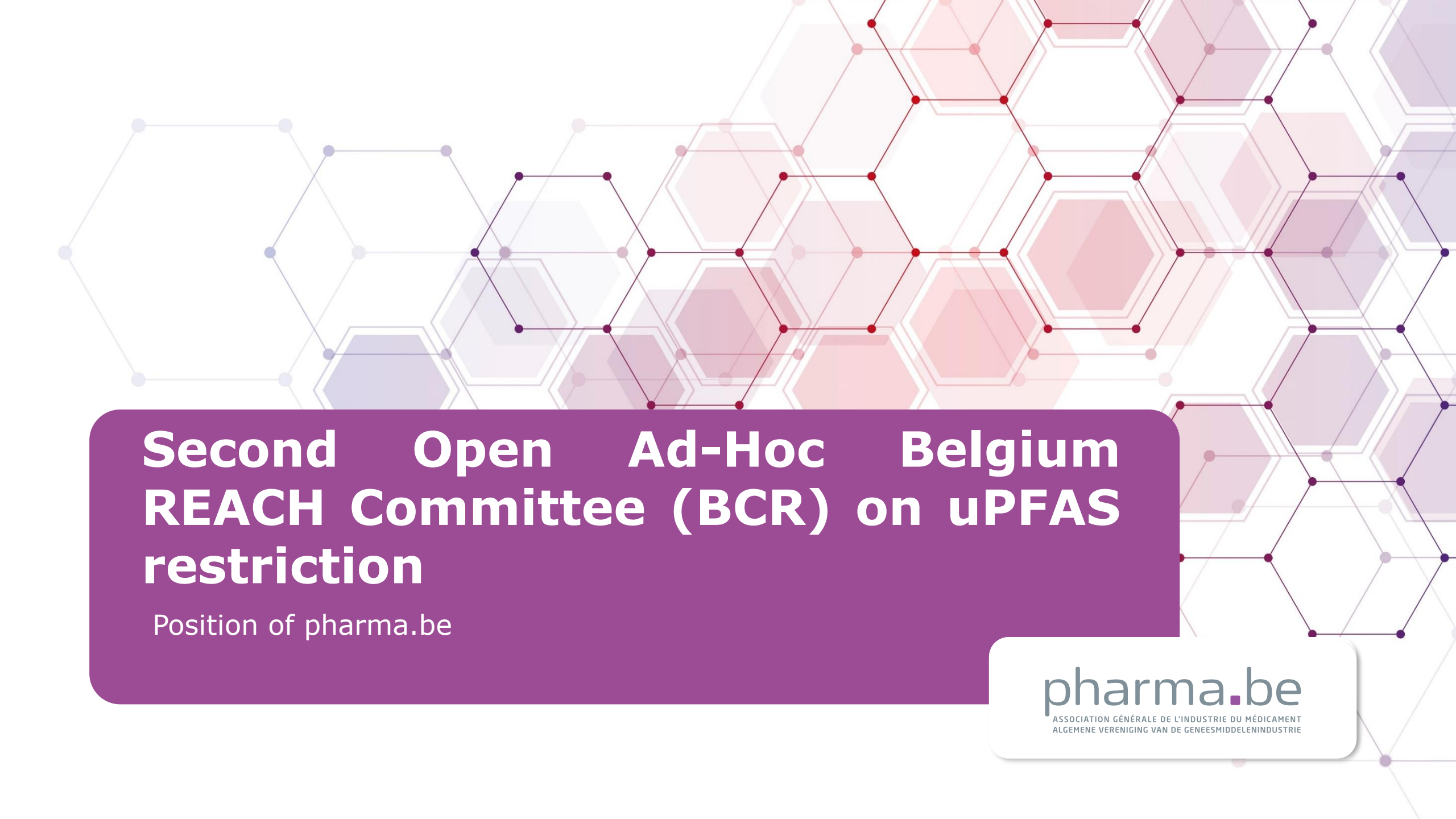




Second Open Ad-Hoc Belgium REACH Committee (BCR) on uPFAS restriction

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ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

The problems with PFAS restrictions

We welcome the fact that API (active pharmaceutical ingredients) have received a derogation.

But it is important to note that more steps are needed to **ensure the continued availability** of medicines and to **avoid negative consequences for patients and public health**.

For the fact of the matter is that there are currently no viable alternatives available for PFAS used in the manufacturing of medicines.

Both the identification of such medicines and obtaining the approval from regulatory authorities would take many years and in the meantime the medicines would not be available due to a potential ban.

The problems with PFAS restrictions

Some examples where PFAS are used in the manufacturing of medicines:

- **Starting materials and chemical intermediates** that qualify as PFAS are used to introduce fluorine into API molecules.
- **Processing aids and process chemicals**, including solvents and reagents also qualify as PFAS.
- Polyfluorinated polymers, e.g. polytetrafluoroethylene (PTFE) are often used as seals for chemical reactors, vials and in **equipment** such as membrane filters, gaskets, liners, O-rings, piping etc. in the manufacturing of medicines and vaccines.
- Likewise, polyfluorinated polymers are **widely used in packaging materials** (blister packs, vial stoppers, etc.) for their proven efficacy in preventing interaction between product and packaging materials >> and this is a regulatory requirement.

Potential consequences

Manufacturing of both pharmaceuticals and vaccines would need to be **relocated outside of the EU**, which goes in contradiction to the aim of bringing production (back) to the EU and shortening supply chains.

Especially in **Belgium** this would have potentially **very negative consequences** as there are more than 30 pharmaceutical companies with production sites in our country.

Furthermore, as already stated this would also lead to problems with the availability of medicines and vaccines and as such would **go against the efforts at EU-level of minister Vandenbroucke to ensure the availability of medicinal products.**

Need for a risk-based approach

PFAS are a group of **more than 4.700 man-made chemicals** and are used in a wide variety of products and applications including industrial processes.

A change in definition in 2021 has widened the scope of which substances should receive the designation of 'PFAS' leading to the addition of thousands more substances to this already long list.

However, it is important to stress that the concerns about persistence in the environment and human health relate to a number of substances classed as PFAS under the previous definition.

Their negative properties as such nor the resulting human health concerns **cannot automatically be extrapolated to this wider group.**

It is therefore important to take **a risk-based approach** when restricting the use of PFAS and **not to resort to a blanket ban.**

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