Terms and conditions for the application „Product information texts (PIT)“

Stand: 05.05.2020

1. Scope of services

Via the internet portal PharmNet.Bund.de, the federal higher authorities are making the special application "Product Information Text“ (PIT) for submission of the final text versions of Summary of Product Characteristics (SmPC) and Package Leaflet (PIL) available to pharmaceutical companies after completion of the procedure. Currently, submissions via special applications can be made to the federal higher authority BfArM which is responsible in accordance with Section 77 AMG.

2. Authorised users

Authorised users are those who are registered at DIMDI and who fulfil the respective requirements. Information on the standard procedure and requirements for registration can be requested from DIMDI (www.dimdi.de). Only persons of legal age are accepted as users.

3. Use of data from the federal higher authorities

In order to prepare the submissions, the necessary electronically available information on marketing authorisation holder and medicinal products is made available via the special application. This information may also contain trade and business secrets.

4. Processing of submissions via the special applications

The federal higher authorities process the submissions received via the special application in their ordinary course of work. The submissions are considered received as soon as they have been transmitted electronically to the federal higher authorities' Medicinal Product and Application Database (AmAnDa) and have been recorded there. This usually happens within a few minutes after successful transmission by the user of the special application.

5. Fees

There are no additional costs for the processing and publication of submissions created and transmitted via the special application as they are already included in the fee for the basic procedure.

6. Blocking of online access

The online access will be blocked immediately in cases of suspected misuse and/or at the request of the marketing authorisation holder.

7. User's duty of care and cooperation

a. Obligation to maintain confidentiality of user ID and password

The user must ensure that exclusively those persons authorised on the user's part obtain knowledge of the access data. In particular, the access data shall not be stored on a computer without protection. Every person who gains access to the login details has the possibility of using the online application. If users discover that an unauthorized person has obtained knowledge of the access data, the password must be changed immediately or access must be blocked. If this cannot be done by the user, the responsible federal higher authority must be informed immediately.

b. Protection of the user system

Since attacks on the security of the online system are possible, users must take the necessary defense measures against such dangers in their own interest and must keep their computers free of all programs that could endanger the security (e.g. computer viruses and so-called Trojans). A variety of anti-virus software for this purpose is commercially available in its respective latest version. Users must ensure that the browser they use has no safety deficiencies and must regularly check the security aspects of the system they use (operating system, browser etc.) to prevent the online system from being compromised. Furthermore, users have to take measures to increase system security, e.g. the installation of program updates for such purposes.

c. Due diligence during transaction

When the welcome screens of the internet portal PharmNet.Bund.de and the online application appear, users must first check the certification of the online address in order to ensure that they are in fact connected with PharmNet.Bund.de. Third parties may otherwise gain knowledge of user ID and password in this way. Users have to check all data they enter for completeness and correctness. Incorrect data can have a direct impact on the content of the marketing authorisations of medicinal products.

8. Marketing authorisation holder's duty of care and cooperation

The marketing authorisation holder must ensure that the user's duties of care and cooperation listed under No. 9 are made known to those authorised representatives of the authorisation holder to whom use of the online procedure is to be transferred. The same duties of care and cooperation that apply to the authorised users also apply to the marketing authorisation holders themselves.

9. Liability

a. The "Statements on Internet Offers, Liability, Links and Linking Policy, Copyright and Privacy" published at www.PharmNet. Bund.de - Imprint (www.pharmnet-bund.de/dynamic/de/impressum.html) apply.

b. Liability for damages resulting from unauthorized, abusive or incorrect use of the user's access data or for other damages, regardless of the cause, is excluded. This does not apply to damages resulting from gross negligence or intent on the part of the federal higher authorities or to the violation of material contractual obligations. However, claims for compensation are limited to foreseeable damages typical for the agreement.

c. These exclusions and limitations of liability do not apply to damages resulting from culpable injury to life, body or health.

10. Withdrawal or modification of submissions

The withdrawal or amendment of submissions can only be carried out outside the online procedure, unless the federal higher authorities expressly provide such an option within the procedure. However, the federal higher authorities can only take into account a withdrawal or an amendment if they receive this submission in due time to allow it to be considered within the framework of the routine workflow.

11. Data protection declaration

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