IFPMA

IFPMA's Response to EML Secretariat proposal to amend square box listings on the EML and EMLc

IFPMA supports the proposed modifications to the usage of the square box symbol (SqB) for the WHO Essential Medicines List (EML) in alignment with the recommendations provided in the recent "Review of the square box symbol uses in the 2019 WHO Model List of Essential Medicines: including proposed revisions to terminology, listings and integration in the electronic EML (e-EML)" report. Among other reasons, since the establishment of the SqB in 1977 the increasing number of biologic medicines on the EML, including the reference to biosimilars as potential alternatives, along with the inconsistent use of the SqB as noted in the recent report, make it imperative to adopt new nomenclature and incorporate new information to better account for the nuances of biologic medicines. Such additional information will be beneficial for countries as they consider medicines, particularly biologics, from the EML and will help prescribers and patients secure the most appropriate medicines to meet healthcare needs. IFPMA appreciates WHO's consideration of the additional points outlined below pertaining to potential modifications to the SqB and the EML.

The current SqB is primarily intended to indicate similar clinical performance within a pharmacological class. IFPMA requests that the WHO consider the following additional recommendations regarding the need for product specific considerations:

- As per the recommendations in the recent report, the SqB should suggest therapeutic equivalence and potentially interchangeability (definition dependent) only where this recommendation is made based on reviews of efficacy and safety and is consistent with the standard treatment guidelines for the indication.
- Any new terminology/approach (or modifications to the EML) should account for differences in indications across products listed as alternatives, particularly for biological medicines. If there are differences in indications across products, evidence to support safety and effectiveness for the same indications as the product originally listed may not exist. If evidence to support safety and efficacy in a given indication is not be available then those medicines cannot be assumed to support similar clinical performance in such indications. The current terminology, however, does not account for indication differences.
- New terminology/approach (or modification to the EML) should also account for differences in the clinical safety and efficacy profile of products listed as alternatives (e.g., adalimumab vs. etanercept vs. infliximab) that would likely necessitate patient monitoring.
- New/revised terminology should also indicate that an SqB or any other symbol suggesting therapeutic equivalence and/or interchangeability does not represent a physician-driven decision.

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