AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

Association of the European Self-Care Industry

AESGP response to the Commission public consultation on the 'One Substance, One Assessment' European Commission package of legislative proposals

Executive Summary

AESGP, the Association of the European Self-Care Industry, is a non-profit organisation that represents the manufacturers of non-prescription medicines, food supplements, and self-care medical devices in Europe, an area also referred to as "self-care" or "consumer healthcare" products, takes the opportunity to share its views on the 'One Substance, One Assessment' (OSOA) package of legislative proposals published on 7 December 2023.

The concept behind the OSOA package to streamline the assessment of chemicals across EU legislation is welcomed as means to bring efficiency and a harmonized approach to chemical assessments and processes. Some potential benefits include reduced animal testing and the prevention of duplicate testing and regulatory activities. The consumer health industry finds it important to have opportunities in the long-term to continue shaping the OSOA approach and the three legislative proposals that implement it.

Overall, regulatory frameworks and processes within Europe on chemicals, food and environment should not hinder innovation and the continuous global supply of medicines, medical devices and other consumer health products. Considering this context, please find below our key general recommendations on the legislative proposals:

- **A full impact assessment should be carried out on behalf of the European Commission on each of these legislative proposals** considering their complex but significant impact on the existing regulatory systems impacting the licence to operate for health products.

- **The European Medicines Agency (EMA) must continue to lead the Benefit/Risk evaluation of medicinal products.** Decisions by the EMA for medicinal products should take precedence over other agencies. The active involvement of the EMA in establishing the common data platform on chemicals is important to ensure they are kept informed and aware of the implications for medicinal products data as well as the aggregated data content that will be published on the platform.

- **The European Chemical Agency (ECHA) must have the necessary expertise to handle the new responsibilities envisaged in the targeted amendments to the Medical Devices Regulation (MDR)**[1], i.e. in specific technologies (medical devices and IVDs) and their respective legislation (MDR and IVDR).

- Taking into account the complexity and the need for transparency, we call on the European Environment Agency (EEA) **to develop a guidance document for identification of emerging chemicals risks** in cooperation with all relevant parties, and reconsideration of current proposed timeline.

[1] The Medical Device Regulation 2017/745 (MDR)

Specific comments per OSOA legislative proposal

1. Proposal for a Regulation establishing a common data platform on chemicals[2] and its annexes.

The European Medicines Agency (EMA) must continue to lead the Benefit/Risk evaluation of medicinal products. Decisions by the EMA for medicinal products should take precedence over other agencies. The active involvement of the EMA in establishing the common data platform on chemicals is important to ensure they are kept informed and aware of the implications for medicinal products data as well as the aggregated data content that will be published on the platform.

Overall, regulatory frameworks and processes within Europe on chemicals, food and environment should not hinder innovation and the continuous global supply of medicines. Considering this context, please find below our key recommendations on the legislative proposals:

- A full impact assessment should be carried out on behalf of the European Commission on this legislative proposal for a common data platform.
- We support that medicinal products are recognised to be of a different nature to all other chemicals and therefore special provisions have been identified for medicinal products data. However, it is important to clarify that **some of the chemical dossiers listed in Annex I (or their ongoing revisions) include pharmaceuticals in their scope**.
- Clarification is required from the Commission and relevant agencies on how they will ensure that, when **migrating data between databases** or from an Agency to ECHA, confidential information will not be disclosed and that the applicable provisions on confidentiality remain.
- For the notification of studies, it is necessary to maintain the **confidentiality of business operators** and laboratories including information on the laboratory or testing facility carrying out the study, and the intended starting and completion date.
- We strongly recommend that the reuse of data should take into account the **context under which data was generated**, and that all data included in the common data platform are reliable and usable within an appropriate regulatory context.
- It is essential that the **General Pharmaceutical Legislation rules,** governing general data protection provisions, **take precedence** over this legislation.
- Regarding the data generation mechanism, we recommend including a mechanism that would **enable industry to provide comments on the studies commissioned by ECHA**, including testing protocol and methodology and draft final reports.
- Taking into account the complexity and the need for transparency, we call on the European Environment Agency (EEA) **to develop a guidance document for identification of emerging chemicals risks** in cooperation with all relevant parties, and reconsideration of current proposed timeline.
- To avoid unintended consequences, it is important to **align with all other legislative proposals** (chemical and pharmaceutical) presently under revisions to enable the smooth functioning of the EU chemicals legislation system.

