Visudyne (verteporfin): Information on the continuing supply restriction until end Q1/2022

Dear Healthcare Professional,

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

Summary

- The current shortage of Visudyne is expected to be resolved by the end of Q1 2022 after supplies resume in November 2021.
- Once EU Visudyne is available, CHEPLAPHARM will prioritize making Visudyne available for patients in the affected member states as soon as possible.

Background on the supply shortage

Visudyne is authorised for treatment of the 'wet' form of age-related macular degeneration (AMD) and choroidal neovascularisation caused by pathologic myopia.

Since May 2020, the supply of Visudyne has been interrupted due to reduced manufacturing capabilities. To restore supply, the manufacturing process has been transferred to an alternative existing production line in the same building, with equivalent machines and using the same technology and process.

To minimize the impact of the shortage in the respective countries, the remaining stocks were distributed in a balanced manner. Additionally, a limited amount of Visudyne products were imported from the United States and distributed using a special licence to some of the affected countries.

Newly manufactured Visudyne bulk product has now been imported to the EU and finalisation of QC testing and first packaging is planned for October 2021. CHEPLAPHARM plans to distribute newly manufactured Visudyne in the EU markets in the course of November 2021. Once newly manufactured Visudyne products are available, CHEPLAPHARM will prioritize making Visudyne available for patients in the concerned member states. Next bulk batch is currently scheduled to be imported to the EU within December 2021.

Management of the supply shortage

<This section needs to be tailored to National communication:

- *In France, a system of controlled distribution has been set up in agreement with ANSM;*

- *Mention may be made that a finite number of vials will be allocated to each specific market based on existing demand, and HCP are expected to allocate accordingly. Specific mechanism if needed subject to agreement with National HA;*
- For other countries prescribers are asked to cooperate with each other and with the local health authorities to provide therapy to those who are particularly affected;
- Visudyne is used off-label in multiple conditions. The national competent authorities may consider those in defining priorities with regards to the conditions for which the medicine will be made available.

Company contact point
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DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Visudyne 15 mg
Marketing authorisation holder(s)	CHEPLAPHARM Arzneimittel GmbH (Germany)
Safety concern and purpose of the communication	Information on the continuing supply restriction of Visudyne 15 mg until end Q1/2022
DHPC recipients	Ophthalmologists and Pharmacists of the centres dispensing Visudyne; (*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	Austria, Belgium, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	14/10/2021
Submission of translated DHPCs to the national competent authorities for review	within 5 working days after final agreement
Agreement of translations by national competent authorities	within 5 working days
Dissemination of DHPC	within 5 working days after agreement with national authorities