Annex IV

Conditions to the marketing authorisations

Conditions of the marketing authorisations

The national competent authorities, coordinated by the reference Member State, shall ensure that the following conditions are fulfilled by the marketing authorisation holders:

Conditions	**Date**
The applicant shall submit an updated RMP taking into consideration the following recommendations: 1. section VI.2.5 Documentation for public summary should include a summary of risk minimisation measures by safety concern. 2. annex 2 should include the proposed text of the package leaflet in addition to the proposed SmPC. 3. annex 7: should include the text of a proposed follow up form to be used for specific adverse event follow-up. 4. part III, pharmacovigilance plan: category 1 should be added for the PASS and the DUS.	Within 3 months of Commission Decision
The applicant shall undertake a DUS to follow the use of prescribed dexamfetamine in the European Union using multiple data sources. As part of this study the MAH shall actively obtain reports of abuse, misuse, diversion and dependence in children with ADHD from poison centres, drug monitoring centres, other databases, publicly available information in the literature and online.	Submission of the protocol in accordance with Article 107n(1) of Directive 2001/83/EC within 3 months of Commission Decision, Submission of the final study results by Q2 2020
The applicant shall conduct a PASS to evaluate the long-term safety profile of dexamfetamine in children with ADHD, specifically targeting key issues such as cardiovascular events, growth and psychiatric related adverse events. This 5 years retrospective (new users) study will also compare the relative risk between dexamfetamine and other stimulants in the patient population.	Submission of the protocol in accordance with Article 107n(1) of Directive 2001/83/EC within 3 months of Commission Decision, Submission of the final study results by Q2 2020