

Global survey reveals common barriers to animal health around the world

28 June 2016, Brussels. The results from a global survey commissioned by HealthforAnimals has revealed the most common regulatory barriers shared by animal health markets worldwide.

Since 1996 HealthforAnimals has benchmarked the status of regional regulatory frameworks for veterinary medicines. The latest Global Benchmarking Survey (GBS) received a total of 79 responses from across Europe, USA, Australia, Japan, China and Brazil.

The focus of the survey centered on animal health and veterinary products, including: pharmaceuticals, in-feed medicinals, biologicals and pesticide-based products.

Shared Barriers:

- 1. Time and expense required for R&D** – The most significant regulatory barriers to innovation identified were the increases to the cost and time for new product development (NPD). All regions surveyed were concerned about these increases with the exception of Canada where overall NPD time has fallen since 2011 due to the decreases in the regulatory review component. The highest costs were reported in Europe, reflecting increases due to the application of requirements for environmental risk assessments and studies addressing the potential development of antimicrobial resistance.
- 2. Market uncertainty** – Alongside increased investment in NPD, the past 4-5 years have seen mounting political pressure on the animal health sector to address the use of antibiotics in all animals. While the continuing political pressure might result in novel non-antibiotic ways of controlling or preventing disease, the common view is that the current situation introduces tremendous strategic and financial uncertainty into the market.
- 3. Increase in Mandatory Defensive R&D (MDR&D) expenditure** – Across the surveyed territories, on average 15-39% of available R&D budget was spent on the studies and regulatory activities necessary to just keep a product on the market. Overall 55% of the companies surveyed reported an increase in R&D expenditure on MDR&D. In particular for Brazil and USA, where a high percentage of companies reported increases in expenditure for MDR&D since 2011.
- 4. Global data harmonisation and e-submissions** – Incompatibilities in e-submission requirements and the cost of ensuring data packages are valid for all territories were factors noted as creating a barrier to efficient and productive data-sharing. In response to these, suggestions by those surveyed were to expand e-submissions and continue to progress the harmonisation of data sharing. VICH, a programme aimed at harmonising technical requirements for veterinary product registration, continues to aim for mutual recognition of standards and data. However, as Brazil and China are not main members of VICH they are not fully involved in all discussions and agreements.
- 5. Pharmaceutical guidelines** – A further common concern is that regulatory expectations for animal health products continue to be inappropriately conditioned by *human* pharmaceutical frameworks, guidelines and procedures. Differing in many respects from human health, the animal health sector is around 2.5% of the total global health market (USD\$24bn in 2015) and encompasses a diversity of species and business types, including companion animal products (CAPs) and livestock.

Commenting on the survey's findings, Executive Director for HealthforAnimals, Mr Carel du Marchie Sarvaas stated: "Progress has been made within the industry and, as seen with Canada's example where review time has reduced, it is possible to push for greater efficiencies in the regulatory process. Positively, the industry is beginning to make more use of new digital tools and approaches. For

Canada, China, Japan and USA there was positive feedback about the regulatory environment from at least 45% of companies.

“Nonetheless, as demonstrated by the survey responses, there remains common barriers to innovation in animal health. Co-operation on a global level will be required to drive innovation in the animal health sector. This is becoming increasingly important in the face of global health challenges such as antimicrobial resistance (AMR).

“With regards to AMR, in the debate between the industry’s science and the politician’s decisions, sadly the voice of science has often not been heeded. Understandably, companies are hesitant to risk investment in developments that might be banned at some unknown point in their pathway to the market, with incalculable cost. It therefore remains vitally important that we continue to search for best regulatory practice and opportunities for improvement.”

Global Industry Aims:

- Further expansion of e-submissions and inter-agency collaboration across territories to make the best use of high-quality foreign data and approvals from well-regulated countries
- Greater transparency, predictability, efficiency and flexibility of agencies, with enhanced staff training and expertise and increased staff numbers, are seen as critical for agencies to overcome the disruptive effects of changes in regulations and guidelines, and to become innovation-ready
- Reduce the costs of maintaining products on the market by streamlining excessive regulation of minor or frequent changes to products and manufacturing
- 32% of companies would like to see further improvement in policy such as the deeper and more consistent application of risk based approaches and simpler rules for CAPs

To read the Global Benchmarking Survey 2015 in full, visit healthforanimals.org. To be the first to hear about upcoming content, follow HealthforAnimals on Twitter @Health4Animals.

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Notes for editors

HealthforAnimals

HealthforAnimals is an organisation representing manufacturers of veterinary medicines, vaccines and other animal health products in both developed and developing countries across five continents. The mission of HealthforAnimals is to foster a greater understanding of animal health matters and promote a predictable, science-based regulatory environment that facilitates the supply of innovative and quality animal medicines, vaccines and other animal health products into a competitive market place. These products contribute to a healthy and safe food supply as well as a high standard of health and welfare for animals and people.

For further information on HealthforAnimals visit: <http://healthforanimals.org/>

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