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MSF Statement: 22nd Expert Committee, WHO Model List of Essential Medicines (EML) including Essential Medicines for Children (EMLc)

MSF would like to draw the attention of the Expert Committee to the following topics:

ARVs, antituberculosis medicines, prophylactic antimalarials:
MSF welcomes all the proposals from the different WHO departments and from Stop TB Partnership / Global Drug Facility, aligned with the recent recommendations and guidelines, respectively for the:

- inclusion and deletion of ARVs and antituberculosis medicines
- change of minimum age for using delamanid in children
- inclusion of FDCs for malaria prophylaxis

Nutritional products:
MSF does not support the inclusion of MNPs and RUTF in the EML, as the nutritious products should follow international **food** quality standards (Codex Alimentarius) and not the regulatory standards for medicines. For RUTF, MNPs and other nutrition products, MSF recommends to consider the development of a separate WHO Model List of Essential Nutritious Products similar to the creation of the WHO Model List of Essential In Vitro Diagnostics (2018), with a clear explanation on why another list is created as the nutritious products differ from the Essential Medicines in terms of standards and manufacturing conditions.
MSF suggests to review the list of nutritional products currently integrated in EML and consider adding them to a separate WHO Model List of Essential Nutritious Products.

Reproductive health:
MSF welcomes all the proposals from the WHO RHR:

- Carbetocin, a heat stable long-awaited alternative to oxytocin, very useful in settings where cold chain cannot be ensured.
- Tranexamic acid as part of the standard post-partum haemorrhage treatment package.
- Moving mifepristone-misoprostol to the core list and removing all notes pertaining to the complementary list.

Nevertheless, MSF emphasizes that carbetocin is currently far too expensive, thus an affordable price should be agreed upon for quality assured product.
Once again, MSF emphasizes that misoprostol should be remained on the EML, as an alternative for prevention of PPH in resource-poor, community and rural settings where uterotonics by injection are unavailable, or challenging to provide.

Neglected diseases: Human African Trypanosomiasis (HAT), scabies:
MSF particularly welcomes fexinidazole, the first oral treatment for HAT and for both haemo-lymphatic and meningo-encephalitic stages, in adults and children ≥ 6 years old and weighing ≥ 20 kg.
MSF has been supporting sleeping sickness control programs since 1986, with 50,000 patients treated. Unlike parenteral pentamidine and NECT, oral fexinidazole can be self-administered by patients and prevents lumbar puncture to determine disease stage before initiating treatment.

Fexinidazole, as a disease stage-independent short duration oral treatment, shows significant improvement compared to previous HAT therapies for patients and treatment providers.

MSF welcomes the new indication of ivermectin for scabies. Single-dose oral treatment option will allow large-scale mass drug administration campaigns, even in hard-to-reach populations and outbreaks in refugee camps.

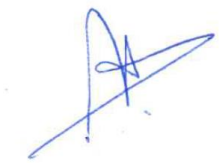
Paediatric dosage forms:
MSF emphasizes that paediatric dosage forms like dispersible tablets easily dissolved in liquids or soft food; oral powder, oral granules, oral pellets should be promoted and should reach internationally agreed quality standards.
Studies on tolerability and pharmacokinetics for all new pediatric formulations are needed.
Paediatric formulations are needed as access to child-friendly formulations is essential to increase ease, safety of administration and adherence to treatment.

General comment:
MSF would like to emphasize that:

- Applications should provide all existing RCTs, pharmacokinetic studies, as well as data on tolerability, availability, affordability, cost-effectiveness.
- All medicines must be quality-assured according internationally agreed quality standards, manufactured under conditions and practices required by the international GMP regulations in order to assure that quality is built into the design and manufacturing process at every step. Moreover, all medicines should be affordable for LMICs and distributed according to international GDP regulations.
- Co-packaging should always be composed of quality assured medicines and manufactured and packaged under international GMP conditions,
- When a medicine is no longer recommended as single one and when co-packaged or co-formulations exist, single medicines should be removed from the EML.
- Alignment between the EML and the prequalification scope continues to be very important and should happen. This should also lead to closer collaboration to ensure availability of quality-assured medicines.

Thank you for giving us the opportunity to share MSF comments, concerns and suggestions.

For Médecins Sans Frontières



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