

ESMO RESPONSE TO THE ROADMAP FOR A NEW PHARMACEUTICAL STRATEGY FOR EUROPE

Representing over 25,000 members from over 160 countries, the European Society for Medical Oncology (ESMO) welcomes the consultation on the roadmap for a new Pharmaceutical Strategy. ESMO considers the following as priorities within the objectives, along with 6 recommendations:

MEDICINES SHORTAGES:

Shortages of inexpensive, essential medicines are a growing public health emergency that require concerted and collaborative action at the EU level. While there is a clear impact of medicines shortages on patient outcomes, their causes are complex and multifactorial and cannot be solved by any Member State alone. Given that treatment of cancer patients is highly affected by the shortages of these inexpensive medicines, ESMO developed 6 reports on medicines shortages. The foundational report & 5 country profiles, done with The Economist Intelligence Unit, indicated that no country is left untouched by the issue of inexpensive, essential medicines shortages.

THUS:



1. ESMO believes that only a supranational EU solution can mitigate the inexpensive, essential medicines shortages, which have been exacerbated by the COVID-19 pandemic.
2. ESMO believes that shortages of inexpensive, essential medicines are due to their unavailability, and the 'shortages' of expensive, innovative medicines are due to their inaccessibility. Thus, in order to ensure a continuous supply of both kinds of products, ESMO would recommend having tailored suggestions for both, especially as anti-cancer medicines are highly affected in both categories.

OFF-LABEL USE OF CERTAIN MEDICINES FOR CERTAIN INDICATIONS:



Off-label use of certain medicines, including old inexpensive medicines as well medicines which may be used in specific situations, e.g. for rare and very rare cancers, are crucial for the treatment of cancer patients. Currently, the existing framework at the European Medicines Agency (EMA) does not allow for approval of these already approved medicines for other indications, in a simple manner.

3. ESMO recommends analyzing the existing situation concerning off-label use of medicines and creating a framework that would be conducive to defining which currently used off-label medicines, supported by robust evidence, for other indications should be made available.
4. ESMO recommends assessing the off-label use of medicines in rare and very rare cancers, through an EU-wide survey.



COLLECTION OF DATA:

ESMO's antineoplastic medicines survey (ANMS) is currently the most comprehensive assessment on the availability of cancer medicines globally, according to the WHO report on pricing of cancer medicines (2018). ESMO will be re-doing the ANMS survey and will be sharing the data with the European Commission, to feed into the Pharmaceutical Strategy.



ECONOMIC MODEL:

ESMO is currently working towards the development of a geographically-adapted value-based reimbursement model to tackle issues related to the reimbursement of expensive, innovative medicines. ESMO will share the details concerning the model with the EU institutions in due course, to feed into the Pharmaceutical Strategy.

PRIORITIZING CANCER MEDICINES:

The ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS) is a tool, assessing EMA-approved medicines, for a rational and structured approach to derive a relative ranking of the Magnitude of Clinically Meaningful Benefit of anti-cancer treatment. It is being used by various countries across the world to prioritize cancer medicines. With the incoming wave of high-cost treatments in similar settings for cancer, there is a need to allow EU Member States to choose medicines appropriately, including the use of biosimilars. A concrete example of countries using the ESMO-MCBS: WHO Report on cancer 2020 (p. 45).

EU GENERAL DATA PROTECTION REGULATION (GDPR) AND THE EU CLINICAL TRIALS REGULATION (CTR)



5. ESMO recommends using cancer medicines as a pilot to jointly assess medicines under the draft Health Technology Assessment (HTA) regulation (joint clinical assessments). The ESMO-MCBS may help facilitate the process, given that it is already being used by the WHO and various countries across the world.

6. ESMO recommends the harmonized implementation of Recitals 33 & 157 of the GDPR, & Recital 29 and Article 28 (2) of the CTR across the EU in order to facilitate scientific research.