

## **PM+: Veterinary medicines review must put investment in innovation first**

Written by Rick Clayton on 19 May 2015 in Opinion Plus  
Opinion Plus

Current EU veterinary medicines review lacks focus on ROI for innovative companies, argues IFAH-Europe's Rick Clayton.



Just under €130m and anything between 6-12 years; this is the general cost and average time it can take to develop a veterinary medicine.

European legislation currently permits a second company to cross-refer to the original developer's data after a period of time.

This period of time is essential in allowing the first company to gain a return on their considerable investment, so improving this period of protecting technical documentation is now more important than ever before, especially in ensuring we have the full range of veterinary medicines to safeguard animal health and welfare at our disposal.

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It's really that simple. Without technical documentation protection - when bringing veterinary medicines to market - there will be no investment.

Without investment in research, fewer products will become available, impacting on the treatment and care options available for Europe's pets and food-producing animals.

A research-based company invests both time and money into producing new products or improving on existing products. In order for that company to deliver a financial return on its investment (ROI) within a reasonable timeframe, it needs the assurance that a second company cannot cross-refer to its data for a certain amount of time.

If not, then there will be little incentive for research-based companies to invest in product development. At the end of the day this won't benefit anyone, including the makers of generic products.

There are several points to bear in mind when it comes to data protection in the veterinary medicine sector: we are a small market - about 1/40th the size of human medicines - and unlike human medicines, our market is further subdivided as we deal with multiple species.

Consequently, our product development costs are disproportionately higher when compared to the target market. On top of that, the veterinary medicines market is a free market (no fixed prices or state subsidies), meaning that prices must be competitive.

These three factors combine to make it very difficult to obtain an ROI in the veterinary medicines sector and it is generally only possible for the 'major' species.

Currently, sufficient incentives to stimulate innovation are lacking and this has inevitably led to a decline in innovation within the sector.

The current EU review of veterinary medicines legislation does make some improvements but still leaves several major gaps.

For example there is no protection for significant new investment into improving existing products - this we believe at IFAH-Europe is a major lost opportunity and there is a legal precedent that five year's protection should be allowed for these.

Further improved data protection is also needed to encourage companies to continue investing in new medicines beyond the 'first' species and to extend use to other species. Currently the protection periods for this are insufficient and ineffective.

Finally, a special case must be made to help stimulate research into new veterinary antibiotics by granting a 20 year protection, as these products are subject to particular hurdles from increased data requirements, restricted market use, and an unpredictable market environment.

The animal health market in Europe is estimated to be worth around €4bn and supports over 50,000 jobs. If we are to remain competitive at a global level, we need legislation that will support more investment in innovation in Europe.

## About the author

Rick Clayton is technical director for IFAH-Europe

IFAH-Europe is the representative body of manufacturers of veterinary medicines, vaccines and other animal health products in Europe. It promotes a single market in veterinary medicines across the EU ensuring the availability of medicines to protect the health and welfare of animals. More information on [www.ifaheurope.org](http://www.ifaheurope.org) [3], on Twitter as @IFAHEurope, and on Facebook: [www.facebook.com/WeCare.petsEurope](http://www.facebook.com/WeCare.petsEurope) [4]

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