Form for notification of a compassionate use programme to the Paul-Ehrlich-Institut

Please use this form for documentation according section 3 para. 2 Ordinance on Medicinal Products for Compassionate Use (AMHV). If information cannot be carried out in the form, please specify the site of additional documentation. Please note: No.11, 12 and 17 are standardized with “not applicable”, as in most notifications no information are needed. In case No. 11, 12 and 17 is applicable, please provide information or site of documentation.

No. according §3, para. 2 AMHV	Information according §3, para. 2 AMHV	Information	Site of documentation
No. 1	Name of firm and address of the responsible person and, where available, that of the representative registered in the European Union or in another State Party to the Agreement of the European Economic Area		
No. 2	The name or code of the medicinal product, the name of the active substances by type and quantity, other constituents by nature, pharmaceutical form, method of administration, dosage and treatment plan		
No. 3	Description of the disease that leads to a serious disability, or is life-threatening, from which the patient is suffering and for the treatment of which the medicinal product is intended		
No. 4	Criteria for the selection of patients and notification of the anticipated number of patients		

No. according §3, para. 2 AMHV	Information according §3, para. 2 AMHV	Information	Site of documentation
No. 5	Grounds explaining why these patients cannot be satisfactorily treated with a medicinal product authorized for placing on the market within the territorial scope of the Law on Medicinal Products		
No. 6	Grounds explaining why the patients cannot be included in an ongoing clinical trial		
No. 7	Evidence to support the fact that the medicinal product is of the appropriate quality in keeping with recognized pharmaceutical regulations, as well as confirmation by the qualified person pursuant to Section 14 of the Law on Medicinal Products that the medicinal product has been manufactured according to the principles and guidelines of good manufacturing practice for medicinal products		
No. 8	Evidence and grounds for the assumption that the medicinal product is safe and effective for the envisaged use, as a rule through submission of the results of confirming clinical trials		
No. 9	Criteria for the suspension or premature discontinuation of the compassionate use programme		

No. according §3, para. 2 AMHV	Information according §3, para. 2 AMHV	Information	Site of documentation
No. 10	Further details regarding: a) The authorized clinical trial of the medicinal product in the envisaged area of application, giving the EudraCT-Number, or b) The clinical trial of the medicinal product in the envisaged area of application in an third state and evidence that this is being conducted according to the internationally harmonized Standards of Good Clinical Practice, or c) The application for authorisation or marketing authorisation, which has been submitted for the medicinal product in the envisaged area of application, to the European Medicines Agency, the competent higher federal authority or to an authority responsible for marketing authorisation in a Member State		

No. according §3, para. 2 AMHV	Information according §3, para. 2 AMHV	Information	Site of documentation
No. 11	In the case of medicinal products which consist of or contain a genetically modified organism or a combination of genetically modified organisms, documents pursuant to Annexes II and III of Directive 2001/18/EC of the European Parliament and the Council of 12th March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJL L 106 of 17/4/2001, p.1)		
No. 12	Grounds for a treatment with a medicinal product the application for marketing authorisation of which has been rejected, withdrawn, revoked or suspended or the authorisation of a clinical trial refused, withdrawn, revoked or suspended, giving the reasons for the decision	Not applicable	Not applicable
No. 13	The current investigator's brochure placed at the disposal of the investigator in the clinical trial or the envisaged draft of a summary of the medicinal product's product characteristics contained in the application for authorisation or marketing authorisation		

No. according §3, para. 2 AMHV	Information according §3, para. 2 AMHV	Information	Site of documentation
No. 14	Information and documents which are given to patients, in German, as well as a description of the procedure for informed consent after instruction by a participating physician		
No. 15	Requirements on the medical facilities and the qualifications of the participating doctors		
No. 16	Description of the envisaged measures to guarantee the safe storage, use and whereabouts of the medicinal products made available		
No. 17	Information, where appropriate, on ongoing compassionate use programmes in Member States of the European Union or other States Party to the Agreement of the European Economic Area and, where available, expert opinions of the Committee for Medicinal Products for Human Use pursuant to Article 83 (4) of Regulation (EC) No. 726/2004	Not applicable	Not applicable
No. 18	Declaration of consent regarding the publication of information on the main features of the notified compassionate use programme		