Direct Healthcare Professional Communication

Suboxone sublingual tablets (buprenorphine / naloxone): inaccurate Braille information on the carton for HU/CZ/SK pack

Dear Healthcare Professional,

Indivior Europe Limited, in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following:

Summary

- **Inaccurate Braille information has been identified on the cartons of Suboxone, marketed in the following countries:**

- **Czechia and Slovakia: for Suboxone 2mg/0,5mg and Suboxone 8mg/2mg sublingual tablets** (MA. no EU / 1/06/359/001, EU/ 1/06/359/003): between the respective concentrations of buprenorphine and naloxone API, instead of a "forward slash" symbol there is an instruction to read the following letter in lower case. In the context of this situation this is meaningless, because the following "letter" is a number. The Braille translation is as follows:
    - Instead of 2mg / 0.5mg, the Braille reads 2mg 0.5mg
    - Instead of 8mg / 2mg, the Braille reads 8mg 2mg
- **Hungary: for Suboxone 8 mg/2mg sublingual tablets** (MA no. EU/ 1/06/359/003): between the respective concentrations of buprenorphine and naloxone API, instead of a "forward slash" symbol there is a ő symbol. i.e.:
    - Instead of 8mg / 2mg, the Braille reads 8mg ő 2mg.
- **The following batches are affected:**
    - Suboxone 8mg/2mg batches 932401, 000207, 004203
    - Suboxone 2mg/0.5mg batches 932501, 001601

Background on the safety concern

Suboxone sublingual tablets are indicated for substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. The intention of the naloxone component is to deter intravenous misuse. Suboxone is indicated in adults and adolescents over 15 years of age who have agreed to be treated for addiction.

Whilst the Braille representation of the respective content of active ingredients in the tablet are correctly detailed on the carton, Indivior believes that there is potential for blind patients to be confused by the symbol, or the lack of a symbol, between the two stated content values.

Blind patients should be reassured that contents of active ingredients in the tablets are correct for the impacted batches and the inaccurate braille is noted by Indivior Europe Ltd. The Braille inaccuracy is in the process of being rectified for future batches manufactured.

Call for reporting

Please ensure all adverse reactions relating to Suboxone sublingual tablets are reported in accordance with the national spontaneous reporting system, and directly to Indivior Europe Ltd through the following email address;

PatientSafetyRoW@indivior.com

Company contact point

For further information relating to this reported defect, please contact:

Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Suboxone 2mg/0,5mg sublingual tablet (buprenorphine / naloxone) Suboxone 8mg/2mg sublingual tablet (buprenorphine / naloxone)
Marketing authorisation holder(s)	Indivior Europe Limited 27 Windsor Place, D02 DK44 Dublin, Ireland
Safety concern and purpose of the communication	Suboxone sublingual tablets; Inaccurate Braille information on the carton for HU/CZ/SK pack. Purpose of the communication is to make HCPs / pharmacists aware of the Braille inaccuracy, in the event of questions or concerns from blind patients utilizing the Braille on the carton
DHPC recipients	All HCPs in markets of CZ, HU and SK in receipt of batches impacted by the Braille inaccuracy. Issue of the DHPC will be facilitated through Indivior partner Wholesalers in each market.
Member States where the DHPC will be distributed	Czechia, Hungary and Slovakia

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP/CMDh	11th June 2020
Submission of translated DHPCs to the national competent authorities for review	16th June 2020
Agreement of translations by national competent authorities	17th June 2020*
Dissemination of DHPC	18th June 2020*

*Anticipated, based on immediate turn around by national CAs.