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

The European Society for Medical Oncology (ESMO) is the leading professional organization for medical oncology. Comprising over 25,000 oncology professionals from over 160 countries, ESMO is the society of reference for oncology education and information at European and global levels.

ESMO'S WORK REGARDING INEXPENSIVE, ESSENTIAL MEDICINES

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 the treatment of cancer patients is highly affected by the shortages of these inexpensive medicines, ESMO developed six reports on medicines shortages. The foundational report and five country profiles, done with The Economist Intelligence Unit (EIU), indicated that no country is left untouched by the issue of inexpensive, essential medicines shortages.
For more information: https://www.esmo.org/policy/shortages-of-inexpensive-essential-cancer-medicines

- ### CANCER MEDICINES SHORTAGES IN EUROPE – POLICY RECOMMENDATIONS TO PREVENT AND MANAGE SHORTAGES:

  In May 2017, ESMO collaborated with The Economist Intelligence Unit (EIU) to produce a report providing six concrete policy recommendations to address and mitigate shortages of inexpensive, essential medicines at the EU Level. The report was launched at the European Parliament, in May 2017, and since then has been presented at various meetings.

- ### FIVE EU COUNTRY PROFILES ON MEDICINES SHORTAGES:

  In April 2019, ESMO, in collaboration with the EIU, produced a set of reports describing the situation of cancer medicines shortages in five countries – Germany, Romania, Bulgaria, Finland and Belgium. The profiles showed that the issue of shortages is severe across all EU countries. For more information: https://www.esmo.org/policy/shortages-of-inexpensive-essential-cancer-medicines

- ### CALL TO ACTION:

  In April 2019, ESMO launched a Call to Action outlining key steps and calling for tangible political commitments to tackle inexpensive, essential medicines shortages in the EU. The document was signed by 20 Members of the European Parliament and 16 stakeholders.

- ### SHORTAGES OF INEXPENSIVE, ESSENTIAL MEDICINES (THE LANCET ONCOLOGY):

  ESMO's comment in The Lancet Oncology on the topic of inexpensive essential medicines shortages (April 2019), notes the need to address both aspects of shortages: the insufficient access to promising new compounds and low supply of good, old, inexpensive essential medicines. This is crucial to ensure equal access to optimal (cancer) care.

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ESMO'S WORK REGARDING EXPENSIVE, INNOVATIVE MEDICINES

Given that access to affordable medicines is key to achieving sustainable cancer care, ESMO continues to address the topic at the European and global levels by developing tools and resources:

- **PRIORITIZING CANCER MEDICINES – ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE (ESMO-MCBS):**

  The 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. This is a tool that helps to assess the value of cancer care and prioritize medicines and also address the challenges of the appropriate use of limited resources to deliver cost-effective and affordable cancer care. 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. For a concrete example of countries using the ESMO-MCBS, please see below.

- **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.

- **BIOSIMILARS PORTAL:**

  Biosimilars are medicinal products containing a similar version of the active substance of their biological originator or reference product and are derived from living organisms. With many expensive cancer medicines coming off patent, ESMO believes that biosimilars present a necessary and timely opportunity as they can positively impact the financial sustainability of healthcare systems while improving access to medicines for patients. This view has been laid down in ESMO's Position Paper on Biosimilars. In order to raise awareness about biosimilars and build confidence among the community, ESMO launched a Biosimilars Portal, containing information on the science, regulation, education and resources for patients (including an infographic) on biosimilars.
  For more information: https://www.esmo.org/policy/biosimilarsportal

DATA COLLECTION

Over the past years, ESMO has gathered data on the availability of cancer medicines in Europe and internationally, by launching two surveys. The findings from the studies were published in the Journal, Annals of Oncology:

- ESMO European Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in Europe (Cherny N et al, 2016)
- ESMO International Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in countries outside of Europe (Cherny N et al, 2017)

The two studies were cited as the most comprehensive assessment on the availability of cancer medicines globally by the World Health Organization (WHO), in the 2018 WHO Technical Report on the pricing of cancer medicines and its impacts. ESMO will be re-doing the Antineoplastic Medicines Survey (ANMS) and will be sharing the new data with the European Commission, to feed into the Pharmaceutical Strategy.

For more information: https://www.esmo.org/policy/anti-cancer-medicines-availability

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CONCRETE EXAMPLES FROM THE WORLD HEALTH ORGANIZATION REPORTS (REGARDING THE ESMO-MCBS & ITS USE IN COUNTRY-SETTINGS):

- **WHO TECHNICAL REPORT: PRICING OF CANCER MEDICINES AND ITS IMPACTS**

  The 2018 WHO Technical Report on Pricing of cancer medicines and its impacts summarizes what is known regarding the impact of price setting on the relation between pricing, research and development (R&D), availability and affordability. It suggests that current pricing policy for cancer medicines have not adequately met health and economic objectives, that prices of cancer medicines are high compared to other therapeutic areas, and that some stakeholders have set cancer medicine prices higher than their true clinical value. The report references the ESMO-MCBS as the tool of preference to facilitate the benefit assessment process of cancer medicines to be considered for the WHO Model List of Essential Medicines (section 2.2, pages 13-14). The report also references the ESMO European and international surveys on the availability of anti-neoplastic medicines, affirming that they represent "the most comprehensive assessment on the availability of cancer medicines globally" (section 4.2.1, page 68, and figures 4.8 and 4.9, pages 69-71).

- **WHO REPORT ON CANCER: SETTING PRIORITIES, INVESTING WISELY AND PROVIDING CARE FOR ALL (P.45):**

  Kazakhstan has made a strong political commitment to cancer control and UHC founded on strong primary health care. After an imPACT mission in 2016, WHO was requested to review the cancer program and to identify interventions that would maintain or increase coverage of cancer services, provide value for money and ensure financial protection. WHO and the Ministry of Health reviewed the country's screening programs and concluded that focusing on three evidence-based programs would have more impact than six. In reviewing the country's cancer treatment standards, WHO enlisted support from ESMO, which analyzed 20 cancer disease settings (over 300 protocols) using the WHO Essential Medicines List (EML), the European Medicines Agency's medicine indications, the ESMO Clinical Practice Guidelines, the ESMO-Magnitude of Clinical Benefit Scale version 1.1, and expert peer review. The assessment supported the Ministry of Health in optimizing its cancer treatment protocols and linking them to the national essential medicines list. Screening coverage increased from 60% to 90% for breast and cervical cancer, and treatment coverage increased from 85% to 89%. By incorporating the recommendations into the Kazakhstan national cancer control plan 2018-2022, the country maintained its long-standing commitment to offer its citizens evidence-based comprehensive cancer care as part of universal health coverage.