

EML Secretariat proposal to amend square box listings on the EML and EMLc

Proposal:

The Expert Committee is requested to consider proposed amendments to the current square box listings on the EML and EMLc.

Background:

The 'square box' symbol has been used in the Model Lists since 1983 to indicate that the listed medicine is representative of therapeutically equivalent alternatives, any of which would be suitable for selection at country level for inclusion on national Essential Medicines Lists. The current definition of the square box symbol is as follows:

"The square box symbol is primarily intended to indicate similar clinical performance within a pharmacological class. The listed medicine should be the example of the class for which there is the best evidence for effectiveness and safety. In some cases, this may be the first medicine that is licensed for marketing; in other instances, subsequently licensed compounds may be safer or more effective. Where there is no difference in terms of efficacy and safety data, the listed medicine should be the one that is generally available at the lowest price, based on international drug price information sources. Therapeutic equivalence is only indicated on the basis of reviews of efficacy and safety and when consistent with WHO clinical guidelines. National lists should not use a similar symbol and should be specific in their final selection, which would depend on local availability and price."

Square box listings on the Model Lists were last reviewed in 2003, when there were 113 medicines listed with a square box. The 2019 Model Lists include 108 entries (involving 93 unique medicines or fixed-dose combinations). There is considerable heterogeneity in the way these listings are presented – some name the specific alternatives, others do not, and others refer to acceptable alternatives, without having a square box listing.

Proposed amendments to square box listings:

The EML Secretariat has undertaken an updated review of square box listings on the EML and EMLc (Attachment 1).

For consistency, and to provide the greatest guidance for countries using the Model Lists, it is proposed that all square box listings be 'qualified' to clearly indicate the acceptable therapeutic alternatives that may be considered for national selection.

Following this review, a series of proposed amendments to current square box listings were developed. Amendments fall into the following groups:

- Group 1: Listed medicines without a square box but with an asterisk denoting accepted alternatives – proposed to be converted to qualified square box listings.
- Group 2: Listed medicines without a square box but with an asterisk denoting accepted alternatives – independent listings are proposed for the alternatives.
- Group 3: Unrestricted square box listings where accepted alternatives are described in the Technical Report of the meeting where the listing was recommended – proposed to be converted to qualified square box listings.
- Group 4: Unrestricted square box listings where the Secretariat proposes specific alternatives for qualified square box listings.
- Group 5: Unrestricted square box listing where alternatives can be defined by pharmacological class at the ATC4 level.
- Group 6: Unrestricted square box listing where the Secretariat proposes removal of the square box due to the absence of suitable alternatives.
- Group 7: Unrestricted square box listings proposed for review of suitable alternatives
- Group 8: Qualified square box listings for which no amendments are proposed.

Full details of the proposed amendments for Expert Committee consideration are presented in Attachment 2.