

EXPLORATORY MEETING

PRI Veterinary Initiative to support developers of microbiome-based veterinary products

This Exploratory Meeting aims to draw together all actors involved in or considering research and development of microbiome-based veterinary medicines in the EU and who are working towards or seeking support in clarifying the Regulatory pathways for such products.

With the advancement of science and technology, the benefits and relationship between the microbiome and the host is becoming more and more understood. The PRI has been fulfilling a pivotal role in the field of human [microbiome-based medicinal products \(MMPs\)](#) since its creation in 2010. It has and continues to support researchers and developers in their efforts to better understand and navigate the regulatory landscape for the application of MMPs in human medicines as well as clarifying competent authorities' expectations when it comes to this newer and heavily dynamic and emerging type of human medicinal products.

Today, [the PRI wields a broad scientific and technical know-how](#) gathered through its collaborative regulatory strategy with competent EU authorities with regards to the research, development, production and (potential) use of MMPs for human medicinal treatment. It is now in a position [to represent its members](#) in wider discussions with European drug authorities thanks to its unique position as a non-profit, financially-independent association, thereby avoiding any overt conflict of interest.

Emerging scientific developments have shown that microbiome-based medicinal products do not only represent a paradigm shift in human medicine, but also in veterinary medicine. As proven by the global initiatives to curtail the indiscriminate and irresponsible use of (last resort) antimicrobials in the treatment of human as well as animal illness, proofs of concept continue to emerge on the potential alternatives using microbial solutions to chemically based antibiotics. In certain animal pathologies for which, similarly to human, few alternatives are currently available for treatment, the body of knowledge acquired by the PRI on researching, navigating and the use of human microbial medicinal products could be highly valuable to companies who are also developing potential microbial product veterinary medicines. In addition, for both companion and livestock animals, these new types of products represent/are perceived as a more natural and sustainable solution by animal owners.

Thus, the PRI intends to hold an Exploratory Meeting in London on July 10th, 2019 from 15h to 18h in order to assess if stakeholders in or interested in the field of animal medicine would choose to participate in such an initiative. As the PRI has been heavily involved in ascertaining the regulatory pathways for microbiome-based medicinal products for potential wide ranging applications in human medicines, it seems like the only natural path to also use the wealth of knowledge and experience to further similar initiatives on the research, registration and potential use of MMPs in Veterinary medicines in the EU market and beyond.

During this meeting the PRI would propose to address the following points with those stakeholders present:

- How does the PRI work with the industry on an everyday basis?
- How could the knowledge acquired by the PRI with regards to human applications also be applicable to veterinary medicines?
- Would the industry be interested in the application of the PRI strategy to Veterinary Medicinal Products?
- Would the industry be interested in any support from the PRI?

- What are the win-wins that the PRI has achieved for human medicine applications with regards to MMPs and what are the other goals in their projections; how can some of these apply to veterinary medicine and what is the potential benefit for the veterinary industry?

After these points, time will be dedicated to exchange between participants and current members of the PRI (in absence of the [PRI Staff](#)) so all questions might be asked by the participants on the actual life and organization of the Association, as well as the quality of the work done by the Association for its Members.

If, at the end of the meeting, those present should wish to pursue such an initiative, the PRI would submit the Veterinary Initiative proposal to the [PRI Board of Directors](#) for formal approval and adoption. The intention is as soon as adopted PRI will commence work with all interested in order to support them in the clarification of the regulatory landscape for registering microbiome-based drug products (in addition to mutually agreed initiatives that will facilitate the development of MMPs) as veterinary medicines in the EU.

Therefore, any organisation/company interested in this initiative is more than welcome to contact the PRI and learn how to get involved. **[This Meeting is open to all Current and Future PRI Regulatory Members.](#)**

For more information about this meeting or any other project coordinated by the PRI, please contact:

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