Concerned Member State Comments on Day 120 Draft Assessment Report to be sent at Day 145 at the latest

1. This document is sent by:

CMS	FRANCE
Contact point, project team leader (name) phone email	 ☎ 💻
Assessors, if applicable (name e-mail, phone)	Regulatory/quality:
Date/Day of procedure	24.07.2017 (Day 145)

2. This document concerns:

Procedure number	UK/H/6370/01/DC
Name of the medicinal product in the RMS	PLENVU
Name of the active substance	Macrogol 3350, Sodium Ascorbate, Sodium Sulfate, Ascorbic acid, Sodium chloride, Potassium chloride
Applicant	Norgine B.V.
Deadline for comments	24.07.2017 (Day 145)

3. Comments, general

3.1 Assessment of the RMS

We fully endorse the RMS assessment, and have no further comments ☐

We endorse the RMS assessment, but also have additional comments ☒

We do not fully endorse the RMS assessment, and have other comments ☐

3.2 Conclusions on the product

Our conclusion is that the product is

Approvable ☐

Approvable, provided that satisfactory responses are given to the list of questions and/or the SmPC/PL/labelling is changed according to the comments ☒

Non-approvable ☐

3.3. List of Questions/Proposed conditions for marketing authorisation

We have grounds of potential serious risks to public health on the following part of the assessment report not already raised by the RMS as major objections

Quality ☐

Non-Clinical ☐

Clinical ☐

SmPC ☐

PL ☐

Labelling ☐

We have additional other concerns on the following part of the assessment report

Quality ☐

Non-Clinical ☐

Clinical ☐

SmPC ☐

PL ☐

Labelling ☐

Module 1 – Application related comments (including product name) ☒

4. Potential serious risk to public health

Quality

Potential serious risk to public health not already raised by the RMS as major objection
Rationale

Non-clinical

Potential serious risk to public health not already raised by the RMS as major objection
Rationale

Clinical

Potential serious risk to public health not already raised by the RMS as major objection
Rationale

SmPC

Potential serious risk to public health not already raised by the RMS as major objection
Rationale

PL

Potential serious risk to public health not already raised by the RMS as major objection
Rationale

Labelling

Potential serious risk to public health not already raised by the RMS as major objection
Rationale

5. Additional other concerns

Quality

Other concerns not already raised by the RMS
Rationale

Non-clinical

Other concerns not already raised by the RMS
Rationale

Clinical

Other concerns not already raised by the RMS
Rationale

SmPC

Other concerns not already raised by the RMS
Rationale

PL

Other concerns not already raised by the RMS
Rationale

Labelling

Other concerns not already raised by the RMS
Rationale

Module I – Application related comments (including product name)[1]

Other concerns not already raised by the RMS - The proposed product name PLENVU, poudre pour solution buvable is acceptable in France. - Taking into account the posology in the SmPC, the only pack which may be authorised under the non-prescription status and delivery through pharmacies will contain only one treatment. If duly justified, the other packs may be authorised but will be hospital use only. Therefore, the Applicant is requested to indicate the packs which will be marketed in France. - 2 samples of the finished product should be sent to : Agence nationale de sécurité du médicament et des produits de santé Direction des vaccins, des médicaments anti-infectieux, en hépato-gastroentérologie, en dermatologie, de thérapie génique et des maladies métaboliques rares (INFHEP) 143/147 bld Anatole France F-93285 Saint-Denis cedex
Rationale

6. Additional information for the Applicant

Additional information on the submission of response documents within the Member State should be included within this section. E.g. Institutional mailbox, etc.

[1] Please note that for 10.1 and 10.3 applications with a centrally authorised product as reference product, the product name in RMS and all CMS must be the same. It is therefore important that comments on the product name are sent early in the procedure in order to reach agreement before day 210/90.