COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Doxorubicine Liposomes SUN 2 mg/ml concentrate for solution for infusion

(doxorubicin hydrochloride)

NL/H/3653/001/DC

Date: 27 July 2018

This module reflects the scientific discussion for the non-approval of Doxorubicine Liposomes SUN 2 mg/ml concentrate for solution for infusion. The procedure was finalised at 2 October 2017.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused granting a marketing authorisation for Doxorubicine Liposomes SUN 2 mg/ml concentrate for solution for infusion from Sun Pharmaceutical Industries Europe B.V.

The indications applied for concerns*:*

- As monotherapy for patients with metastatic breast cancer, where there is an increased cardiac risk.
- For treatment of advanced ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen.
- In combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant.

The marketing authorisation was applied pursuant to Article 10(3) of Directive 2001/83/EC, a hybrid application.

The concerned member states in this procedure were Austria, Belgium, Germany, Denmark, Spain, Finland, France, Hungary, Italy, Norway, Poland, Romania, Sweden, Slovak Republic and the United Kingdom.

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted due to potential serious risk to public health as defined in the Guideline on the definition of a potential serious risk to public health in the context of Article 29(1) and (2) of Directive 2001/83/EC — March 2006 (2006/C 133/05).

There are doubts concerning the reliability of the study data of bioequivalence study PKD/14/172. Therefore no conclusion can be drawn concerning bioequivalence with the reference product and the benefit/risk balance of the product applied for has not been established. A GCP inspection of the CRO and relevant clinical sites is warranted before the product can be accepted for registration.

Therefore, the Board concluded that the marketing authorisation for Doxorubicine Liposomes SUN 2 mg/ml concentrate for solution for infusion cannot be granted. Agreement on this conclusion was reached with the concerned member states. The decentralised procedure was finalised with a negative outcome on 2 October 2017.