

## **Guidance for Notification of Herd-specific/Autologous Vaccines**

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## 1. General

### 1.1. Login

To submit the notification of Herd-specific/Autologous Vaccines in accordance with Section 7(2) of the Austrian Veterinary Medicinal Products Act (TAMG, Federal Law Gazette I No 186/2023), you do not need to register on the eService Portal of the AGES Austrian Medicines and Medical Devices Agency. Please simply click on the following link and fill in the required fields and Excel form in a correct and complete manner. <u>Formular: BASG - TForms</u>



## **1.2.** Assistance for entering data

You can get help filling in several points of the form by moving the cursor over the information icon next to the respective input field.

Anlage Bitte laden Sie als Anhang das unten bereitgestellte Excel-Formular zur Meldung der Bestandsspezifischen Impfstoff Datei au Dateiformate xls und xlsx.

## 2. Contact details

In the section contact details (Kontaktdaten) you can enter one or more specific e-mail addresses. These e-mail addresses will be used to contact you in case of essential enquiries and for sending the confirmation of the submission of notification.

Name des Inverkehrbringers			[erforderlich]
Straße	[erforderlich]	Hausnummer	[erforderlich]
Postleitzahl	[erforderlich]	Ort	[erforderlich]
Land			[erforderlich]
Österreich			$\sim$
E-Mail	[erforderlich]	Telefon	

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#### 3. Type and content of the notification

When submitting the notification, you must specify the **type of notification** (Art der Meldung). You can choose between the regular "Quarterly notification (Quartalsmeldung)" or, if necessary, a "Correction notification (Korrekturmeldung)" in case you have already submitted an incomplete or incorrect report in the respective quarter (see sections 3.1 and 3.2 of this Guidance below).

Please upload the completed Excel-file "Form for quarterly reporting of herd-specific vaccines" by clicking on "Datei auswählen (Select file)". The Excel form must be named with the corresponding year and quarter (e.g. III-2024).

In section "**Number of batches** (Anzahl der Chargen)" the number of vaccines produced from one or more defined pathogens for each animal/herd/epidemiological unit must be indicated. Each completed line of the Excelfile 'Form for quarterly notification of herd-specific vaccines' corresponds to one batch.

Areach metading	[erforderlich]
Bitte auswählen	~
Bitte führen Sie die Meldung quartalsweise durch und reichen Sie die gesamten Daten für d	das betroffene Quartal ein.
Sollten Sie in diesem Quartal bereits eine Meldung durchgeführt haben, führen sie bitte eir gesamten Datensatz durch.	ne Korrekturmeldung mit dem
Anlage 🛈	
Datei auswählen Keine Datei ausgewählt	
Hier finden Sie das Formular zur quartalsmäßigen Meldung der <u>Bestandsspezifischen Imp</u> i	fstoffe.
Anzahl der Chargen 🛈	[erforderlich]

### 3.1. Quarterly notification

Please select in the field type of nofication (Art der Meldung) the option "**Quarterly report** (Quartalsmeldung)" to submit the report for the current or previous quarter. Please always provide the quarterly report with the entire dataset for a quarter.

#### 3.2. Correction of notification

If you notice that the already submitted report for a quarter is incomplete or incorrect, you will have the option of submitting a correction report for the current quarter and up to 4 quarters retroactively. In this case you must select the option "**Correction notification** (Korrekturmeldung)" in the section type of notification (Art der Meldung). Please always provide the correction report with the entire data set for the respective quarter.

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### 4. Completion of the notification

Before submission of the notification please confirm in the field confirmation (Bestätigung) the correctness and completeness of the data that you have filled in.

By clicking on button **\*Absenden** (Send)<sup>*m*</sup> you complete the submission of the notification. You will automatically receive a confirmation to your e-mail address(es).

	[erforderlig
Ich bestätige, dass ich die Angaben nach bestem Wissen und Gewissen richtig und vollständig gemach	ht habe.
Spamschutz	[erforderlich
Ich bin ein Mensch	

### 5. Contact points

For specific questions on the content of the notification, please contact: <u>basg-heve@basg.gv.at</u> For technical questions, please contact: <u>basg-eservices@basg.gv.at</u>