Académie nationale de Pharmacie

REFORM OF THE EUROPEAN PHARMACEUTICAL LEGISLATION

The French Academy of Pharmacy intends to formulate concrete proposals in its areas of expertise.

The French Academy of Pharmacy welcomes the Commission proposals[1] to reform the pharmaceutical legislation of the European Union. On 13 December 2021, the Academy suggested various lines of thoughts in its response to the Commission consultation process.

The complex and extensive nature of this reform calls for a careful analysis of the proposals for a Directive, for a Regulation and for a Recommendation, published in English at the end of April. Their transmission to Council and Parliament will probably take time due to translation delays. Negotiations between European Institutions are expected to be long and difficult.

The Academy is willing to make concrete suggestions based on its areas of expertise, in connection with concerned French authorities. Supplying the European Union with indispensable medicinal products, together with a greater industrial autonomy and simplified and more flexible regulatory processes, should be prioritized during these debates. Awaiting the translation of the proposals, a preliminary analysis was conducted (see annex).

Besides the reform, the impact of recent measures such as the reinforcement of the capacities of the European Medicines Agency (EMA) to respond to crisis and of the creation of the European Health Emergency preparedness and Response Authority (HERA) must be assessed. In this context, the Academy welcomes the EMA recommendations for the prevention of shortages that should be swiftly enforced.

[1] Proposal for a Directive on the Union Code relating medicinal products for human– COM (23) 192 final and Annexes + Proposal of a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014– COM (2023) 193 final and Annexes.

Annex

Preliminary remarks on the European pharmaceutical reform

- **The Academy notes that certain concerns have been met** in the Commission proposals, in particular the choice of a directive as a legal instrument adapted to national health realities, such as the so-called status of "pharmacien responsable". Nevertheless, the huge responsibilities of the marketing authorization holder should be reflected in a more compelling status linked to real operational capacities, which are sometimes sub-delegated to other entities.

- **The unavailability of indispensable medicines** has been the subject of considerable work by the Academy. The availability of "old" indispensable medicines is an important public health issue, especially during crisis. On such aspects, harmonizing national notifications of shortages, creating national contact points and establishing an European list of "critical medicines" by the Commission on proposal from an executive committee of Heads of agency representatives (present MSSG) corresponds to the wishes of the Academy. Nevertheless, the establishment of closer operational connections between the EMA, HERA and the European Pharmacopoeia was not retained, as suggested by the Academy.

- As requested, the Commission acknowledges the possibility of **making variations of marketing authorizations more flexible** according to the ICH12 guideline. Other measures of regulatory simplification are welcomed such as the reduction of marketing authorization time-lines, digitalization to reduce the workload of industry and authorities, electronic and multi-lingual package leaflets.

- **The creation of « regulatory sand boxes »** should accompany major innovations (personalized medicine, phages) is a new approach. The Academy wishes to take part in these debates, in particular on methodology.

- The Academy intends to closely **monitor measures to fight antimicrobial resistance and the evaluation of environmental risks related to medicines**. The introduction of environmental risk assessment for "old" medicines should not lead to additional shortages, especially for "critical" medicines.

- The Academy **regrets that the present reform does not cover the regulation of clinical studies** when the excessively lengthy transposition of Regulation 2014/536 is not yet completed and raises important issues for the future of European clinical research. On that point, the Academy advocated the principle of a centralized authorization for trials related to medicines to be evaluated by the EMA in the centralized marketing authorization procedure.