|  |
| --- |
| **Form** |
| **Notification of a release into environment, transmission to a person/animal of an authorized GT/GMO** |
| **Identification number:** | BW314\_00\_991 |
| **Version:** | 1.1 |
| **Valid from:** | 02.10.2023 |

Form for reporting a release into the environment, transmission to another person / animal of an authorised gene therapy product (GT) or an authorised product consisting of, or containing, genetically modified organisms (GMO).

# Basic information

*(Date format: dd.mm.yyyy)*

|  |  |
| --- | --- |
| **Date of submission:** | …… |
| **Date of receipt by the authorisation holder / reporting individual:** | …… |
| **Initial report:** | [ ]  |  |
| **Follow-Up:** | [ ]  | No.: ……, associated intial report dated: …… |
| **Name of GT/GMO:** | …… |
| **Active substance:** | …… |
| **Authorisation number:** | …… |
| **Product category:** | [ ]  | Ex vivo gene therapy |
| [ ]  | In vivo gene therapy |
| [ ]  | Medicinal product consisting of, or containing, genetically modified organisms (GMO) |
| **Release into the environment:** | [ ]  |
| **Transmission to another person:** | [ ]  |
| **Transmission to an animal / animal species:** | [ ]  |
| **Country (location of event):** | …… |
| **Case number for sender / authorisation holder:** | …… |

# Adresses

## Marketing authorisation holder

|  |  |
| --- | --- |
| Company name / Institution: | …… |
| Street / no.: | …… |
| Postcode, town/city: | …… |
| Telephone: | …… |
| E-mail: | …… |

## Address for correspondence *(if not the same as 2.1)*

|  |  |
| --- | --- |
| Company name / Institution: | …… |
| Street / no: | …… |
| Postcode, town/city: | …… |
| Telephone: | …… |
| E-mail: | …… |

## Legal representative *(if not the same as 2.1)*

|  |  |
| --- | --- |
| Name: | …… |
| Street / no: | …… |
| Postcode, town/city: | …… |
| Telephone: | …… |
| E-mail: | …… |
| **Does Swissmedic already possess the power of attorney?** [ ]  yes [ ]  no, the power of attorney is enclosed with this application (incl. original signature) |

# Further information

|  |  |  |
| --- | --- | --- |
| **Report type:** | [ ]  | Spontaneous |
| [ ]  | Literature |
| [ ]  | Other: …… |
| **Reported by:** | [ ]  | Authorisation holder |
|  | [ ]  | Manufacturer |
|  | [ ]  | Hospital/doctor |
|  | [ ]  | Pharmacy |
|  | [ ]  | Patient |
|  | [ ]  | Other: …… |
| **Description of the release / transmission:** |  | …… |
| **Risk evaluation:** |  | …… |
| **Measures taken to date:** |  | …… |

# Signature

|  |
| --- |
| **All the entries made in this form are certified to be complete and accurate:***(company stamp of the applicant, optional)*…… |
| *Authorised signatory* | *Other responsibilities (Optional signature)* |
| Place, date: ……Signature: …………………………….. | Place, date: ……Signature: …………………………….. |
| Last name: | …… | Last name: | …… |
| First name: | …… | First name: | …… |
| Position: | …… | Position: | …… |
| Telephone: | …… |  |
| E-mail: | …… |
|  |
| **The notification must be sent to:** | **For enquiries contact:** |
| biovigilance@swissmedic.ch | Telefon +41 58 462 02 81E-Mail biovigilance@swissmedic.ch |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 1.1 | Reduction of the form to notifications of release / transmission of authorized GT/GMO.Adjustment of the designation of the form.  | pad |
| 1.0 | Transfer ATMP processes in the area of authorisationsNew ID number assignedFormal adjustments, new layout | dei |