Zypadhera (olanzapine pamoate monohydrate): Information on ZYPADHERA – Injection kits to temporarily include only three 38 mm safety needles instead of two 38 mm and two 50 mm safety needles.

Dear Healthcare Professional,

CHEPLAPHARM Registration GmbH in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following:

Summary

- Manufacturing problems with the 50 mm safety needles that are co-packaged with Zypadhera have led to supply shortages of all strengths of the medicine. In order to mitigate the shortage, existing supplies have been redistributed between EU countries to ensure that sufficient supplies of at least one strength of Zypadhera are available at all times.
- In addition, Zypadhera kits for injection will now temporarily contain three 38 mm needles (19-gauge) instead of the two 38 mm and two 50 mm needles (19-gauge) normally provided in these kits.
- These three 38 mm safety needles ensure that the medicine can be used in normal-weight patients.
- For patients with obesity, the practitioner must provide 19-gauge, 50 mm needles separately.

Background information on the medicinal product

ZYPADHERA powder for prolonged release suspension for injection contains the active ingredient olanzapine pamoate monohydrate. It is indicated for the maintenance treatment of adult patients with schizophrenia sufficiently stabilised during acute treatment with oral olanzapine tablets. Olanzapine is an antipsychotic, antimanic and mood stabilising agent that demonstrates a broad pharmacologic profile across a number of receptor systems.

ZYPADHERA is intended for intramuscular injection and should only be administered by deep intramuscular gluteal injection by a healthcare professional trained in the appropriate injection technique.

Before use, ZYPADHERA must be reconstituted according to the Summary of Product Characteristics.

In the case of kits containing three 38 mm needles:

- The required quantity of solvent is withdrawn using the syringe with the attached 38 mm needle (needle 1) and injected into the powder vial.
- The needle is then removed and discarded.

- After the powder has been completely reconstituted, the second 38 mm needle should be used to withdraw the required amount of solution for injection from the vial.
- Before deep intramuscular injection into normal-weight patients, the needle should be changed once more and the third 38 mm needle should be attached to the syringe.
- For injection into patients with obesity, a 19-gauge, 50 mm needle must be used. As these needles will temporarily not be included in the kit, they must be provided by the user.
- Due to the standardised Luer-Lock system, all needles with the 19-gauge, 50 mm specification will fit.

If these 19-gauge, 50 mm needles are not part of the basic equipment in your facility, we recommend procuring and storing them promptly so that you are prepared at all times.

Management of the supply shortage

<This section needs to be tailored to National communication:

- *Mention may be made that a finite number of kits will be distributed to each specific market based on approval by national health authorities. Specific mechanism if needed subject to agreement with National HA;*

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DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Zypadhera - Powder and solvent for prolonged release suspension for injection / olanzapine pamoate
Marketing authorisation holder(s)	CHEPLAPHARM Registration GmbH (Germany)
Safety concern and purpose of the communication	ZYPADHERA - Kits transitionally contain three 38 mm safety needles instead of two 38 mm and two 50 mm safety needles
DHPC recipients	Hospital pharmacies and all Customers who already ordered Zypadhera and new Customers receiving deviating packs. (*final list of recipients to be agreed at national level including professional societies and national associations, depending on the national healthcare system)*
Member States where the DHPC will be distributed	Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Norway, Finland, France, Greece, Hungary, Netherlands, Poland, Romania, Slovakia, Spain

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	24.05
Submission of translated DHPCs to the national competent authorities for review	06.06.2024
Agreement of translations by national competent authorities	12.06.2024
Dissemination of DHPC	19.06.2024