Annex

Conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the member states

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The Member States shall agree the final educational material with the Marketing Authorization Holder (MAH) prior to launch of the product in their territory.

The Member States shall ensure that the MAH provides all physicians who are expected to prescribe or use Eurartesim a healthcare professional educational pack containing the following:

- The Summary of Product Characteristics
- The Patient Information Leaflet
- The Physician Leaflet including the *Contraindicated Conditions of Use and Contraindicated Concomitant Medication checklist*

The Physician Leaflet should contain the following key messages:

- That Eurartesim has a potential to prolong the QTc interval that may lead to potentially lethal arrhythmias.
- That piperaquine absorption is increased in the presence of food, therefore to reduce this risk of QTc interval prolongation, the patients should be advised to take the tablets with water, without food, no less than three hours after the last food intake. No food should be taken within 3 hours after each dose.
- That Eurartesim is contraindicated in patients with severe malaria according to WHO definition and in patients with a history of clinical conditions that may lead to QTc interval prolongation, and in patients taking drugs that are known to prolong the QTc interval.
- The ECG monitoring recommendations.
- The scope and use of the Contraindicated Conditions of Use and Contraindicated Concomitant Medication checklist
- That there is a potential risk of teratogenicity and so Eurartesim should not be used in situations where other suitable and effective anti-malarials are available.
- The need to counsel patients on important risks associated with Eurartesim therapy and appropriate precautions when using the medicine.
- That patients should be advised to contact their doctor about adverse events and that physicians/pharmacists should report suspected adverse reactions to Eurartesim, and in particular, those associated with a QT prolongation.
- The existence and scope of the pregnancy register and details of how to enter patients in it.
- In Member States where the EU safety registry will be available, the educational materials should include details on the registry and how to enter patients in it.