19th Expert Committee on the Selection and Use of Essential Medicines
April 8-12; 2013
Expert peer review on application for “Addition of Human Normal Immunoglobulin 20% for subcutaneous administration”

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes
   
   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      N/A. This is a proposal for new formulation.
   
   c. Please provide any additional relevant information with reference

2. Assessment of safety
   a. Have all relevant studies on safety been included
   
   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      N/A. This is a proposal for new formulation.
   
   c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
   a. Have all relevant data on cost and availability provided
      No; with all formulations available on the market.
   
   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)
      N/A. This is a proposal for new formulation.
   
   c. Please provide any additional relevant information with reference
   
   d. Is the product available in several low and middle income countries?
      No.

4. Assessment of public health need
   
   b. Do guidelines (especially WHO guidelines) recommend this product?
      No, in WHO guidelines.
5. Are there special requirements for use or training needed for safe/effective use?
   Yes. As per administration of other immunoglobulins.

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

7. Any other comments
   1. Human Normal Immunoglobulins are available with very diverse formulations both in method of administration (IV, IM SC) and protein contents.
   2. Intramuscular administration is usually used for post-exposure prophylaxis for viral or pathogenic infection (e.g. Hepatitis A, Rubella).
   3. Intravenous injection route is still the most common method of administration.
   4. Subcutaneous immunoglobulin (SCIg) as replacement therapy for primary immune deficiency disease and as immunomodulatory therapy for some autoimmune diseases, including peripheral neuropathies, can be a safe, effective, and convenient alternative to intravenous therapy.
   5. There is no comparative study available evaluating current formulations on the market for their safety, efficacy and cost effectiveness.

8. What is your recommendation to the committee (please provide the rationale)
   1. Due to diversity of the product on the market I recommend do not specify any dosage for the list and proposal for final listing would be as following:

   | Human normal immunoglobulin | intravenous/ subcutaneous/intramuscular administration |

   With this explanatory note: “Due to the diversity of marketed formulations of immunoglobulins, prescribers should consider the comparative advantages of intravenous and subcutaneous administration for individual patients requiring immunoglobulin treatment where this is clinically appropriate”.

   Ref: Clinical guidelines for immunoglobulins use; www.dh.gov.uk.