[2] https://environment.ec.europa.eu/publications/proposal-regulation-establishing-common-data-platform-chemicals_en

- It is important to **learn from the implementation of the existing legislation** like the Transparency Regulation[3] which has significantly impacted the EU risk assessment in the food sector and avoid its pitfalls.

- It is important **not to duplicate initiatives**. The IMI Project PREMIER sets up a database for environmental risk assessments (ERA) for new or marketed active pharmaceutical ingredients and in accordance with requirements of the European Medicines Agency (EMA).

- AESGP supports the submission by the European Federation of Pharmaceutical Industries and Associations (EFPIA)[4] and the MedTech Europe.[5]

Regulatory frameworks and processes within Europe on chemicals, food and environment should not hinder innovation and the continuous global supply of medicines. It is important to note that the EU Fitness check of all chemical legislations which is the basis behind this proposal, excluded pharmaceuticals from scope. Therefore, the clear functioning and impact of the proposed OS-OA concept on medicines and vaccines is unknown.

While there are no economic, social or environment impacts foreseen from the implementation of the OS-OA concept, our sector has significant concerns over the availability and supply of safe medicines and vaccines to citizens in Europe. Overall, regulatory frameworks and processes within Europe on chemicals, food, and environment must also be tailored to enable innovation and continuous global supply of medicines.

Ultimately, the impact of any unilateral EU restriction or ban of products or raw materials for medicinal products will have a direct impact on the global supply of medicines across all countries, inside and outside of the EU. As previously requested during the call for evidence in development of this legislation, AESGP continues to request that a full impact assessment is carried out on behalf of the European Commission.

We enclose in Annex our detailed comments on the legislative proposal.

2. Proposal for a Regulation amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

AESGP recognises that the reattribution of scientific and technical tasks will have a significant impact on ECHA; and not only in terms of budgetary implications and human/administrative resources required. **A reorganization of the work of the Agency will be necessary to ensure that its committees will cope with the increased workload without compromising the quality and the timeliness of their work**.

Further to additional budget and staffing, the setup as well as the organisation of the work need to be considered. With no clarity on the future structure of the Agency's scientific committees it is impossible to conclude on whether the proposed resources will be sufficient for the Agency to manage the increased workload.

[3] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (Text with EEA relevance.), OJ L 231, 6.9.2019, p. 1–28

[4] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13459-Chemical-safety-better-access-to-chemicals-data-for-safety-assessments/F3461642_en

[5] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13459-Chemical-safety-better-access-to-chemicals-data-for-safety-assessments/F3456919_en

Without a proposal for an ECHA Basic Regulation it is unclear whether and how the Agency (incl. its committees and working groups) will be adapted to allow for the smooth and efficient integration of the new tasks. It is therefore difficult for the industry to provide specific comments on this proposal beyond the specific amendments introduced by the proposed text. **A full impact assessment should be carried out** on behalf of the European Commission on this legislative proposal for the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals when a proposal for an ECHA Basic Regulation will be available.

Amendment to the Medical Devices Regulation 2017/745 (MDR)

The targeted amendment to the MDR is twofold. On the one hand, it adds justification requirements for substances that will be identified as per the new CLP hazard class for Endocrine Disruptors to Human Health Category 1. On on the other hand, ECHA will replace the role of SCHEER in issuing guidelines on how to perform the benefit-risk assessment on the presence of CMR or endocrine-disrupting substances in medical devices.

