CHIOMENTI

Newsletter

Business Unit: Pharma, Healthcare and Life Sciences

EU: OPENING OF A CONSULTATION ON THE REVISION OF PHARMACEUTICAL LEGISLATION

I. Pharmaceutical strategy and Health Union

On 28 September 2021, the European Commission has launched an important public consultation aimed at reforming EU legislation in the pharmaceutical sector.

This initiative is part of the reform projects already announced on November 2020 with the "Pharmaceutical Strategy for Europe", by which the Commission underlined the necessity to ensure access to affordable medicines for patients and support competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high quality, safe, effective and greener medicines

Always on November 2020, with its communication "Building a European Health Union", the Commission also remarked specific necessities (also in light of the pandemic), such as: (i) fulfilling unmet medical needs; (ii) supporting a competitive and innovative European pharmaceutical industry; (iii) enhancing resilience through diversified supply chains, environmental sustainability, and crisis preparedness; and (iv) promoting high standards for medical products globally.

II. "Flagship" actions: revision of EU legislation

Since the above-mentioned Pharmaceutical strategy, the Commission has been working on a number of actions (in close cooperation with Member States and the EMA).

Among these, an important flagship action is the revision of the general pharmaceutical legislation, foreseen for end 2022 (almost twenty years after the last revision).

Other flagship actions of the Strategy focus on Health Technology Assessment, EU Health Data Space, legislation on rare diseases and medicines for children and strengthening the continuity and security of supply of medicines in the EU.

III. The consultation

The announced consultation has the aim to collect views of stakeholders and the general public in order to support the evaluation of the existing general pharmaceutical legislation on medicines for human use, and the impact assessment of its revision to ensure a future-proof and crisis-resistant medicines regulatory system.

In particular, the consultation will address the following topics:

- the performance of general pharmaceutical legislation;
- unmet medical needs;
- incentives for innovation;
- antimicrobial resistance;
- an adequate regulatory framework for novel products;
- improved access to affordable medicines;
- repurposing of medicines;
- security of supply of medicines;
- quality and manufacturing;
- environmental challenges for a greener pharmaceutical sector.

The consultation, that you can reach at this link, will run for twelve weeks, until 21 December 2021.

Contacts:

Luca Liistro
Partner – Chiomenti
M&A Department - Head of Business Unit Pharma, Healthcare & Life Sciences
T. +39 02 72157 322
luca.liistro@chiomenti.net

Guido Bellitti
Partner – Chiomenti
European Law Department
T. +39.06.46622.309
guido.bellitti@chiomenti.net

Gian Michele Roberti
Partner – Chiomenti
European Law Department
T. +39 06 46622308
gianmichele.roberti@chiomenti.net