WHO EML Secretariat
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On Behalf of the International Society of Oncology Pharmacy Practitioners (ISOPP)

Advocacy Committee Co-Chairs
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With Respect to the Following Drugs for Proposed Addition to the WHO EML

- Anti-PD1 Inhibitors (Pembrolizumab, nivolumab, atezolizumab, cemiplimab, tislelizumab, toripalimab), CDK 4/6 Inhibitors (Palbociclib, ribociclib, abemaciclib), Osimertinib, Zanubrutinib, Brentuximab vedotin, ALK inhibitors (crizotinib), CAR-T cell therapy

- Pegfilgrastim
ISOPP Recommendations to EML Secretariat

- **Addition of peg-filgrastim to the EML**
  - Approved in most LMICs, useful in LMICs for patients without access to suitable storage conditions
- **Remaining medicines have low probability of adoption to national lists**
- **PD-L1 inhibitors, CDK 4/6 inhibitors, brentuximab vedotin, ALK inhibitors:** Mostly approved but unfunded, not equitably accessible at the national level.
- **Osimertinib, Zanubrutinib:** 1st line uptake of Osimertinib is not yet favorable, zanubrutinib is mostly not approved in LMICs
- **CAR-T cell therapy**
  - Exorbitant cost
  - Requires a significant health care system infrastructure
  - Tocilizumab has been suggested, but not for CRS related to CAR-T cell therapy
- **Additional barriers in LMICs:**
  - Access and affordability of requisite biomarker testing to identify patients who are most likely to benefit (PD-L1 testing, EGFR testing etc.)
  - Need of additional human resources to safely administer and monitor for safety/toxicity
- **Standardized regimens for resource-constrained settings**
Statement to WHO EML Secretariat on behalf of ISOPP

Dear secretary, and esteemed members of the WHO EML Secretariat; my name is Esin Kandemir, I’m a research associate at the University of Oldenburg, Germany. Today I am presenting on behalf of the International Society of Oncology Pharmacy Practitioners. I would like to thank the EML Secretariat for inviting us to make a presentation.

First, we wish to acknowledge the hard work of organizations and individuals who submitted proposals for addition to the essential medicines list this year. Our remarks are with respect to the agents we list here. I would like to highlight that there many members from lower-and middle-income countries (LMICs) in our advocacy committee.

Our members support the addition of PEG-filgrastim to the list as we have observed that it is already in use in most of the countries. It is especially important for patients without access to refrigeration.

Our members practicing in LMICs stated that many of the remaining medicines have a low probability of being adopted on to their national list of essential medicines. To be sure, in the case of immunotherapeutic agents and targeted therapies; while they represent important breakthroughs to treat cancer, however they are still not curative.

PD-L1 inhibitors, CDK 4/6 inhibitors, brentuximab vedotin and ALK inhibitors are mostly approved but unfunded in LMICs. We separately discussed tislelizumab and toripalimab. Our members stated that the use of these drugs is not currently in question, however adoption of these drugs is not totally excluded, so it remains possible in future to adopt these regimens in accordance with their clinical efficacy, safety, and cost-effectiveness data.

Most of the LMICs are not yet ready for the uptake of Osimertinib for the first line treatment of NSCLC. Beyond that, zanubrutinib is not approved in most of the LMICs.

The cost impacts of CAR-T cell therapy are exorbitant even for high income countries. Cellular therapies require significant investments in health care infrastructure (physical and human resources) and the availability of tocilizumab for the emergency treatment of CAR-T related CRS.

In conclusion, the main barriers in LMICs to adopting these agents is cost. Equitable access to high quality, standardized biomarker testing is improving but remains an important issue in LMICs. The
need for additional human resources to safely administer and monitor toxicities of these treatments should additionally be considered.

At this point, I would like to mention our society’s position paper for your consideration, which highlights the role of oncology pharmacy team in cancer care.

Finally, we support the further development of standardized disease specific treatment regimens linked with the WHO EML for resource constrained settings.

Thank you again, for giving us the opportunity to present here today.