Ref. Ares(2022)5348176 - 25/07/2022

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Subject: Meeting report - Meeting of 8 July 2022 with EFPIA - REACH Revision
Attachments: Pharmaceutical Supply Chain_Applicability of REACH and CLP.pdf; REACH and Medicinal Products Infographic_1 July 2022.pdf

Participants :

- GROW.F.1: [redacted]
- EFPIA (European Federation of Pharmaceutical Industries Association): [redacted] (EFPIA), [redacted] Eli Lilly), [redacted] (Bayer), [redacted] (Johnson & Johnson)

EFPIA wished to discuss the following points:

- Overlap between pharmaceutical legislation and REACH; limitations of REACH exemptions
- Essential uses
- Ongoing Commission impact assessment

Overlap between pharmaceutical legislation and REACH; limitations of REACH exemptions

EFPIA recalled that the exemptions from the REACH authorisation and restrictions titles are not the same (active pharmaceutical ingredients are not exempted from REACH restrictions, see infographic attached). This caused them some concern in the light of the planned GRA extension.

GROW.F.1 stated that, although pharmaceuticals were not likely to be a priority for restrictions based on human health concerns, they might indeed more likely be on the radar for environmental concerns (cf experience under the Water Framework Directive).

EFPIA pointed towards the efforts of the industry to tackle environmental concerns, e.g. impact minimisation measures and self-regulation. They also pointed out that the pharmaceutical industry was not included in the impact assessment for the CLP Revision.

GROW.F.1 acknowledged that the assessment of impacts of the GRA extension under REACH is a rough estimate, considering the complexity of the tasks that the contractor is undertaking under the constraints of the timeline for the impact assessment. Where possible, the contractor is undertaking a sensitivity analysis given the large uncertainties of the estimates.

EFPIA pointed out that reformulation/replacement of pharmaceuticals takes many years, and that the duration of the (re)authorisation process (e.g. with EMA) could take up to 10 years; GROW.F.1 confirmed that it was aware.

EFPIA saw promise in public-private partnerships for substitution and urged DG GROW to support these when DG RTD would consult on future priorities for such partnerships.

Essential uses

EFPIA expressed some concerns regarding the recent Caracal paper referring to notions such as "advanced health care" and "treatment of major health issues" which appeared to exclude the possible application of the essential uses concept to minor health issues. Another concern was that ECHA Secretariat would be expected to assess alternatives in the same product category. In EFPIA's view, pharmaceuticals in the same therapeutic class are not interchangeable; e.g., for antidepressants, medical professionals will choose the most appropriate product for each

individual patient. EFPIA also expressed the opinion that the options for either the REACH Committee or the MSC to assess essentiality were inappropriate in the case of pharmaceutical products and insisted for EMA to be involved. In sum, EFPIA took the view that an authorised pharmaceutical product would have to be deemed to fulfil the essentiality criterion.
GROW.F.1 recognised that COM would not want to interfere with medical professionals assessments, but that it might not be possible to avoid such discussions on alternatives.
EFPIA offered to contribute with its expertise, for example following the authorisation applications for OPE, in the development of guidance for the revised REACH. GROW.F.1 informed that in view of the early stage of the REACH revision, guidance was not currently on the table. However, there was a clear commitment for guidance and this would need lots of discussion.
As to the One Substance One Assessment concept, EFPIA expressed concern regarding its application for the risk-benefit assessment for pharmaceuticals. They expressed some doubts whether EMA was properly engaged in the ongoing discussions. They urged for the risk-benefit assessment to take precedence for pharmaceutical products as well as for the avoidance of delays in pharmaceutical products reaching the market.
GROW.F.1 welcomed EFPIA's offer to contact EMA in order to make them aware of the importance of the One Substance One Assessment discussions, although it was noted that EMA is already involved in Commission's internal meetings on the subject.

<u>Ongoing Commission impact assessment</u>
EFPIA confirmed that it was collecting and preparing data on the number of substances that would fall under the GRA extension in order to support the ongoing Commission impact assessment for the REACH Revision and inquired about the applicable timelines. EFPIA noted that the REACH registration data might not provide the full picture for the pharmaceutical sector, because pharmaceuticals are not subject to REACH registration requirements. GROW.F.1 informed that the impact assessment was scheduled for submission to the Regulatory Scrutiny Board mid-September and would therefore have to be finalised a few weeks before that. Therefore, the timeline to submit any additional data is very tight and data would need to be submitted by the end of August at the latest. EFPIA agreed to share what information they can collect from their members within this timeline.

The infographics referred to by EFPIA in the meeting are attached.