On the proposed amendment to involve ECHA in the assessment of chemicals (i.e. phthalates and Endocrine Disruptors) in medical devices and issuing guidelines, we call on the Commission to clarify how ECHA will be funded for carrying out these new activities, their timelines and processes for doing so, but also how it will be ensured that ECHA will be equipped with the necessary expertise on medical devices to carry out its newly assigned tasks in a timely manner.

Today, the experience of the medical device industry already demonstrates that the MDR is costly, highly complex, and takes a significant amount of time from product design to regulatory approval and placing on the market. Mandating another external agency in the medical technology field should result in a reduction of administrative complexity, not an increase. Furthermore, it should ensure that not only the necessary technical and medical expertise and experience is included, but also profound know-how in healthcare.

We, therefore, ask that the **industry and/or other actors such as SCHEER, Notified Bodies, etc. have the right to contribute to these processes to ensure that the technical knowledge on medical technologies is available** (e.g. knowledge revolving around clinical trials, and the riskbenefit assessment under MDR, which is different to the risk-assessment that is performed under REACH, etc.). On the second change proposed to the MDR, namely in Annex I Section 10.4.1(b) to identify Endocrine Disruptors for Human Health (Category 1), per the new hazard classes introduced in CLP in 2022, we underline that this hazard class is currently only applicable to the EU market, as it is not adopted at the UN GHS level.

3. *Proposal for a Directive on the re-attribution of scientific and technical tasks to the European Chemicals Agency*

The concept behind the OSOA package to streamline the assessment of chemicals across EU legislation is welcomed as means to bring efficiency and a harmonized approach to chemical assessments and processes. **Some potential benefits include reduced animal testing and the prevention of duplicate testing and regulatory activities**.

The consumer health industry finds it important to have opportunities in the long-term to continue shaping the OSOA approach and the three legislative proposals that implement it.

Given this, we consider that several clarifications are needed to optimize the legislative proposals in the OSOA package, namely:

- Ensuring **ECHA has the necessary expertise to handle the new responsibilities** envisaged in the targeted

amendments to the Medical Devices Regulation (MDR).

- Ensuring that a **formal Impact Assessment is carried out**, considering the additional resources and budget needed for ECHA to deliver on its new tasks.

- Providing ECHA with the **necessary funding via the ECHA Founding Regulation**, to ensure it is empowered to complete its (new) tasks. The reallocation of tasks to an already overburdened ECHA and its Committees raises concerns about resource efficiency, effectiveness and accuracy of evaluation outcomes.

- Using the OS-OA package and specifically the common data platform as an **opportunity to streamline existing databases and regulatory requirements for business operators and remove any such duplication** of existing information requirements.

- A common data platform seems to be an improvement in principle; however, more details need to be provided as to what information will be made available in the public domain and how **confidential business information will be protected.**

ANNEX

Detailed comments on Proposal for a Regulation establishing a common data platform on chemicals and its annexes[6].

1. *Limiting the scope for medicinal products* (Annex II)

We welcome the recognition of the different nature of the risk and hazard assessments performed under Union acts on medicinal products, when compared to those performed under the main Union acts on chemicals (Recital 8). For this reason, we support the position that the scope of regulation establishing a common data platform should apply only to chemicals data related to environmental risk assessments for human and veterinary medicines, non-clinical studies for human medicines and maximum residue limit (MRL) values established by the European Medicines Agency ('EMA'), as well as specific reference values, should be included under the scope of regulation establishing a common data platform. For medicinal active substances, we agree that only data on relevant substances as described under paragraph 8 of the Regulation Preamble should be included under the scope of the common data platform.

It is however also important to note that in Annex I, 70 legislations are listed, a number of these (or their ongoing revisions) include pharmaceuticals in their scope, and therefore pharmaceutical data is not restricted only to the data referred to in Annex II.

