Expert peer review on application for Colchicine Reinstatement

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes ✓ No (if no, please provide reference and information)

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

      Current international recommendations and guidelines for the management of Gout attack propose Colchicine low dose as first-line treatment. The study review by German & Turkish Physicians in 2007 for FMF and the review from Shohat in 2011 also recommend this medicine.

   c. Please provide any additional relevant information with reference

2. Assessment of safety
   a. Have all relevant studies on safety been included
      Yes ✓ No (if no, please provide reference and information)

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

      The adverse effects/reactions have been described fully and analysed, from frequent, infrequent and rare. The frequent side effects are in the GIT and are mild and reversible on lowering the dose.

   c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
   a. Have all relevant data on cost been provided
      Yes No (if no, please provide reference and information)

   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)

      The public cost of Colchicine in most countries is between 0.11 and 0.13 USD for 1mg tablet. No cost effective studies available except one in the USA but inconsistent.

   c. Please provide any additional relevant information with reference

   d. Is the product available in several low and middle income countries? Yes

4. Assessment of public health need
   a. Please provide the public health need for this product (1-2 sentences)
Gout is the most common inflammatory arthritis and is associated with reduced quality of life. Familial Mediterranean fever is a common auto-inflammatory disease.

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

Yes √

It is on the American Guidelines and the British Society for Rheumatology.

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

No. This information is taught during the medical school training programs.

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

Yes √  No

7. Any other comments

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

Having used Colchicine several times with good results, it would be beneficial to have it on the EML.