COM(2014) 558	**1st Reading EP started in October 2014**
Lead committee: ENVI	**Opinion committee: AGRI**

REGULATION ON VETERINARY MEDICINES

TOPIC: STIMULATING INNOVATION

What is the issue?

The legislation allows a company to cross-refer to the data of another company in order to produce and market a generic version of a medicine without contributing towards the costs of developing the original product. It is a major disincentive towards investment in new products and other innovation if your competitors can directly benefit from your investments.

To allow the originator to obtain a financial **return on their investment** (**ROI**) in product development and registration within a reasonable period of time, the generic company is prevented from cross-referring to the originator's data for a set period of time. These "protection" time periods are defined in the COM proposal in **Section 8 - Protection of technical documentation** (i.e. the scientific studies that comprise the data dossier).

What is the current data protection system?

The current system is "10+1+1+1 years", as described below:

- A new veterinary medicine has 10 years "protection" from the date of first registration.
- This period can be extended by +1 year for the addition of a new food-animal to the product label provided it is done within 5 years of the registration of the first product.
- This period can be extended up to 3 times (+1+1+1), so the maximum possible data protection is 13 years if 3 additional food-animals can be added within the deadline.
- The data dossiers for fish and bee medicines get the maximum 13 years of protection.

The big challenge

- The veterinary medicines market is small - 1/40th of the size of the human medicines market - and this small market is also fragmented across multiple animal species.
- Product development costs are high (similar requirements to human medicines); for food-animals extra data are needed to address both consumer and environmental safety.
- In this market obtaining a ROI within a reasonable period of time is very challenging and is only possible for products for "major" species.
- Incentives to develop/update and improve existing products are missing.

What is the problem with the current system?

- There is no protection for significant data packages submitted to the authorities for the improvement of existing products – such as new formulations and updated dosing regimens. Therefore there is no investment into the stock of existing products.
- The +1 year is not a sufficient incentive to stimulate the investment in redeveloping the product to include other species (where applicable).
- The 5 years deadline to develop and register 3 additional species is simply not feasible.
- The restrictions on the use of antibiotics and unpredictable market influences are a major disincentive to develop new antibiotics for veterinary medicine.

Consequently innovation in the veterinary medicines sector has declined significantly.

P.T.O.

What is proposed in COM(2014) 558?

- The Commission has proposed some improvements to the system (see column 3 in the table below).
- **However** - the changes as proposed will not be sufficient to address the problem and to stimulate an increase in investment in innovation in the veterinary medicines sector:
  - **There is no protection to support investment in existing products**
  - There is no incentive to add a major species to the product (we already know +1 year does not work from experience with the current Directive)
  - Maximum incentive is needed to stimulate investment in new antibiotics

What is the solution?

Give protection to significant new investments for improvement of existing products.
Improve the basic periods of protection for all additional species (major and minor).
Give maximum stimulus for research into new antibiotics for veterinary medicine.

- **For existing products**: allow **5 years** protection for significant investments in data generated to improve an existing product.
- Increase the additional periods of protection for both major and minor species, and consequently also the maximum attainable period of protection - the impact assessment recommended extensions of +3 years and a maximum period of 20 years (page 38).
- Multiple species in the original dossier should qualify for the extended protection period.
- Grant 20 years protection for the development of a new antibiotic, which would be more proportionate with the requirements for its development and the restrictions on its use.

The EU market for Animal Health products is valued at over €4 billion euro and supports over 50,000 jobs. In order to retain competitiveness on the global level, it needs to have legislation that is supportive of innovation in Veterinary Medicines.

Table: The existing situation and what is needed (in years)

	Current	COM(2014) 558	What is needed
New data packages for existing products			5 years (stand-alone)
1st product (1st species) – can be extended	10 years	10 years	10 years
- extended by adding another species	+1 for food-species	+1 for a major species +4 for a minor species	+3 for a major species +5 for a minor species
Max. prolonged period	13 years (i.e. 10+1+1+1)	18 years	20 years
Minor species	13 fish and bees only	14 for minor species 18 for bees	15 for minor species 20 for bees
NEW antibiotic	-	14 years	20 years

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