ANNEX

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

The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

The MAH, in agreement with the competent authorities in the Member States, shall implement, prior to the launch, an educational programme for physicians aiming to provide educational material on correct diagnosis and therapeutic managements of the treatment of inborn errors in primary bile acid synthesis due to 3β-Hydroxy-Δ^5-C_{27}-steroid oxidoreductase deficiency or Δ^4-3-Oxosteroid-5β-reductase deficiency and to inform on expected and potential risks associated with the treatment.

The physician educational programme should contain the following key elements:

- Prescription of a supratherapeutic dose (MedDRA term: drug toxicity)
- Risk of gallstones