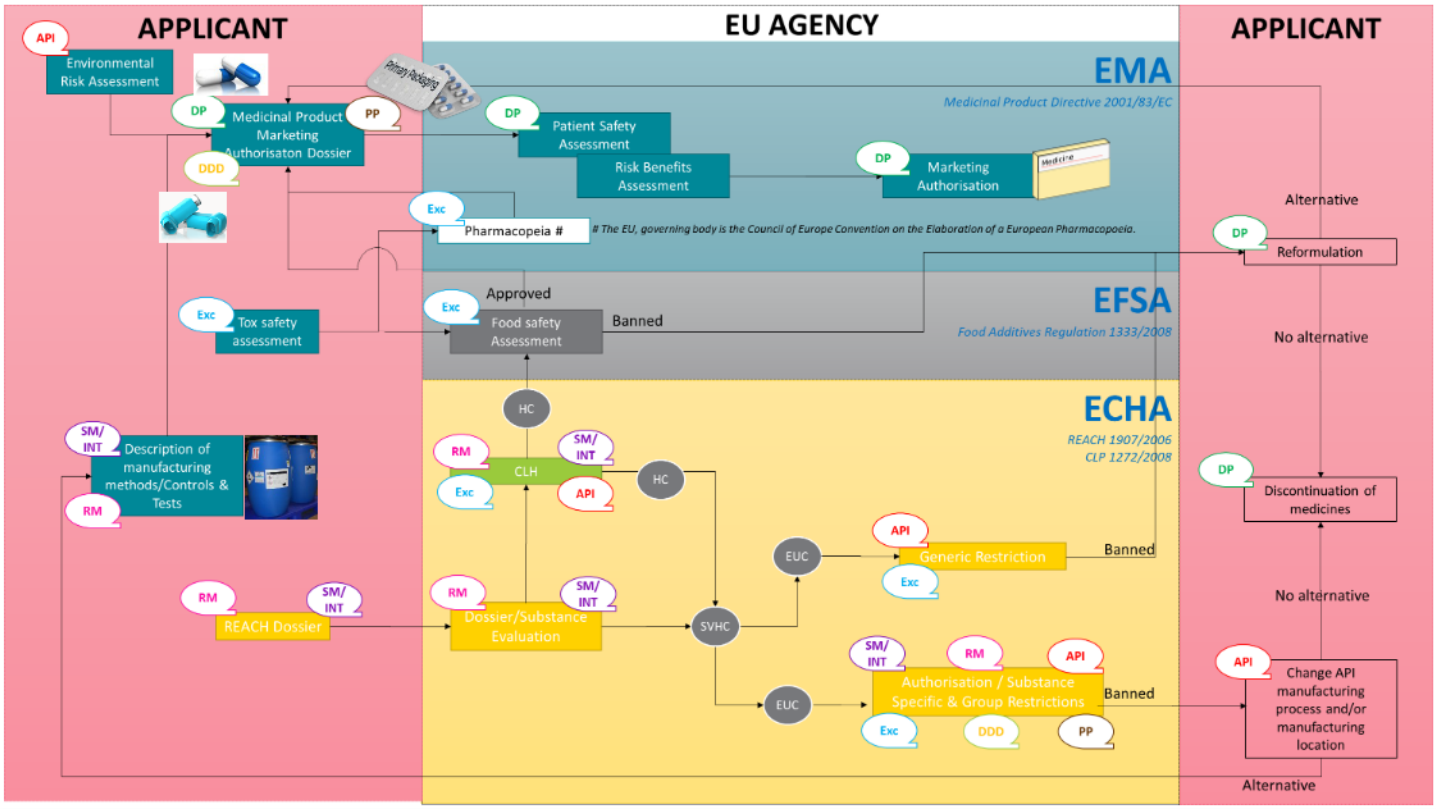
Ref. Ares(2022)5348176 - 25/07/2022

1 July 2022

Chemicals Strategy for Sustainability and Medicinal Products: How the EU Chemicals Legislation Interlinks with the EU Pharmaceutical Sectoral Legislation

The intent of this infographic is to show the linkage between REACH & CLP, EU chemicals management legislation and the provisions of the Medicinal Products Directive 2001/83/EC, which are also amended currently. Proposals on the reform of the REACH Authorisation and Restriction process will require changes to marketing authorisation application of medicinal products. The unintended consequences of this overlap between sectoral specific legislation such as medicinal products legislation and the REACH reform include potential disruption in patient accessibility to medicines. At the time of compilation, this infographic represents our best interpretation of information provided during stakeholder consultations on the Essential Use Concept and the Extension of Generic Approach to Risk Management.



GLOSSARY

API	**Active Pharmaceutical Ingredient** Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body. [ICH Q7 Good manufacturing practice for active pharmaceutical ingredients] => As per Article 2(5)(a) of REACH: Active substances used in the manufacture of medicinal products are exempt from Registration and Authorisation.
DP	**Drug (Medicinal) Product** As defined in Directive 2001/83/EC is any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.
Exc	**Excipient** A constituent of a medicine other than the active ingredient. => As per Article 2(5)(a) of REACH: Excipients used in the manufacture of medicinal products are exempt from Registration and Authorisation.
SM	**(API) Starting Material** A substance, intermediate, or API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. => Meets the definition of Intermediate as defined in Article 3(15) of REACH; As per Article 2(8)(b) of REACH: Intermediates, as defined in Article 3 (15), are exempt from Authorisation.
INT	**Intermediate** A material produced during steps of the processing of an API that undergoes further molecular change or purification before it becomes an API. Intermediates may or may not be isolated. => Meets the definition of Intermediate as defined in Article 3(15) of REACH; => As per Article 2(8)(b) of REACH: Intermediates, as defined in Article 3(15), are exempt from Authorisation.
RM	**Raw Material** A raw material is a substance or mixture of substances that is used in the production process of a drug substance, but which is not incorporated as a significant structural fragment into the structure of the drug substance (e.g. process solvent, catalyst, reagent)". => Pharmaceutical manufacturers are typically the downstream user of raw materials.
PP	**Primary Packaging** Any packaging material intended to be in direct contact with the active substance or medicinal product. The materials may be part of the container, the closure or seal or of other parts of the container closure system(s).
DDD	**Drug Delivery Device** 1. Devices that when placed on the market or put into service incorporate, as an integral part, a substance that, if used separately, would be considered as a medicinal product, provided that the action of the substance is principal (Article 1(8) MDR). 2. Devices intended to administer a medicinal product, where they form a single integral product intended exclusively for use in the given combination and which is not reusable (Article 1(9) MDR).

CLH = Classification & Labeling Harmonisation | **CLP** = Classification, Labeling & Packaging| **ECHA** = European Chemicals Agency | **EFSA** = European Food and Safety Agency | **EMA** = European Medicines Agency | **EUC** = Essential Use Concept | **GRA** = Generic Approach to Risk Management | **HC** = Hazard Category | **REACH** = Registration, Evaluation, Authorization and Restriction of Chemicals | **SVHC** = Substances of Very High Concern