## (SPF Santé Publique - FOD Volksgezondheid)

**Van:** Reach (SPF Santé Publique - FOD Volksgezondheid) <[redacted]@health.fgov.be>
**Verzonden:** woensdag, 22 november 2023 11:09
**Aan:**
**CC:**
**Onderwerp:** RE: Regulatory challenges faced by medicinal products

Dear ,

Thank you for your mail and apologies for my delayed response.

Unfortunately we will not be able to organize any more stakeholder meetings this year.
However you are kindly invited to send us written information, which we can then share with the Belgian Committee for REACH (BCR).

Kind regards,

Health
Food Chain Safety
Environment

Chemicals policy advisor
[redacted]@health.fgov.be

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**From:** @fipra.com>
**Sent:** mardi, 14 novembre 2023 14:31
**To:** (SPF Santé Publique - FOD Volksgezondheid) < @health.fgov.be>
**Cc:** @fipra.com>
**Subject:** Regulatory challenges faced by medicinal products

Dear ,

I am contacting you on behalf of MSD Animal Health, a company developing and producing medicinal products for veterinary uses. We would like to discuss with you the impacts of ongoing regulatory changes in the field of chemicals on the sector.

As you know, veterinary medicinal products are currently exempt from REACH authorizations and restrictions. However, certain changes brought by the EU Chemicals Strategy for Sustainability would directly threaten the affordability and accessibility of medicines in the EU as the exemptions do not cover manufacturing and packaging of our products for instance. Packaging, manufacturing as well as imports and exports are being affected in different ways by current

regulatory changes in the field of chemicals, including a possible full stop in the use of certain critical substances for products performance and safety as we now can witness also from the current universal PFAS restriction.

Medicinal products are supervised by the European Medicines Agency, subject to very strict sectoral regulations, complex authorization procedures as well as long R&D cycles and costly clinical trials. This makes substitution far more challenging than for almost any other product. Due to various industry activities and particularly to our sectoral regulations, the risks both in terms of health and environment are sufficiently under control and we are constantly looking at ways to improve.

Given the active role your country has taken on chemicals, and given the importance to keep medicines supplies available in the EU, would you be available for a call over the next month to discuss these challenges for the veterinary medicinal products sector?

We appreciate your kind consideration and look forward to hearing back from you.

Kind regards,
Eliot Goarant

**Consultant**

**M:**

**A:** Rue de la Loi 227, Brussels 1040, Belgium

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