**NOTIFICATION OF THE COMMENCEMENT OF DISTRIBUTION ACTIVITIES WITHIN THE TERRITORY OF THE CZECH REPUBLIC BASED UPON DISTRIBUTION AUTHORISATION FOR MEDICINAL PRODUCTS ISSUED BY ANOTHER EU MEMBER STATE**

**The obligation to notify in advance pursuant to Section 75 par. 4 of Act No 378/2007 Coll., on Pharmaceuticals, as amended**

|  |  |
| --- | --- |
| **Name -** distributor’s trade company; name and surname for a natural person |  |
| **Distributor's address** – country and registered office address for legal persons; address of business premises for natural persons  |  |
| **Distributor's statutory representative**, in case of a legal person – name, surname |  |
| **Identification company number as in the official registry** |  |
| **Distributor's contact details** – contact person, phone, fax, e-mail |  |
| **Date of distribution commencement in the CR** |  |
| **Competent authority of the other Member State, which has issued the distribution authorisation – name, address** |  |
| **Type and scope of distribution** |  |
| **Addresses of all distribution sites from which distribution will be performed[[1]](#footnote-1)** (if there is insufficient space, please provide the data on a separate sheet) |  |
| **Annexes to the application** – please check annexes submitted together with this form |
| a) Proof of distribution authorisation issued by the relevant state as currently valid (with Czech or English translation) | [ ]  |
| b) others – please specify | [ ]  |

**I hereby declare that the data in the form and attached documentation are true and correct and that I am aware of all the obligations imposed on me by Section 77 of the Act on Pharmaceuticals, in particular of the obligation to report regularly to the State Institute for Drug Control data concerning the volume of medicinal products distributed to healthcare facilities incl. pharmacies in line with the SUKL Guideline.**

**Date: Signature (signature of the statutory representative for legal persons)**

 **Name, surname:**

**NOTIFICATION OF A CHANGE IN INFORMATION ON THE DISTRIBUTOR PERFORMING DISTRIBUTION ACTIVITIES WITHIN THE TERRITORY OF THE CZECH REPUBLIC BASED UPON DISTRIBUTION AUTHORISATION FOR MEDICINAL PRODUCTS ISSUED BY ANOTHER EU MEMBER STATE**

**Original notification submitted on .......................**

**The obligation to provide the data necessary for co-operation between the State Institute for Drug Control and the distributor and other information on the scope of distribution and location of distribution stores pursuant to Section 75 par. 4 of Act No 378/2007 Coll., on Pharmaceuticals, as amended**

|  |  |
| --- | --- |
| **Name -** distributor’s trade company; name and surname for a natural person |  |
| **Distributor's address** – country and registered office address for legal persons; address of business premises for natural persons  |  |
| **Identification company number as in the official registry** |  |
| **Distributor's contact details** – contact person, phone, fax, e-mail |  |
| **Changes to originally notified data** - please list all proposed changes, in the case of a change in the distribution authorisation issued by the Competent Authority, annex the copy of the authorisation (if there is insufficient space, please provide the data on a separate sheet) | Present | Proposed |
|  |  |
| **Annexes to the application** – please check annexes submitted together with this form |
| 1. Proof of distribution authorisation issued by the relevant state as currently valid (with Czech or English translation)
 | [ ]  |
| 1. others – please specify
 | [ ]  |

**I hereby declare that the data in the form and attached documentation are true and correct.**

**Date: Signature (signature of a statutory representative for legal persons)**

 **Name, surname:**

1. Where such distributor establishes distribution stores in the CR, he or she shall be subject to the obligation provided for in Section 75 par. 4 of Act No 378/2007 Coll. to obtain beforehand a distribution authorisation from the State Institute for Drug Control. [↑](#footnote-ref-1)