National Agency for the Safety of Medicine and Health Products
143-147 bd Anatole France
93285 Saint Denis cedex
France

Nov. 08, 2016

# LETTER OF ACCESS

Number of Active Substance Master File: Applicant's part version 7.0/ Restricted part version 6.0
The national ASMF reference number of FR ( )
Name of Active Substance: Bimatoprost

Manufacturing site:

Active Substance Master File Holder:

The aforementioned Active Substance Master File holder hereby authorises the *National Agency for the Safety of Medicine and Health Products / France* to refer to and review the above mentioned Active Substance Master File in support of the following Marketing Authorisation Application submitted by *Laboratoire CHAUVIN*:

Name of product: **VIZIBIM DUO 0.3 mg/mL + 5 mg/mL, collyre en solution**
Number of DCP: **DK/H/2711/001/DC**

Name of Applicant or Marketing Authorization holder : **Laboratoire CHAUVIN**
**416 rue Samuel Morse CS 99535**
**MONTPELLIER Cedex 2,**
**34961,**
**France**

The aforementioned Active Substance Master File holder commits to ensure batch to batch consistency and to inform the *National Agency for the Safety of Medicine and Health Products / France* and *Laboratoire CHAUVIN* of any change in the Active Substance Master File.

The aforementioned Active Substance Master File holder hereby is informed of and accepts that the EEA National Competent Authorities, the EMA including all CHMP and CVMP Members and their experts, and the Certification of Substances Division of the European Directorate for the Quality of Medicines & Healthcare may share the Assessment Reports of the above mentioned Active Substance Master File amongst themselves.

Sincerely,

*Dr.*
*Director of Quality Department*