Visudyne (verteporfin): Information on the continuing supply limitation until end of 2023

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

- Visudyne's supply capacity was restored in Q1/2022, but not with the full extent required. Therefore, although deliveries are consistent available quantities will be limited until the end of 2023.
- CHEPLAPHARM is asking healthcare professionals to take this into account when planning and prioritizing treatments.
- CHEPLAPHARM will ensure a fair allocation and prioritize supply of Visudyne to patients in the member states that are most affected.

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 an unexpected breakdown of the filling line. 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. In Q1/2022 the production was restored, but with limited capacity. As a result, deliveries will be consistent but quantities of Visudyne are expected to be limited for the years 2022 and 2023.

The limited availability continues to affect all countries where the product is marketed. Based on historic demands, CHEPLAPHARM will ensure the fair allocation of Visudyne to the markets to safeguard the treatment of urgent cases.

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.

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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 limitation of Visudyne 15 mg until end of 2023
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	21 July 2022
Submission of translated DHPCs to the national competent authorities for review	by 28 July 2022
Agreement of translations by national competent authorities	by 5 August 2022
Dissemination of DHPC	by 12 August 2022