SCIENTIFIC DISCUSSION

1. Introduction

This application has been submitted as an informed consent application in accordance with Article 10c of Directive 2001/83/EC, as amended.
Therefore, consent from the MAH of the FOSAVANCE application, which had been submitted as a full application under Art 8(3) of Directive 2001/83/EC as amended, has been given allowing access to Module 2 to Module 5 of the initial dossier of this authorised product and any subsequent post-marketing procedures submitted, assessed and approved.

As a consequence, quality, safety and efficacy of the ADROVANCE medicinal product is identical to the up-to-date quality, safety and efficacy profile of FOSAVANCE. Information on the scientific discussions can be found in the FOSAVANCE CHMP assessment report and in the European Public Assessment Report (EPAR).

The approved indication is: “Treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency. ADROVANCE reduces the risk of vertebral and hip fractures”.

2. Quality aspects

Since this application is an informed consent of the FOSAVANCE application, the quality data in support of the ADROVANCE application are identical to the up-to-date quality data of the FOSAVANCE dossier which have been assessed and approved (including all post-marketing procedures).

3. Non-clinical aspects

Since this application is an informed consent of the FOSAVANCE application, the non-clinical data in support of the ADROVANCE application are identical to the up-to-date non-clinical data of the FOSAVANCE dossier, which have been assessed and approved (including all post-marketing procedures).

4. Clinical aspects

Since this application is an informed consent of the FOSAVANCE application, the clinical data in support of the ADROVANCE application are identical to the up-to-date clinical data of the FOSAVANCE dossier, which have been assessed and approved (including all post-marketing procedures).

- User consultation

Since this application is an informed consent of the FOSAVANCE application, the user consultation submitted for the ADROVANCE application is identical to the one submitted for the FOSAVANCE dossier, which was considered acceptable by the CHMP.

5. Pharmacovigilance

PSUR

As requested by the MAH and agreed by the CHMP, the PSUR cycle of ADROVANCE will correspond to the one attributed to the cross-referred product, FOSAVANCE, until otherwise specified.

Detailed description of the Pharmacovigilance system

The CHMP considered that the Pharmacovigilance system as described by the applicant fulfils the legislative requirements.

Risk Management Plan

The applicant submitted a risk management plan. The CHMP considered that routine pharmacovigilance was adequate to monitor the safety of the product.
The CHMP, having considered the data submitted in the application, is of the opinion that no additional risk minimisation activities are required beyond those included in the product information. However, the applicant is asked to provide an updated Risk Management Plan taken into account the comments raised during the assessment, at the time of the first PSUR.

6. Overall conclusions, risk/benefit assessment and recommendation

Since this application is an informed consent of the FOSAVANCE application, the CHMP considered that the risk-benefit balance of ADROVANCE (70 mg alendronic acid as alendronate sodium trihydrate and /70 micrograms colecalciferol) tablet given once weekly was favourable and therefore recommended the granting of the marketing authorisation for the following indication:

"Treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency. ADROVANCE reduces the risk of vertebral and hip fractures."