Compassionate use intended

1. Is the compassionate use intended for a single (named) patient only? yes no

2. Does the medicinal product intended for the compassionate use programme require a marketing authorisation in general but is not licensed in any Member State of the EU/EEA? yes no

3. Does the group of patients for which the medicinal product is intended suffer from a serious debilitating or life-threatening disease? yes no

4. Can the group of patients for which the medicinal product is intended be treated satisfactorily by a medicinal product in authorised Germany? yes no

5. Is the medicinal product subject of a marketing authorisation application in this medical indication either at EMA or in any other Member State of the EU/EEA? ja no

6. Is a clinical trial ongoing in the EU/EEA in this medical indication? yes nein

7. Is a ICH-GCP compliant clinical trial ongoing in a third country in this medical indication? yes no

8. Is the clinical trial also conducted in Germany? yes nein

9. Can patients be included in the clinical trial? yes nein

10. According to the Ordinance on Medicinal Products for Compassionate Use (AMHV) the general prerequisites for compassionate use programmes are fulfilled. Prior to commencement the compassionate use programme must be notified to the competent authority (BfArM or PEI).