<Date>

**Direct Healthcare Professional Communication**

**<Active substance(s), name(s) of medicinal product(s) and main message** *(e.g., introduction of a warning or a contraindication)***>**

Dear healthcare professional,

<Name(s) of the marketing authorisation holder(s)> would like to inform you of the following:

**Summary**

*Guidance on style: A larger font size should be used in this section than in the other DHPC sections, and the text in this section should be laid out in bullet points, using a bulletin list.*

* <Brief description of safety issue, recommendations for risk minimisation (*e.g., contraindications, warnings, precautions of use)* and alternative treatments, if applicable>
* <Information regarding recall, if applicable, including level of recall (pharmacy or patient) and date>

<Statement that the distribution of information is conducted in accordance with the national competent authority or the European Medicines Agency, if applicable.>

<If the DHPC contains information regarding several or very many medicines authorised nationally in Latvia or via the centralised procedure in European Union, this information should be indicated in the letter.>

**Further information regarding safety concerns and recommendations**

<Important information regarding the safety concern (severity of adverse reaction, information regarding potential causal relationship, and, if known, regarding the pharmacodynamic mechanism, temporal relationship, positive re-challenge or de-challenge, risk factors), as well as the reason for distribution of the DHPC at that time.>

<Data regarding the frequency of adverse drug reactions or frequency of reports in relation to the number of patients exposed to the medicinal product.>

<Indication of a connection between the adverse drug reaction and off-label use, if applicable>

<Information regarding recommendations for risk minimisation, if applicable>

<Risk assessment in the context of the benefit>

<Indication of any previous, recently distributed DHPC in relation to the current safety concerns>

<Schedule for follow-up actions to be carried out by the marketing authorisation holder/competent authority>

**More information**

<Link/reference to other available related information, for example, information available on the website of the competent authority>

<Therapeutic indications of the medicinal product, if not mentioned before>

**Call for reporting**

<Reminder about the necessity to report adverse reactions and how to report them in accordance with the national spontaneous reporting system. The following standard text should be included:

|  |
| --- |
| Atgādinām, ka saskaņā ar zāļu blakusparādību ziņošanas noteikumiemFarmakovigilances kārtību Latvijā ārstniecības personām un farmaceitiem jāziņo par novērotām iespējamām zāļu blaknēm Zāļu valsts aģentūrai (ZVA) elektroniski ZVA mājaslapātīmekļa vietnē www.zva.gov.lv, klikšķinot uz izvēlnes “Ziņot par zāļu blaknēm, negadījumiem ar ierīcēm, biovigilanci” un zem “Veselības aprūpes speciālistiem” izvēloties “ZiņoZiņot par zāļu blaknēm”, un “Ārstniecības personas, farmaceita ziņojuma veidlapa”.” vai skenējot zemāk attēloto QR kodu. Papildinformācijas nepieciešamības gadījumā jāsazinās ar ZVA pa tālr.: 67078438. |

*(“We would like to remind you that in accordance with the pharmacovigilance procedure in effect in Latvia healthcare professionals and pharmacists should report observed suspected adverse reactions to the State Agency of Medicines via SAM website* [*www.zva.gov.lv*](http://www.zva.gov.lv)*, by selecting “Report Adverse Drug Reactions, Incidents with Devices, Biovigilance” and under “For Healthcare Professionals”, or by scanning the QR code below.* *For additional information please contact SAM via phone by calling 67078438.”)*

If the relevant medicinal product is biological (biological medicinal product or similar biological medicinal product), the text should be supplemented with: “This medicinal product is a biological medicinal product, therefore, the original name and batch number of the medicinal product should be indicated when reporting adverse reactions”>

<Indication, if the medicinal product is subjected to additional monitoring and the reason for it>

**Company contact information**

<Contact information for obtaining further information; the MAH contact details must be specified (phone number and e-mail address)>

**Annexes**

<Relevant section of the amended product information (with changes highlighted), if applicable>

<Detailed scientific information, if necessary>

<List of references to literature, if applicable>