EuropaBio response to the public consultation on the EC draft Delegated Regulation as regards the examination of variations to the terms of marketing authorisations for medicinal products for human use

EuropaBio welcomes the initiative from the European Commission to revise the "variation framework" last updated by the Commission Regulation (EU) No 712/2012.

In the light of the Pharmaceutical Strategy for Europe, the need to revise the variation framework in a stepwise approach is particularly relevant considering the wide range of instruments currently discussed with the aim of future-proofing Europe's regulatory framework. The new variation framework must be able to enable innovation, embrace technical and scientific progress and render the granting of variations more efficient. Simplifying and streamlining the variation system is key as currently a disproportionate amount of resources are required to handle and maintain a marketing authorisation (MA), both at Competent Authority and Marketing Authorisation Holder levels.

Building on more than a decade of experience with the current framework, EuropaBio supports the goal of streamlining and simplifying post marketing lifecycle management and invites the Commission to ensure the proposed initiative is fit for purpose and does not increase burden on MA holders, including small and mid-size developers.

EuropaBio welcomes the draft Delegated Regulation on the examination of variations to the terms of marketing authorisations for medicinal products for human use, and **in particular changes introduced to**:

- Introduce the new concept of super grouping across multiple marketing authorizations to also include purely national authorizations
- In the light of a public health emergency, increase regulatory flexibility regarding variations to a relevant human vaccine
- Harmonise and streamline the principle of change categorisation, both science-based and risk-based; update the list of variations in Annex II, for example removing the default classification to Type II for manufacturing changes for biologics.
- Introduce an annual update the classification guidelines to take into account scientific and technical progress and making use of the mechanism of recommendations on unforeseen variations according to Article 5
- Introduce the option of ranges in alignment with the relevant authority for certain changes (new Article 6a)
- Allow annual reporting of minor changes, whilst retaining the option of submission flexibility based on readily achievable acceptance of justifications

EuropaBio asks

Considering the limited scope of the revision as part of an intermediate step before more significant changes to the variation framework planned after the entry into force of the revised general pharmaceutical legislation, **EuropaBio would like to invite the European Commission to consider additional amendments to the draft Delegated Regulation to enable the full implementation of ICH Q12 guidelines before the revised pharmaceutical legislation becomes applicable**.

Furthermore, in the spirit of streamlining, **reporting obligations already in place for medical devices and IVDs under the MDR and IVDR should not be required to be duplicated**, as well as **increasing scope and flexibility in grouping** as an example possibility to include grouping of type IA and IB that are not consequential in the context of a type II CMC variation.

Importantly, the revision of the variations framework will only be able to achieve its objectives through a comprehensive and sensible revision of the classification guidelines that will be undertaken as a subsequent step of the revision of the EU rules on changes to marketing authorisation. **EuropaBio is looking forward to contributing and providing input to the revision of the classification guidelines when made available for public consultation**.

Conclusion

EuropaBio remains fully committed to work and partner with the relevant stakeholders and European institutions in order to help shaping a regulatory framework that delivers innovative therapies to patients across the EU.