NEW APPLICATION:

Artemether
(20 mg/ml for intramuscular administration)
(Section 6.5.3.1. Antimalarial medicines, for curative treatment)

Search strategy and 4 studies missing:

The strategy employed for systematic search of relevant articles and reviews included a search of the PubMed database by using the following terms: artemether and intramuscular injection. All relevant evidence was collected. Most of the clinical trial evidence was retrieved in adults since clinic trials in children leads to more ethical discussions. However, 15 trials testing the intramuscular artemether injection in children with severe malaria were retrieved. They all concluded that the artemether intramuscular injection was rapidly effective and well tolerated. If compared with the standard quinine iv monotherapy there were generally no differences except for the adverse events, which seem to be less with the artemether treatment.
The expert committee noted that four studies, discussion the efficacy of the artemether intramuscular injection in children with severe malaria, were not included in the application. For some reasons they were not retrieved with the search strategy employed above. However after a close look to these four references (Omari et al., 2007, Huda et al., 2003; Satti et al., 2002 and Ojuawo et al., 1998) the same conclusion as written above could be made.

Pharmacokinetics of artemether in mygliol

Since studies in children are unethical Dafra Pharma did a pharmacokinetic study with his 80 mg/ml artemether intramuscular injection using the same vehicle (mygliol) in healthy adults.
We compared the pharmacokinetic parameters with those obtained with the reference product Paluether®, using arachis oil as vehicle solution. Because of the fact that the expert committee noted that it was a non-comparative study that was not described adequately to allow assessment of the validity of the results we decided to disclose the full study report (see annex 1)

EMEA

The subcommittee mentioned that the application reported that the product was being considered by the EMEA. Dafra Pharma is not aware that this is mentioned in its submission. Indeed, Dafra Pharma had an informal meeting with EMEA but decided to go for WHO prequalification.