General conditions of use and data protection declaration for the use of the portal for the submission of batch release applications (PEI-C Rebuild) of the Paul-Ehrlich-Institut via PharmNet.Bund.de

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1. Scope
The Paul-Ehrlich-Institut – Federal Institute for Vaccines and Biomedicines (PEI) together with the Federal Institute for Drugs and Medical Devices (BfArM) provides an online tool for pharmaceutical companies via the internet portal "PharmNet.Bund.de", with which applications for official batch releases pursuant to Section 32 of the German Medicines Act (Deutsches Arzneimittelgesetz, AMG) and applications for so-called EU certificates can be sent electronically to PEI as the competent senior federal authority The PEI uses the same online application to inform the applying companies on the notifications on the release and to provide the required certificates electronically.

2. Persons authorised to use the portal
Persons authorised to use the portal are registered holders of at least one valid marketing authorisation pursuant to Sections 21 and 25 of the German Medicines Act (Arzneimittelgesetz, AMG) or pursuant to Section 11 Animal Health Act (Tiergesundheitsgesetz, TierGesG) in connection with Section 20ff Animal Vaccines Regulation (Tierimpfstoff-Verordnung), or an authorisation for the placing on the marketing pursuant to Article 3 of Regulation (EC) No 726/2004 for medicinal products, for which the respective product is subject to official batch control testing pursuant to Section 32 AMG (hereinafter referred to as marketing authorisation holder). Persons authorised to act for the marketing authorisation holders include designated persons for whom an account has been set up via the online application RuBen (Registrierung und Benutzerverwaltung, Registration and User Administration). Only persons who have reached the age of majority are accepted as users. To use the online procedure, marketing authorisation holders must undergo a one-off registration procedure. Additional users will then be administrated by the marketing authorisation holders. Only one single registration is possible for each marketing authorisation holder. The registration, which can also be carried out by an authorised representative must fulfil the conditions for use of the online application RuBen. With the user ID, the password, and the X.509 certificate submitted during the registration procedure, users can create and transmit batch release applications for all active marketing authorisations entered in the respective user's name. The marketing authorisation holder has the sole responsibility for the disclosure of user ID, password, and certificate to an authorised representative. The marketing authorisation holder is responsible for all actions carried out by means of his user ID by a user set up as his representative.

3. Procedure
Submitting applications by means of the online procedure takes place by logging on in the internet portal PharmNet.Bund.de using the user ID and password. After the logon procedure, the online tool is available. Instructions are available in PharmNet.Bund.de describing the different online tools.

4. Use of data from the senior federal authorities
Within the process of submitting batch release applications using the online portal, information available at the senior federal authority on the user and his marketing authorisations will be made available to the user. This information can also contain company and business secrets.

5. Storage of marketing authorisation holder's data and documents
The data captured by the user as part of the online submission of batch release applications (such as batch number, number of containers, etc.) are stored in the database of the online software until further notice. In addition to representing the information for the pure processing of the application, these data also serve as the basis for future researches and evaluations as part of the PEI's official duties.
The accompanying documents uploaded during the capture of the batch release applications into the online application (documents providing evidence for the cool chain, delivery slip, certificate of analysis, package scan, etc.) are removed from the database of the online application after two years following the application. However, the documents remain in an in-house database of the PEI so that they can be searched and retraced even after the two years mentioned above.

6. Processing of batch release applications by means of the online procedure
The PEI will process the batch release applications submitted by the online procedure by means of the usual work process. The applications are considered as submitted as soon as the transmission procedure has been confirmed by the online portal.

7. Fees
No (extra) fees are payable for online processing the batch release applications besides those laid down in the applicable statutory cost regulations (PEI-KostenVO, statutory cost regulations for official duties of the Paul-Ehrlich-Institut or Tierimpfstoff-KostVO, statutory cost regulation relating to vaccines for veterinary use).

8. Change of password
The user has the right to change his password at his own responsibility at any time. After a change of the password, the previous password will become non-valid, cf. Conditions of use RuBen.

9. Blocking of online access
In the event of a suspected abuse, the PEI will be entitled to lock the online access of individual users or all users of a marketing authorisation holder. Access will be locked at the request of the marketing authorisation holder. The appropriate notifications should be transmitted by email to pei_cr_support@pei.de or by De-Mail to pei@pei.de-mail.de.

10. Obligation of the user to co-operate and proceed with the necessary care
a. Secrecy obligation for the user ID and the password

The user is obliged to ensure that his access data are not disclosed to unauthorised persons. Anyone who is in the possession of the access data is able to use the online tool improperly.

If a user finds that the access data have been disclosed to an unauthorised person and that such a person has access to the account, he must change his password without delay or get the access locked, if the user is not/no longer able to change his password at his own responsibility.

b. Protection of the user system

PEI and BfArM have implemented all necessary technical and organizational measures to guarantee the data security of the online system. However, cyberattacks cannot be ruled out entirely. The user must therefore also take the necessary steps to avert such risks in his own interest and keep his computer system free from all software that might jeopardise security (e.g. computer viruses, trojans, malware, etc.). The user must ascertain that the browser used by him and his operating system are at the most up-to-date security status available at any time. If the provider of this software does not close the security gaps identified without delay by the necessary updates, the user must resort to other programs/access systems.

c. Obligation to take the necessary care during data transmission

When the welcome screen appears on PharmNet.Bund.de and the online applications, the user must first check the certificate of the online address to ensure that he has actually made contact with PharmNet.Bund.de. Otherwise there is the risk of third parties having used this channel of communication to obtain the user ID and the password. The user must check all data entered by him for completeness and accuracy.

11. Obligation of the marketing authorisation holder to cooperate and take the necessary care
The marketing authorisation holder must ensure that the users authorised by him fulfil the user's obligation to take care and co-operate as laid down in Section 10.

12. Liability
a. The "Erklärungen zum Internetangebot, zur Haftung, zu Links und Verlinkung, zum Urheberrecht und Datenschutz" (Declarations concerning internet content, liability, links and linking, copyright, and data protection) published in www.pharmnet-bund.de – Impressum (=information on this website) (www.pharmnet-bund.de/dynamic/de/ impressum.html) shall apply.

b. Any liability for damage arising from unauthorised or abusive use or the user's access data or other damage, regardless of their cause is ruled out. This does not apply to damage due to gross negligence or intent on the part of the PEI or the BfArM or to a breach of material contractual obligation. A claim for

damages, however, is limited to typically foreseeable damage.

c. The above disclaimer and limitation of liability does not apply to negligent damage to life, body and health.

13. Withdrawals or modifications of batch release applications

A withdrawal of an application for batch release submitted in error can be performed by the user at the selection of a function button designed for this purpose.

A modification to applications (e.g. type of application, batch number, expiry date) cannot be carried out within the online procedure unless the PEI expressly allows for such an option in the online portal. Any changes required must be reported by email to pei_cr_support@pei.de.

Missing documents or documents requested at a later stage can be submitted by the user at a later date using a function button designed for this purpose.

14. Privacy statement

The "Erklärungen zum Internetangebot, zur Haftung, zu Links und Verlinkung, zum Urheberrecht und Datenschutz" (Declarations concerning internet content, liability, links and linking, copyright, and data protection) published in www.pharmnet-bund.de – Impressum (=information on this website) (https://www.pharmnet-bund.de/static/de/impressum/) shall apply.