WHO Expert Committee on Drug Dependence
Open session

16th November 2015, Geneva
Ketamine

. Current use at MSF
. Worrying access challenges foreseen by MSF / ICRC if stricter controls are set, even if just added on the Green List of psychotropic medicines as a Schedule IV product
Ketamine at MSF

• On the MSF Essential drugs guidelines, 2013,
• Indication: induction and maintenance of general anaesthesia
• Use in MSF projects: surgery (general surgical, orthopedic and obstetric procedures) in settings struck by natural disasters or conflicts, or with insufficient health care infrastructures
• Used in 37 countries
  ✓ More than 10,000 vials since Jan. 2013:
    - Afghanistan, Chad, South Sudan, Yemen
  ✓ More than 20,000 vials since Jan. 2013:
    - Central African Republic, Democratic Republic of Congo
  ✓ More than 50,000 vials since Jan. 2013:
    - Syria
Ketamine at MSF

• Supply of ketamine by MSF European Supply Centres to surgical projects (since 1\textsuperscript{st} January 2013):
  \(\sim\) 190,000 vials

• Internal MSF survey on the use of ketamine over a sample of 60,000 surgical procedures run by 2 MSF operational centres:
  ✓ ketamine was needed in:
  \begin{itemize}
    \item 65\% of general anesthesia set up without intubation
    \item 10\% of general anesthesia set up with intubation
  \end{itemize}
Ketamine at MSF

• First marketed in 1965; has proven to have a positive efficacy and safety profile as a general anaesthetic, with specific added value in low resource countries

• Main pharmacological assets
  ✓ allows mono-pharmacological anaesthesia without needing to combine a pure anaesthetic with a pure analgesic
  ✓ no depressant action on the cardiorespiratory system, thus best option to proceed to general anaesthesia without intubation, since it does not abolish laryngeal reflects and prevents regurgitation or vomiting
  ✓ can be administered to patients with haemorrhagic shocks, since it raises the blood pressure itself, helping the management of any hypotension
Ketamine at MSF

• In higher income countries
  ✓ brief procedures in paediatric and ambulatory anaesthesia, use in the treatment of burning wound patients and anaesthesia in patients suffering from haemodynamic instability

• In low resource countries/conflicts/natural disasters
  ✓ easy use by non-physician anaesthetists in settings lacking basic mechanical monitoring
Stricter controls over ketamine?

- Impossible to add ketamine in emergency kits shipped to countries with a functional regulatory agency.
- For countries hit by conflicts/natural disasters, MSF/ICRC are totally dependent on the responsiveness/availability of regulatory agencies in export countries to get swift delivery of export licenses (e.g. France, Switzerland, Belgium).
- Systematic import license to expect from importing countries leading to huge administrative overburden at MSF/ICRC and to unjustified delays to import ketamine:
  - Delays up to one year or more in some countries for the delivery of import licenses.
  - Not all countries delivering import licenses for controlled medicines leading to the set up of specific negotiations with export countries.
  - Endless list of errors on import licenses which then cannot be endorsed by the export countries and have to be required again.
Stricter controls over ketamine?

- When looking at the controls currently set on phenobarbital and diazepam (Schedule IV – psychotropics medicines)
  - Need to revert to the local markets where often quality-assured sources are not available
  - In many countries with local quota allocation for production, manufacturers are not interested to manufacture these medicines
  - When not available from quality-assured sources, need to switch to not proper equivalents or to not ideal pharmaceutical formulations

  What if the same happens for ketamine? Which equivalent to rely upon?

- If quotas were to be set on ketamine like for other controlled medicines, major threat to have quotas grossly insufficient in comparison to real needs

- Only 3 major manufacturers of quality-assured ketamine today worldwide, what sustainability to expect if the market becomes more fragmented with supply limited to local purchases?
Conclusions

• By bringing ketamine under stricter control, even more scarce access can be anticipated in low resource countries to the poorest patients, with the following consequences in both stable and emergency contexts:
  ✓ less access to safe anaesthesia in contexts with lack of properly trained health staff
  ✓ risks of stock-outs due to non predictable lead time in the export/importation processes
  ✓ higher risks linked to local purchases in unsafe markets
  ✓ increased cost to proceed to anaesthesia due to:
    . the need to procure newer anaesthetics with more sophisticated equipment, to look for both anaesthetics and analgesics to be combined
    . increased HR/administrative burden to manage the different licenses required