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A.26 - Anti-rabies virus monoclonal antibodies

MSF strongly supports the application for the inclusion of anti-rabies virus monoclonal antibodies (ARV mAbs) in the WHO Model List of Essential Medicines (EML) and in the WHO Model List of Essential Medicines for Children (EMLc).

MSF is aligned with the 2018 WHO recommendations on anti-rabies virus monoclonal antibodies published in the WHO position paper on rabies vaccines (Weekly epidemiological record, 20 April 2018).

Currently, only human rabies immunoglobulins (hRIG) are included in the EML. MSF also strongly supports the re-instatement of equine rabies immunoglobulins (eRIG) in the EML and EMLc.

Mortality from rabies remains currently high: around 60 000 human deaths annually in over 150 countries, with 95% of cases occurring in Africa and Asia. Even though the main component of post-exposure prophylaxis (PEP) remains the immediate washing and flushing of the bite wound (+/- the application of a virucidal agents) and a series of rabies vaccine administrations promptly started after exposure, the absence of the timely administration of rabies immunoglobulin (RIG) neutralizing rabies virus at the wound site for specific severe exposures might contribute to PEP failures and subsequent deaths. In case of severe exposure[1], local injections of RIG into and around the wound is highly effective. Dog's vaccination and PEP are both highly cost-effective strategy, especially when RIG are part of PEP.
According to the WHO position paper on rabies vaccines, a single anti-rabies virus monoclonal antibody, which was licensed in India in 2017, has been demonstrated to be safe and effective in clinical trials. The comparative advantages of ARV mAbs include large-scale production with standardized quality, greater effectiveness than RIG, elimination of the use of animals in the production process, and reduction in the risk of adverse events.

[1] Severe exposure (i.e category 3) are defined in the 2018 WHO position paper on rabies vaccines: single or multiple transdermal bites or scratches, contamination of mucous membrane or broken skin with saliva from animal licks, exposures due to direct contact with bats.

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

- In addition to the inclusion of ARV mAbs in the EML and EMLc and its promotion, WHO must also in parallel put more emphasis on the wound washing combined with immediate vaccination and its full completion course, as this results already in itself in >99% patients survival.

- The inclusion of ARV mAbs into the EML and EMLc for rabies PEP represents an opportunity for large scale production of safe, effective, well-characterized, and quality-assured biologics. Manufacturing costs for ARV mAbs are expected to be further reduced in the long-term. The price for ARV mAbs is currently intermediate in comparison to human RIG and equine RIG, but could become the lowest among the three products in the longer term.

- The inclusion of the ARV mAbs on the WHO prequalification process is extremely important to allow a larger use of this product.

MSF treats approximately 5000 patients per year with human rabies immunoglobulins. MSF is only using hRIG due to the lack of prequalified eRIG and the lack of alternative. The prequalification by WHO or the licensure of eRIG or ARV mAbs by stringent regulatory authorities would allow MSF to use them.

MSF urges the 23rd Expert Committee on the Selection and Use of Essential Medicines to include anti-rabies virus monoclonal antibodies in both the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children.

For Médecins Sans Frontières

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