Vaccines Europe response to the revision of the pharma package:
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en

Vaccines Europe (VE) concurs with the responses submitted by EFPIA, whilst raising implications and concerns regarding the proposed revision of the General Pharmaceutical Legislation (GPL) for vaccines and the industry developing and manufacturing them.

Although the vaccine industry is a relatively small part of the overall pharmaceutical industry, it is particularly important for the EU and its citizens as it delivers more value than any other innovative industry. While vaccines fall under the same regulatory framework as other medicinal products, vaccines' unique specificities should be taken into account therein.

The European Commission should take a holistic approach to health: from prevention to care. The Covid-19 pandemic was a painful reminder of the value of vaccination and the need to incentivise innovation in the vaccine sector.

Below are some of VE recommendations. More details and further recommendations can be found in Annex.

1. Given the heterogenicity of national immunisation programmes, vaccine assessment and decision making, tendering and manufacturing complexity, no vaccine developer would be able to fulfil conditions for additional 2 years of Regulatory Data Protection (RDP). Such RDP modulation would not address the root causes of significant delays and inequality in population access to vaccination across the EU, but only further hinder innovation.
2. The definition of unmet medical need should be more inclusive and embrace the perspective of target populations, recognising the value of preventing diseases in the first place and of community protection.
3. The flexibility of product naming should be maintained for vaccines to account for specific complexities where an International Non-proprietary Name (INN) cannot be assigned or where seasonality or emergency preparedness means that INN assignment could impede immediate access.
4. The requirement of reporting clinical studies which involve the use of vaccines in the paediatric population within 6 months of the completion of the study should be revised to the standard timeline of 12 months, to allow time to complete all procedural steps.
5. The implementation of electronic product information (ePI) for HCP-administered products, such as vaccines, should be transitioned first, fully replacing the paper information leaflet, and allowing for a faster adoption across the EU – given positive outcomes of pilot projects.
6. The possibility of EU common packaging for vaccines should be considered to optimise manufacturing processes, allow more flexible allocation of vaccines from one MS to another, ensure greater security of supply and the prevention of shortages. This could also contribute to further reducing pack size, thus facilitating storage and transport, and contributing to supply efficiencies and EU's Green Deal.
7. The introduction of Temporary Emergency Marketing Authorisation requires additional clarifications to ensure that the mechanism is agile, fast, simplified and in line with experience gained from the COVID-19 pandemic.
8. The expansion of the master files concept to include platform technologies to enable use of prior knowledge and foster innovation.
9. The new broad definition of vaccine is welcomed as it offers a clear point of reference. However, it should be sufficiently broad to cover existing and future technologies, whilst some terms need to be clarified or added to remove ambiguity.

10. Vaccination has been widely recognised to be a cost-effective, complementary tool in the fight against AMR, and as such, should become an integral part of the GPL revision to foster an innovative ecosystem in this area.
11. To address vaccine shortages and support resilient supply chains, standardised definitions and reporting of shortages should be established in EU, along with a harmonised prevention and mitigation system. Shortages Prevention Plans (SPPs) should be required for critical medicines only, not for all products.

VE is committed to working with all stakeholders in an open dialogue towards fulfilling its mission to protect people against infectious diseases at all stages of life.

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