Please use the following form to notify and submit the required information according to Section 3 sub-section 2 of the German Ordinance on Compassionate use (AMHV). If the required information is not directly presented in the form please indicate where the relevant information is contained in the dossier. Please note: The default value for No 11, 12 and 17 is “not applicable” because this is true for the majority of compassionate use programmes. If, however, one of those topics is applicable you are asked to provide additional information.

| **No according to Section 3 sub-section 2 AMHV** | **Required information/documentation according to Section 3 sub-section 2 AMHV** | **Information/documentation** | **Location in the dossier** |
| --- | --- | --- | --- |
| 1) | Name or 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 |  |  |
| 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 |  |  |
| 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 |  |  |
| 4) | Criteria for the selection of patients and notification of the anticipated number of patients |  |  |
| 5) | Grounds explaining why these patients cannot be satisfactorily treated with a medicinal product authorised for placing on the market within the territorial scope of the Law on Medicinal Products |  |  |
| 6) | Grounds explaining why the patients cannot be included in an ongoing clinical trial |  |  |
| 7) | Evidence to support the fact that the medicinal product is of the appropriate quality in keeping with recognised 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 |  |  |
| 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 |  |  |
| 9) | Criteria for the suspension or premature discontinuation of the compassionate use programme |  |  |
| 10) | Further details regarding:  a) the authorised 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 a third state and evidence that this is being conducted according to the internationally harmonised 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 |  |  |
| 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) | not applicable | not applicable |
| 12) | Grounds for a treatment with a medicinal product the application for marketing authorization of which has been rejected, withdrawn, revoked or suspended or the authorization of a clinical trial refused, withdrawn, revoked or suspended, giving the reasons for the decision | not applicable | not applicable |
| 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 |  |  |
| 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 |  |  |
| 15) | Requirements on the medical facilities and the qualifications of the participating doctors |  |  |
| 16) | Description of the envisaged measures to guarantee the safe storage, use and whereabouts of the medicinal products made available |  |  |
| 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 |
| 18) | Declaration of consent regarding the publication of information on the main features of the notified compassionate use programme |  |  |