are considered as proprietary data and so cannot be disclosed to or relied upon by third parties for their own regulatory submissions for a defined period. This is known as the data protection or data exclusivity period.

Studies regarding new chemical entities are protected against any unfair commercial use pursuant to Article 39 of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which precludes third parties from unfairly relying on proprietary data for commercial purposes (for example, obtaining market approval).

For veterinary medicinal products IFAH considers the TRIPS minimum standard on the protection of safety and efficacy data to be applicable to new chemicals/products but also to existing ones when new data that involve a considerable effort have been generated for new uses or maintenance of the market approval. All Member States of WTO (World Trade Organization) under which the agreement has been established have committed to implement such concepts in their national legislation.

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IFAH position on minimum criteria for the protection of registration data for existing and new veterinary medicinal products

Effective protection of proprietary safety and efficacy data from unfair commercial use requires:

- Ensuring a minimum ten-year data exclusivity period for new veterinary medicinal products, to the holder of the original market approval (beginning from the date of market approval of the innovative product in the country where the product is approved).
- Providing five years of data exclusivity for additional information required to extend the label (e.g. an additional species, indications, formulations….) and/or maintain the market approval (re-registration).
- Authorizing the market entry of a referencing product following the expiry of the data exclusivity period based on safety and efficacy data generated by the first registrant should include a provision for the copy product registrant to demonstrate that safety and efficacy of the referencing product is equivalent to the original product, and that the copy product therefore does not represent an unacceptable risk to animals, users, the environment, or public health in general.
- Establishing that any publication of data summaries prior to the expiration of data exclusivity periods for the benefit of transparency does not represent disclosure to the public domain and the loss of protection.
- More far reaching national or regional legislation apply and supersede the above criteria that are considered to constitute the minimum standards.

A data exclusivity period during which no third party may enter the market without filing its own safety and efficacy data – unless it has the approval of the titleholder of the data – is a widely adopted mechanism to protect regulatory data against unfair commercial use.

Abbreviated approval procedures

Abbreviated approval procedures allow registrants to copy a veterinary medicinal product and obtain market approval without filing the corresponding safety and efficacy studies. Market approval is granted based on the established safety and efficacy data package of a reference product filed by the first registrant (normally the innovator) which has previously been evaluated by the regulatory authority.

International regulatory and legal standards require that abbreviated approval procedures are only granted for substances and products which:

- have obtained legitimate access to the supporting studies; and
- meet the corresponding quality requirements and bio-equivalence standards.

Approval granted to nonequivalent formulated products potentially jeopardizes public health, animal health, the environment, and potential viability of farming enterprises.

Article 39 of Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement

TRIPS Article 39 creates obligations to protect safety and efficacy studies against both unfair commercial use and disclosure into the public domain.

The obligation to protect against unfair commercial use is typically limited in time by a redefined exclusivity period. Exclusivity periods are implemented to provide an adequate balance between protecting the efforts and investments of the generator of the regulatory data and enabling market entry of generic products after expiry of the exclusivity periods, without requiring the independent duplication of safety & efficacy studies.

The obligation to protect against the disclosure of the data persists even after the expiration of the exclusivity period. Expiry of exclusivity for regulatory data does not constitute the release of the information into the public domain. On the contrary, the information continues to be the sole property of the submitter and must continue to be protected against disclosure.

The partial disclosure of data for noncommercial purposes (e.g. in order to allow third parties to consult and discuss the results of the studies) permitted under TRIPS Article 39 does not imply that the protection against unfair commercial use is lost. Test data are viewed as a whole, and revealing a part of the data does not imply that the complete studies have been placed in the public domain, nor that protection is lost. Likewise, data does not lose protection against unfair commercial use when, after it is filed with the authority, it becomes necessary to disclose test data results in the public interest. Therefore safety and efficacy studies remain de jure undisclosed, notwithstanding the fact that summaries or abstracts of them are published. Following any such disclosure article 39 states “steps [must be] taken [by TRIPS members] to ensure that the data are protected against unfair commercial use”.

Research & Development for Animal Health products

As the amount of data required to gain approval to market products with new active ingredients increase around the world, so does the interest in the protection of the intellectual property which supports the approval. With many millions of euros and dollars being spent on the development of products it is of great concern to primary producers (innovators) that they have sufficient opportunity to obtain a reward (a financial return on the investment) for the generation of the data and the expenses associated with their investment, without unfair competition.

In this regard regulatory data protection must be differentiated from patent protection. Patent protection is the reward for the disclosure of an invention and for carrying out the basic research, whereas data protection is the recompense for investing in the necessary supporting data and for taking the risk that the results will be acceptable. Such regulatory Data Protection / Data Exclusivity is therefore a second essential issue for investments in innovations of the Animal Health industry. Since more and more “older” compounds (without any patent protection anymore) from the human pharmaceutical as well as from crop protection side are being developed by the AH industry, the regulatory data protection principles are of greatest, increasing importance to IFAH.

Effective implementation of an adequate protection period for submitted regulatory data permits the Animal Health industry to continue the costly development of new veterinary medicinal products and to maintain existing approvals and availability of veterinary medicines.

Conclusion

The protection against unfair commercial use of undisclosed safety and efficacy test data filed for the approval of new veterinary medicinal products must not be lower than 10 years of data exclusivity and 5 years data exclusivity for any additional documentation required to extend the label and/or maintain existing approvals.

The effective implementation and enforcement of such provisions is vital for innovation in the veterinary sector, to ensure confidence and stimulate research and development investment, making it possible to develop modern and innovative veterinary medicinal products.
Such principles are a key driver for a sufficient availability of veterinary medicines in the future.