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PM+: Time to simplify complex EU animal medicine rules

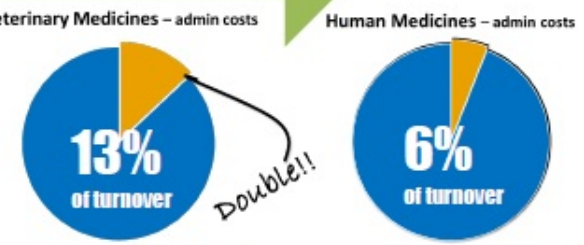
Written by Rick Clayton on 11 May 2015 in Opinion Plus
Opinion Plus

Cutting the red tape surrounding veterinary medicines will free up resources and bring new innovation, argues Rick Clayton of IFAH-Europe.

Veterinary vaccines and medicines play an essential role not only in safeguarding public and animal health but also as key tools supporting Europe's agri-food business.

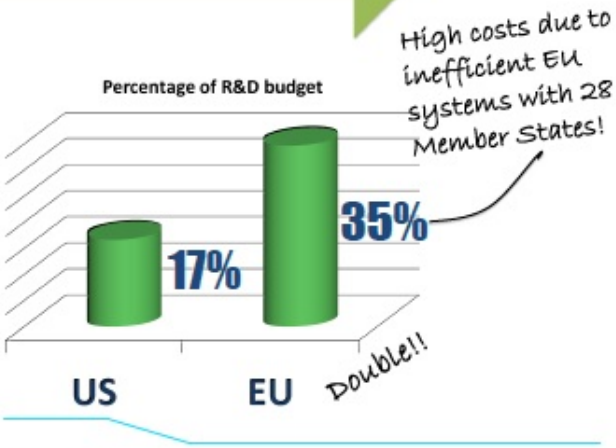
Animal Medicines in Europe:
The Administrative Burden

Vet/human comparison



The breakdown (€M / annum)

Costs of Defensive Research
Necessary to maintain a product range



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Representing the European Animal Health Industry

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Revised legislation governing veterinary medicines is currently on the European parliament's environment, public health and food safety committee agenda, so now is the moment to simplify the overly complex and burdensome administrative procedures and create a streamlined approach to developing these vital tools for Europe's farmers, veterinarians and pet owners.

Europe's animal-based products are worth approximately €141m a year at producer level so keeping these animals healthy is crucial.

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It also is interesting to note that the European single market exists in terms of the free movement of animals, of animal-derived products, and for food, but strangely not for animal medicines.

Another interesting fact, unearthed by the European commission's own impact assessment carried out prior to the current legislative review, is that the administrative burden on the veterinary medicines sector is double that of the human medicines sector - 13 per cent against six per cent (as a proportion of turnover).

Looking at the detail (see infographic), the big culprits are basically the regulatory systems used to submit variations to a marketing authorisation (MA) and the complexity of packaging requirements for the European market.

So how can this burden be significantly reduced - without lowering high levels of public safety - to free up scarce resources for more productive tasks such as developing and bringing new innovations in animal health to the marketplace?

The commission has made several proposals towards this goal, such as opening up the 'centralised' procedure to any product (currently restricted to innovative and 'biotech' products).

IN PARLIAMENT

Later this week (Wednesday 6 May) MEPs in the European parliament's environment, public health and food safety committee will consider the draft report on Veterinary medicinal products by veteran French EPP deputy Françoise Grossetête.

A centralised procedure resulting in a single marketing authorisation for Europe is much more efficient than a multiple member state system which, unsurprisingly, results in multiple national authorisations.

Also a considerable amount of paperwork can be cut by moving from bureaucratic processes to risk-

based processes, such as those proposed for the 'variations' and pharmacovigilance procedures.

If we can make these two systems effective and efficient then the need for a five-year renewal of the MA becomes redundant.

The variations system should keep all the necessary paperwork well up to date. If we can continually monitor the safety of the product in the marketplace with an efficient pharmacovigilance system, then there is clearly no point waiting until a fixed five-year time-point to review the safety of the product.

So what more can be done? In the 'centralised' procedure, run by the European Medicines Agency, there is a majority voting system in the scientific committee for veterinary medicinal products.

Introducing this voting system in the decentralised procedure is another good proposal from the commission, as it will help streamline things. However we need to ensure that introducing this results in a single EU marketing authorisation, and not in multiple national MAs.

Similarly, regarding harmonisations of the conditions of use of like-for-like products, the efforts involved in this harmonisation should be rewarded by allowing for multiple national MAs to be turned into a single European MA.

The goal must be to halve the current administrative burden by streamlining all these administrative tasks.

According to the impact assessment, this would free up around €270m which could be invested in the development of new veterinary medicines and vaccines to the benefit of the health and welfare of Europe's animals.

Keeping in mind the Europe 2020 strategy for growth and European commission president Jean-Claude Juncker's commitment to reducing administrative burdens, we need to be bold in our policymaking.

We must cut down on red tape where possible and forge a pathway to renewed investment and innovation in animal health.

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 [4], on Twitter as @IFAHEurope, and on Facebook: www.facebook.com/WeCare.petsEurope [5]

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