animalhealth europe | THE VOICE OF THE ANIMAL MEDICINES INDUSTRY

Secretary General

Brussels, 12 April 2018

First Vice-President of the Commission
Frans Timmermans
European Commission
building BERL - 1049 - Bruxelles
Rue de la Loi, 200
1040 Brussels

Ref. RFE 2018/019

Dear Vice-President Timmermans,

I write on behalf of AnimalhealthEurope to alert you to our concerns regarding an impending policy decision within the on-going review of the patent and Supplementary Protection Certificate (SPC) system in the medicines sector. One policy option under consideration is the introduction of an SPC manufacturing waiver. AnimalhealthEurope asks that this option is not supported, as it will further under-mine the intellectual property environment in the veterinary medicines sector. Investment and innovation in our sector is already in decline.

To make the contents of this letter short and accessible, I have placed the background information in attachment, covering: (a) who is AnimalhealthEurope; (b) what is the policy initiative to which we refer; (c) what is an SPC; and (d) the 'imbalanced' profile of innovation in our sector, showing that investment and innovation are already under direct pressure.

We appeal to you to consider the information in this letter in the spirit of the EU's jobs & growth agenda, the EU's innovation principle and the better regulation principles.

The animal health industry invests heavily in research and development (R&D), and has delivered numerous advances in veterinary medicine, including vaccines for existing or emerging livestock diseases, analgesics, anesthetics and cancer treatments, reflecting our industry's commitment to invest an average of 10% of turnover in R&D per annum.

However, in recent years, this level of investment has fallen by 20% to 7.8% in 2015 (figure 1). Furthermore, changes to our legal framework have led to a substantial switch from investment in new products to generic versions, to the extent that today 80% of all new veterinary medicinal product registrations are generic (figure 2). When benchmarked with other key regions of the world, the EU regulatory environment for veterinary medicines is extensively perceived as negative (figure 3). We believe further diluting intellectual property (IP) protection would be detrimental to Europe's competitiveness on the global R&D investment stage.

Innovation and investment in product development relies on an efficient system of IP rights. At only 3% the size of the human medicines market, but with equivalent market entry requirements, obtaining a return on investment in our sector can be very challenging. SPCs are an important part of the mix of IP available for our innovative companies. An SPC provides compensation for time-consuming R&D necessary for product

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registration, and therefore we are highly concerned by the proposal to reduce the effective term of the SPC.

By allowing an SPC manufacturing waiver, a generic company could enter the market between 6 and 12 months earlier, thus undermining the period during which an originator might obtain a return on their investment in R&D - a key component in any business investment decision.
The profile of innovation in our sector illustrates that many companies are finding growing barriers to innovation in the EU, making it increasingly difficult to realize a return on their investments. This has and will have consequences on the objectives to improve animal health, to improve the sustainability of livestock production, and to up-hold the One Health role of animal medicines in controlling zoonotic disease. Investment is needed to face the growing challenges of exotic diseases emerging in Europe and the development of antibiotic resistance, for which alternative therapies are needed.

The roadmap for the ongoing policy review (see 'Inception impact assessment' in the attached background information) has been followed by two consultations:

1) A technical consultation studying the legal aspects of SPCs, conducted by the Max Planck Institute for IP, for which the final report has not been published yet;

2) a public consultation on these issues with objectives and policy options as outlined in the inception document, which closed on 4 January 2018; summary and analysis from the public consultation have also not been published to date.

We are led to understand that one policy option, an SPC manufacturing exemption, may be introduced early without these reports being published and fully considered. This process does not appear to follow the Commission's Better Regulation agenda. We believe individual policy options should not be brought forward in the review process until further evidence on the positive and negative effects of all the components of the SPC package revision are available. The policy impact must be examined in a comprehensive manner in order to avoid any additional unintended detrimental effects on a sector already under pressure.

AnimalhealthEurope asks the European Commission to pursue policies that will support the fresh stimulation of investment in our sector, and to not support policies that would further undermine the protection of intellectual property in Europe.

I remain at your disposal for further clarification of these points, if required.

