EHA statement regarding the European Parliament's position on the Pharmaceutical Legislation

23 April 2024

The reform of the **European Union's pharmaceutical legislation**, proposed by the Commission in April 2023, provides a unique and indispensable opportunity to tackle access and affordability shortcomings and inequalities across Europe, to address unmet medical needs, to position Europe as a breeding ground for patient-centered innovation and, not least important, to continue developing the European Health Union.

Whilst EHA is pleased with the position agreed upon in the **European Parliament**, and recognizes several additions that enhance the Commission's proposals, a few concerns remain. Find our observations, per subject, below:

- **Unmet Medical Need (UMN):** Unfortunately, key elements of UMN such as quality of life, burden of disease, and the consideration of patient experience data (PED) were only added to the recitals. Article 83 should be amended accordingly, to prevent disparate implementation. Furthermore, consultation of HCPs within the context of EMA's scientific guidelines should be mentioned explicitly.

- **Hospital exemption (HE):** EHA commends the Parliament's efforts to reduce fragmentation and to instate requirements that ensure the safety, effectiveness, and quality of these treatments in every Member State. However, the definition of 'non-routine' in article 2(1) neglects the potential benefit and usage of an approved HE beyond a single patient. Finally, the possibility for cross-border exchange of HE is a vital improvement, as well as the creation of a publicly accessible repository.

- **Incentives:** Regrettably, the reasonable baseline protection proposed by the EC was not maintained. In addition, more could have been done to incentivize research & development of medicines on European soil, which yields both an economic and strategic benefit, and allows for the specificities of European patient populations to be duly considered. It is worth reiterating that incentives entail an expenditure of billions of euros and constitute a tremendous load on public health systems which, at the moment, is not being reinvested in Europe.

- **Financial support reporting:** EHA welcomes the EP amendments to article 57, which greatly improve funding transparency. We add that insight into R&D costs more generally would benefit affordability as well as enhance the position of Member States when negotiating prices.

- **Declarations of interest:** While EHA fully subscribes to the importance of transparency, we worry that the stricter wording adopted in article 208 might lead to the exclusion of valuable expertise, particularly, when it comes to rare diseases, for which there are very few experts to begin with.

- **Drug repurposing:** EHA supports the extension of the provision's scope beyond unmet medical need, and iterates the value of repurposing medicinal products for reaching more patients, faster.

- **Bolar exemption:** We welcome the strengthening of article 85, which addresses unnecessary delays for generics to enter the market immediately after regulatory protection has expired. Faster timelines are of great benefit to all patients.