2. *Protection of confidential information and data (Articles 5(2), 16 and 17(3))*

AESGP supports the overall aim of open access to safety data for chemicals while recognising the critical importance of keeping information on company names and personnel confidential. However, we are concerned that confidential data generated in the context of the applicable sector-specific legislation will be made available to the public for multi-use chemicals (i.e., those with pharmaceutical and non-pharmaceutical uses). We would appreciate clarification from the Commission and relevant agencies on how they will ensure that, when migrating data between databases or from an Agency to ECHA, confidential information will not be disclosed and that the existing provisions on confidentiality remain applicable.

Whilst we appreciate the inclusion of some provisions on the protection of confidential information, we are of the opinion that these provisions need to be strengthened to ensure that the protection of confidential information afforded under the applicable sector-specific legislation is not undermined by this proposal. Furthermore, in case of conflict between the provisions on confidentiality of this proposal and those laid in sector-specific legislation, the latter should prevail.

3. *Notification of studies (Article 22)*

AESGP supports the proposal's aims to increase transparency as well as to enable authorities to have prior knowledge on the studies commissioned by business operators and carried out by laboratories and in scope of Union acts. It is essential for AESGP that the confidentiality of such data remains.

However, we are concerned that the study notification obligation set out in Article 22 of the proposal will result in the disclosure of business sensitive information and would be putting at risk the conduct of the study and site personnel. Therefore, we consider it essential that confidentiality be protected for business operators and

[6] Aligned with EFPIA comments https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13459-Chemical-safety-better-access-to-chemicals-data-for-safety-assessments/F3461642_en

laboratories including information on laboratory or testing facility carrying out any studies, and the intended starting and completion dates. The notification obligations for medicinal products should take account of the confidentiality principles already set for studies notified to the European Chemicals Agency (ECHA) under Article 40(2) of Regulation (EC) 1097/2006 (REACH). Under that existing legislation, only the name of the substance, the endpoint for which the testing is carried out and the regulatory purpose of the study are made publicly available, with the other information being kept confidential. It could be considered that notification is only required after the market authorisation application has been submitted.

As we understand that, under Article 22(7) of the proposal, ECHA will lay down the practical arrangements for the study notification, we would welcome the opportunity to participate in ECHA's process to lay down such arrangements to ensure that confidential information is always protected.

Additionally, we are welcoming the fact that studies carried out for another purpose than the Union acts listed in Annex I, will not require notification to ECHA, as the reverse would potentially place the EU operators at a disadvantage and be seen as an obstacle to carry out testing in the EU.

4. Reuse of data by authorities (Article 17)

While we understand and support the proposal's aim to encourage the reuse of chemicals data to improve the effectiveness, efficiency and coherence of chemicals-related assessments, we are calling attention to the following:

- As currently drafted, Article 17(1) would allow authorities to use the data included in the common data platform for the "*development or implementation of chemicals legislation and policy*". This provision appears unduly generic and would entail unwarranted consequences for both authorities and industry. The reuse of data should be carefully regulated to ensure that only relevant data generated on one substance under the applicable legislation (e.g., the Cosmetics Regulation (EC) 1223/2009) is reused for the assessment of the same substance when used in a different application (e.g., medicinal products). In other words, the reuse of data should take into account the context under which data was generated, i.e., physical form of the tested substance (solid, liquid, powder), specific uses, exposure routes, volumes, impurity profiles, etc.

- The data in the common data platform are to include *"data generated as part of Union, national or international legislation, programmes or research activities"* (Article 5). If data generated for research purposes are to be reused by authorities (and considering their potential significant regulatory impact), it is critical that they fulfil minimal quality standards with respect to experimental practices and available documentation. The same should apply to all results from peer-reviewed publications included in the common data platform as parts of registration dossiers under any legislation covered by the OS-OA framework. Ideally, research institutions should make their experimental protocols and raw data available to ECHA in order to ensure studies reliability and usability within a regulatory context.