Please be informed that a similar letter has been sent to:

- Vice-President and Commissioner Katainen
- Commissioner Hogan
- Commissioner Bieńkowska
- Commissioner Andriukaitis

Yours sincerely,

[redacted]

Roxane Feller
Secretary General
AnimalhealthEurope

Background information

a) Who is AnimalhealthEurope

AnimalhealthEurope represents twenty national associations and twelve of Europe's leading manufacturers of animal health products including vaccines, covering over 90% of the EU Market, supporting 293.000 direct and indirect jobs (incl. veterinarians), the health and welfare of billion animals in Europe - both livestock and companion animals in 80 million households across Europe, and the livelihoods of 10 million farmers.

b) What is the policy initiative to which we refer;

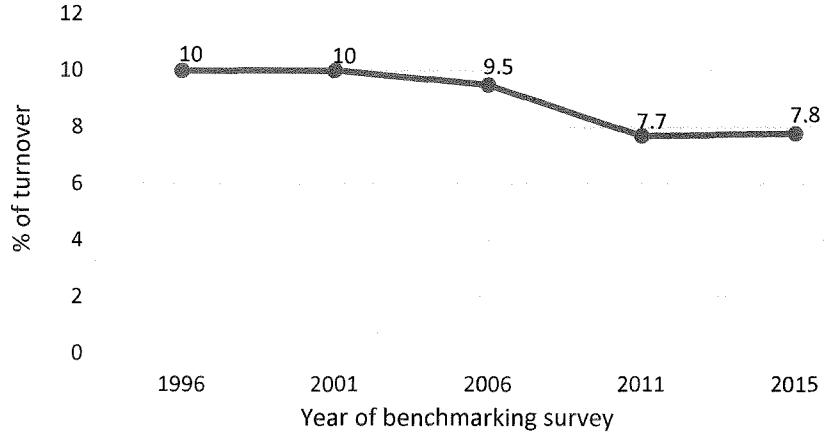
Title of the EC initiative: Optimising the Internal Market's industrial property legal framework relating to supplementary protection certificates (SPC) and patent research exemptions for sectors whose products are subject to regulated market authorisations.
Inception impact assessment: published by the European Commission on 15 February 2017
Responsible Unit: DG Growth - Unit F5 Intellectual Property and Fight Against Counterfeiting
Context: The Single Market Strategy, adopted in October 2015 (COM(2015)550), announced that the Commission will "consult, consider and propose further measures, as appropriate, to improve the patent system in Europe, notably for pharmaceutical and other industries whose products are subject to regulated market authorisations". In particular, it will explore certain aspects of patent and SPC protection, and policy options could comprise the following three elements: the creation of a European SPC title; an update of the scope of the EU patent research exemptions; and the introduction of an SPC manufacturing waiver.

c) What is an SPC

Because the development and registration of a new medicine can take up to 10 years, the patent life of a new pharmaceutical molecule can be "supplemented" with the addition of 5 years onto the patent term, to allow the investing company sufficient time to reach the marketplace and obtain a return on the investment.

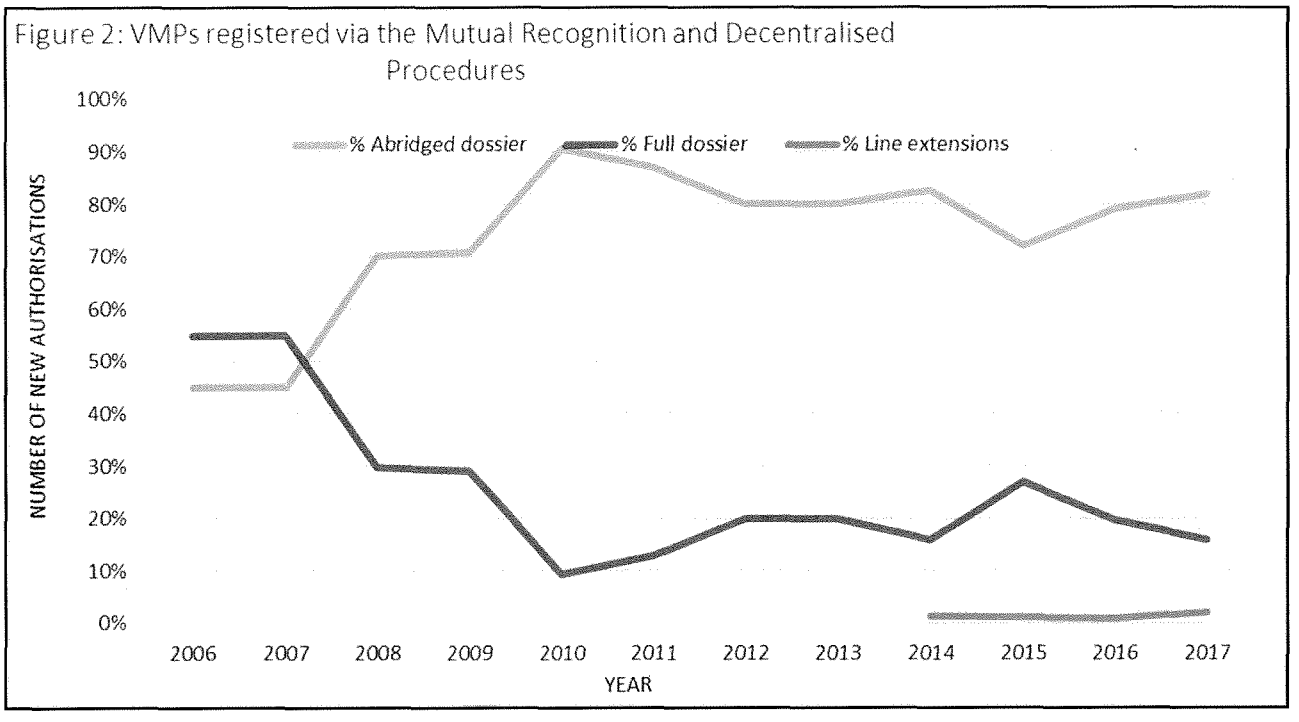
d) The profile of innovation and investment in our sector

