Expert peer review on application for MORPHIN CHLORHYDRATE (Injection and tablet)

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes
      Morphine (hydrochloride, sulfate) is strong analgesic used to release severe, acute pain or moderate to severe, chronic pain (e.g., in terminally ill patients). Morphine is also parenterally used as a supplement to anesthesia and for analgesia during labor.

   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

   c. Please provide any additional relevant information with reference

2. Assessment of safety
   a. Have all relevant studies on safety been included
      Yes
      1. Morphine can induce physical and psychological dependence with repeated administration. Sudden discontinuation of long courses of treatment leads to withdrawal symptoms.
      2. Use with caution in the elderly, patients with liver or renal failure, hypothyroidism, adrenal failure, shock and patient with urethra-prostate disorders, with asthma or with elevated intracranial pressure (head trauma) or with myasthenia gravis
      3. Safety in pregnancy: Morphine may cause neonatal respiratory depression since morphine cross placenta and affect the child. Morphine should not be used to mother 3-4 hours before expected labor.
      4. Safety in breast feeding: The infant receives between 0,8% - 12% of the maternal dose. Therefore it should discontinues breastfeeding if the mother takes morphine

   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

   c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
   a. Have all relevant data on safety provided
      Yes
   b. Summarize the data on cost and cost effectiveness, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      Morphine hydrochloride (tablet and injectable) is available as generic products
      The price of local generic morphine products are from 40-50% the price of imported products.
   c. Please provide any additional relevant information with reference
d. Is the product available in several low and middle income countries?

Morphine products are available in several low and middle income countries as generic products manufactured by local pharmaceutical industry

4. Assessment of public health need
a. Please provide the public health need for this product (1-2 sentences)

Morphine formulations (tablet and injectable) are drugs needed for public health to treat intense pain and pain not responsive to other analgesics in: Post-traumatic and post-operative patients, cancer patients, for anesthesia and pre-anesthesia...

b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2 international preferable

1. Morphine sulfate formulations (injection 10mg/mL and tablet 10mg/tablet) are listed in 17th WHO EM List (2011)
2. Morphine sulfate formulations (injection 10mg/mL and tablet 10mg/tablet) are listed in 2011 National List of Essential Medicines of INDIA
3. Morphine sulfate formulations (injection 10mg/mL and tablet 10mg/tablet) are listed in 2008 National List of Essential Medicines of INDONESIA

5. Are there special requirements for use or training needed for safe/effective use?
If yes, please provide details in 1-2 sentences

Due to narcotic addition is a current social evil in many countries, it is necessary:

1. To train the health staff to implement the Guidelines/Treatment Regimen relating narcotic safe/effective use for medical purposes
2. To promulgate document and training materials for safe/effective use morphine and opioid pharmaceutical products and narcotic products
3. To conduct control/inspection activities relating narcotic products
4. To supervise the implementation of Narcotic Law and regulatory documents relating narcotics
5. Misuse and Abuse:
Morphine injection has emerged as one of the most problematic abuse opiate agonist in many countries; therefore, patients should be advised about the risk of theft, and clinicians should be informed about abuse and diversion issues

6. Is the proposed product registered by a stringent regulatory authority?
Yes

National Medicines Administration Authority and Narcotics Control Authority

7. Any other comments

8. What is your recommendation to the committee (please provide the rationale)

Morphine hydrochloride/sulfate formulations (injection, tablet) need to be listed in WHO EML due to pain control potency, low cost and availability

It is necessary to promulgate guidelines on the measures for limitation of addiction of opioid pharmaceutical products (strictly control the registration, manufacture, import-exportation, distribution/sale, prescription ...).