- In medicines development, regulatory data protection (RDP) protects innovative companies' investment in generating the extensive body of data (relating to preclinical and clinical trials to demonstrate the quality, efficacy, and safety) through a limited period of exclusivity on the data, starting from marketing authorisation. This proposal should not circumvent the data protection provisions set out in the pharmaceutical legislation and should not allow Member States competent authorities to reuse the data developed by applicants in support of their marketing authorisations application in favour of other applicants, unless the relevant data protection periods have expired.

5. Data generation mechanism (Article 21)

We are concerned that the provisions on the data generation mechanism, as currently drafted, would deprive business operators of their right to be consulted. As the results of the studies commissioned by ECHA, on its own initiative or at the European Commission's request, have the potential of bearing important consequences for the industry, we are of the opinion that Article 21 should include a mechanism that would enable the industry to provide comments on the studies commissioned by ECHA, including comments on testing protocol and methodology.

More specifically, ECHA should be requested to publish, on its website, the study it wishes to commission along with the relevant justification, the study protocol, and the financing mechanism, followed by a 60-day public consultation that would enable interested stakeholders to comment. ECHA would also need to publish the testing facilities and study dates should the same standard be applied to industry under Article 22. ECHA should consider the comments received during the public consultation before adopting a formal decision to commission the study. Interested stakeholders should also be able to appeal the decision to commission the study before the Board of Appeal and Article 91 of the REACH should be amended accordingly to enable interested stakeholders to appeal the decision.

6. Early warning and action system for emerging chemical risks (Article 19)

The European Environment Agency (EEA) has been mandated to develop an early warning and action system for chemicals to ensure that EU policies address emerging chemical risks as soon as identified by monitoring and research. Whilst we support this initiative, we would like to note that the interpretation of even the minimum sets of data from sources specified in Article 19(2) represents a complex task that can take significant time. Furthermore, as identification of emerging chemicals risk is envisioned to be followed by the generation of further chemicals data and ultimately regulatory action, this process needs to be conducted transparently and in line with clearly defined and science-based set of rules.

We would therefore like to call on the EEA to develop a guidance document for identification of emerging chemicals risks in cooperation with all relevant parties, based on current ECHA stakeholder practices. To ensure sufficient time for such a guidance document to be developed, there is a need to reconsider the timeline currently proposed in Article 19(4).

7. Aligning legislative changes

Since there are significant legislative revisions underway on various chemical and environment dossiers, including the revision of the pharmaceutical legislation, it would be appreciated to align the proposals on human pharmaceuticals with other legislative changes to enable the smooth functioning of the EU system.

We are also cautious that the proposal for a basic regulation on the strengthening of ECHA, its governance and future role hasn't been published yet, and that some concerns might also raise for the interlinkage of all those regulations.

8. Environmental database for human medicinal products

As mentioned above, AESGP welcomes that the risk and hazard assessments of medicinal products are recognized to be of different nature when compared to those performed under the main Union acts on chemicals. This also applies when building a database for active pharmaceutical ingredients in medicinal products. In this

regard, we kindly point to the ongoing activities and ambition of the IMI PREMIER[7] project (public private partnership project, co-funded by the Commission and AESGP).

One key aspect of PREMIER is building a database following FAIR principles[8] that provides physico-chemical, fate, and ecotoxicological data as used in environmental risk assessments (ERA) for new or marketed products and in accordance with requirements of the European Medicines Agency (EMA). In addition, relevant and reliable data beyond ERA are considered. This database as well as a digital assessment system (DAS) are currently being built in close collaboration with the EMA. The project database experts (Mario Negri Institute) have already successfully developed similar databases, e.g., in collaboration with the European Food Safety Authority (EFSA). The PREMIER database is being developed as a IUCLID compatible resource in alignment with requirements of the Commission. This will facilitate integration with future software developments via the commission and its agencies. PREMIER is therefore well placed to support the commission proposals to develop such a database from a programme already funded in part by the commission and in collaboration with the data owners. It is important not to replicate this ongoing work.

[7] https://imi-premier.eu/
[8] https://www.efsa.europa.eu/en/efsajournal/pub/e200917