European Federation of Pharmaceutical Industries and Associations

EFPIA EHSEG Paper on Material Declaration

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There is an increasing need to demonstrate material compliance under different EU regulatory frameworks. In order to ensure compliance with requirements on the presence of hazardous substances in articles[1], we ask our suppliers **to provide a full transparency of the chemical composition of the materials used in the articles supplied to us.** Mutual collaboration can guarantee the level of trust to protect intellectual property. Further context is provided in this document.

Regulatory background

Over the last 15 years, chemical regulatory compliance has moved from identifying and substituting chemicals used in the workplace towards focusing on chemicals used within products sold to consumers (e.g. EU REACH, EU Medical Device Regulation 2017/745, EU Waste Framework Directive 2018/851, Stockholm Convention on Persistent Organic Pollutants, California Proposition 65). As any other industry placing articles on the market, the pharmaceutical industry has had to incorporate within its compliance programs an increasing number of requirements to notify, justify, label, assess and/or provide downstream communication in case of presence of hazardous substances in its products. Moreover, many of our customers have voluntary sustainability programs and are introducing green procurement processes, which often go beyond regulatory requirements and add an additional layer of information to be provided for products placed on the market. We understand this trend is set to continue, with recent announcements in the EU Green Deal on a Chemicals Strategy for Sustainability and a Sustainable Product Policies.

Material declarations

Ad hoc management of chemical regulatory requirements is no longer an option: the list of regulated substances is dynamic and requires periodic screening and updating. Correspondingly, more companies are asking suppliers for ‘material declarations’. These declarations provide information on the chemical composition of the materials within the supplied articles and therefore on presence and/or absence of hazardous substances. Additionally, a trend to adopt electronic tools supporting the material declaration process and information flow is emerging.

Material declarations can be delivered with a different level of transparency. Full material declarations (FMDs) disclose the full chemical composition offering complete transparency. FMDs allow for an automated assessment against all current, new and proposed compliance

[1] REACH defines an article as an object which during production is given a special shape, surface or design that determines its function to a greater degree than its chemical composition (https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles)

requirements and reduces long-term effort for all parties involved. On the other end of the spectrum, regulatory compliance declarations (RCDs) (also referred to as 'negative declarations') confirm the absence of substances thereby not disclosing the actual composition of the article. The latter is often called upon to protect intellectual property (IP) in formulation of the article(s).

Within the pharmaceutical industry, a clear preference is given towards FMDs, especially considering the regulated substance requirements under the EU MDR Annex I section 10.4 and the reduction of overhead in screening. Only transparency can guarantee that we deliver safe devices to our patients while at the same time reducing the increased effort of data collection.

We understand that IP might be compromised by this. There are several ways to overcome IP issues such as:

- ensuring that confidentiality agreements are in place between actors in the supply chain.
- agreeing on the process of how confidential substance-level information is communicated between companies and by reassuring each party, who in the receiving company can access the information (e.g. limiting data access to Regulatory Affairs/Environmental Product Compliance teams).
- using dedicated online 3rd party software that firewalls IP between customer and supplier.

Data Exchange

Within the pharmaceutical industry, as in other industries, we aim to harmonize and standardize our requests so that our suppliers can service multiple customers simultaneously. However, the effort in collecting the declarations cannot rest solely upon the pharma industry and we expect our suppliers to live up to their responsibilities of contributing to the seamless transfer of material declarations throughout the supply chain, in the common interest of all involved. This effort includes supplier readiness to collect and generate the necessary data, to have appropriate interfaces and contacts in their supply chain and to provide the requested information in a format that is readable by and compatible to currently used electronic systems. We encourage the use of data exchange standards such as the IPC1752 and the IEC62474 standards which can serve as input towards a common data exchange standard, thus streamlining and facilitating the sharing of information.

Conclusion

As our industry is held responsible to demonstrate material compliance, we must strive to obtain FMDs. This can only be achieved in close mutual collaboration to ensure that trust is built, and IP is properly protected. Our industry calls upon our suppliers to take up their responsibility and start the journey to provide the required level of transparency.