The Netherlands: key questions and comments in response to the public consultation on the combined evaluation roadmap / inception impact assessment for the general pharmaceutical acts

26 April 2021

The Netherlands welcomes the opportunity to respond to the open consultation of the European Commission on the revision of the general pharmaceutical acts (Regulation (EC) No. 726/2004 and Directive 2001/83/EC).

In order of the topics of the proposed combined evaluation roadmap / inception impact assessment, the Netherlands would like to submit several key questions and comments for consideration by the European Commission.

Evaluation

It is indicated that the evaluation should assess the extent to which the basic pharmaceutical regulations have met the original objectives. We would like to ask for several clarifications:

- Why is the evaluation limited to the objectives of the Pharmaceutical Strategy? What specific provisions will be evaluated?
- Is the choice of separation, overlap and coherence between the different legislative instruments also evaluated?
- In addition to achieving the stated goals, is the evaluation looking at relevance, redundancy, incitement of/vulnerability to misuse or unintended consequences? It is also necessary to consider starting points to adjust original goals where necessary.

Problem the initiative aims to tackle

This section clarifies which problems should be solved by the revision of the general pharmaceutical legislation. The Netherlands believes the following questions and comments should also be addressed by the initiative:

- Is the current registration system the appropriate tool for quality and safety assessment in small numbers of patients, personalised medicines and ATMPs?
- Is the current registration system an appropriate tool for the incorporation of a new (genetic and genomic) taxonomy of human disease?
- Does the current legislative framework in practice provide a level playing field for new small innovative businesses and established large companies with innovative departments?
- Is the current registration system adaptive to data from the daily practice of third parties?
- Do other overarching regulatory systems require changes in the general pharmaceutical legislation (i.e. GDPR)?
- Administrative burden and loss of time in case of changes in dossier contributes as a cause of the withdrawal of essential medicines.

Policy options

Apart from the baseline scenario, the roadmap/IIA does not provide specific policy options. This raises the following questions:

- Will additional, specific policy options be published in due time for consultation?
- Could the completely new design of the regulations be one of the policy options?

In addition, we wish to comment as follows:

- Under 'Elements to be covered by policy options' under 'd.' more generally: incentives for medicines with similar (im)possibilities with regard to a viable business case should also be considered.

Likely economic impacts

The document states that 'SMEs stand to gain most from a simplified regulatory system and flexibilities related to modern developments'. However, larger companies would also benefit from a simplified regulatory system.

Evidence base

This section lists the data sources to be used by the Commission for the evaluation of the legislation. In addition to the sources mentioned, use should also be made of research done into the suitability of registration/market authorisation systems in small numbers of patients and personalised medicines.