

22nd Expert Meeting, WHO Model List of Essential Medicines (EML) including Essential Medicines for Children (EMLc)

MSF reflections and comments

ARVs, antituberculosis, antimalarials

MSF welcomes the proposal from the WHO departments (+ Stop TB /GDF)

- All inclusions and deletions in line with recent recommendations and guidelines
- Change of minimum age for delamanid in children (lowered to 3)
- Inclusion of FDCs = SP IPTi , SP IPTp and SP-AQ for malaria prophylaxis in infant and during pregnancy

Nutritional products = Ready-to-Use Therapeutic Food and Multiple Micronutrient Powders

- Not medicines and therefore not manufactured according to pharmaceutical manufacturing standards
- RUTF and MNPS should follow international food quality standards (Codex Alimentarius)
- MSF in favor of a separate WHO Model List for Nutritional Products (similar as EDL created in 2018)

Medicines for reproductive health

MSF welcomes

- carbetocin, long-awaited heat stable alternative to oxytocin but price is an issue
- tranexamic acid for PPH
- moving mifepristone-misoprostol to Core list

Misoprostol for PPH should be remained on the EML for settings where injectable uterotonics are challenging to provide

Neglected diseases: Human African Trypanosomiasis, scabies

MSF warmly welcomes

- Fexinidazole, a disease stage-independent short duration oral treatment for HAT: a significant simplification of treatment without hospitalisation
- Ivermectin, a single dose oral treatment for scabies, allowing large-scale mass drug administration campaigns

Paediatric dosage forms

- Child friendly formulations (oral granules, dispersible tablets, oral pellets) are needed in order to increase efficacy, safety of administration and adherence to treatment.
- Urgent to continue development of quality-assured formulations (WHO-PQ as reference)

Insulin analogues

- Lack of data for many countries (including in low resource settings) where the EML is most relevant
 - What are the benefits and risks in the context of food insecurity?
 - What should we do for migrants with diabetes? How about for children with diabetes living in food insecure contexts?
- Price issues
 - We now know the cost of production for insulins
 - Price reductions will be achieved if a number of biosimilar manufacturers enter the market.
 - Ensure regulatory processes support quality assured biosimilar insulins to enter the market. Expedite / prioritize WHO PQ for biosimilar insulins.

A few additional and final points

- Submissions for EML should provide all existing studies (RCTs, PK, cost-effectiveness...) and data (effectiveness, tolerability, availability, affordability)
- All medicines must be
 - quality-assured (internationally agreed quality standards),
 - manufactured according international GMP regulations,
 - affordable for LMICs,
 - distributed according to international GDP regulations.
- Combi-packs and co-packaging must be composed of quality-assured medicines and manufactured under international GMP regulations

A few additional and final points

- When a medicine is no longer recommended as single, but in combination: if co-packaged/co-formulations available, single medicine should be deleted from the EML
- Alignment between EML and prequalification scope is very important, should lead to closer collaboration to ensure availability of quality-assured medicine

Thank You