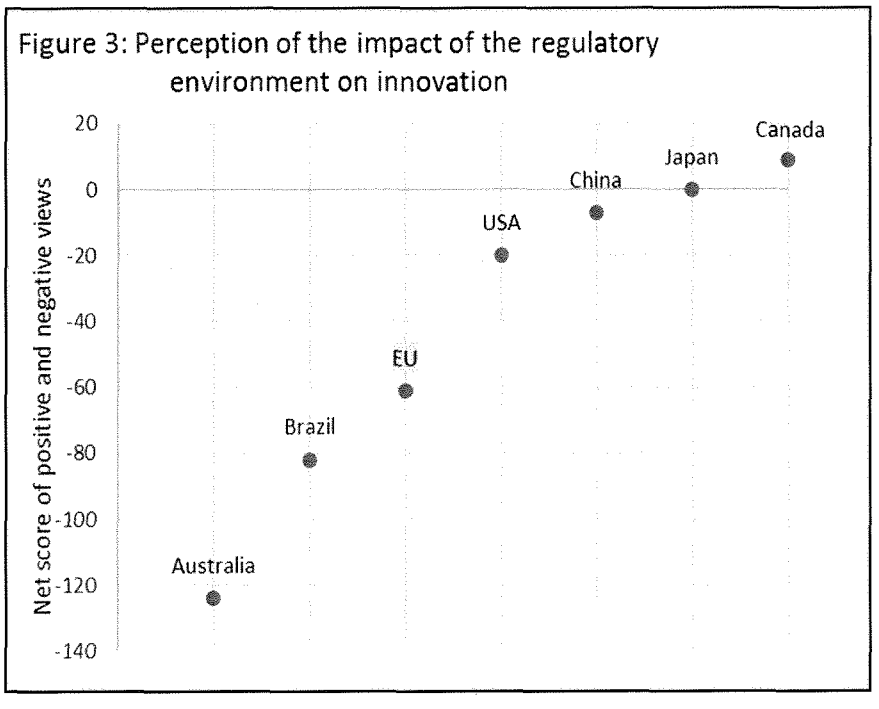
Figure 1: R&D investment as % of sector turnover



HealthforAnimals Global Benchmarking survey 2015: the level of investment in new product development in veterinary medicines has historically been 10% of the sector's turnover. In 2007 this began to drop, coinciding with Directive 2004/28/EC becoming applicable, and by 2015 it had fallen by 20% to 7.8%.

Figure 2: Directive 2004/28/EC, which began to have an impact in 2006-2007, led to a substantial switch from investment in new products to generic versions, to the extent that today 80% of all new veterinary medicinal product registrations are generic. Before 2006 the marketplace was balanced with 55% new products and 45% generic product registrations p.a. *Data from CMDv annual reports, published by the Heads of Medicines Agencies http://www.hma.eu/veterinarymedicines.html*





HealthforAnimals Global Benchmarking survey 2015: When benchmarked with other key regions of the world, the EU regulatory environment for veterinary medicines is extensively perceived as negative. The EU lags far behind USA, China, Japan and Canada. The only surveyed countries perceived as more negative than the EU are Brazil and Australia, which at the time were experiencing major crises and over-hauls within their regulatory systems.