LEGAL BACKGROUND

Directive 2001/83/EC

CHAPTER 4: Mutual recognition procedure and decentralised procedure

Article 27(1)

“A coordination group shall be set up for the examination of any question relating to marketing authorisation of a medicinal product in two or more Member States in accordance with the procedures laid down in this Chapter.”

Rules of Procedure

ADVICE: ARTICLE 12

“Requests for advice submitted by applicants or MAH or by one or more EU Member State or EFTA states shall be dealt with in accordance with a defined procedure to be adopted by CMDh including the criteria for acceptance of such a request. Advice on scientific matters should be referred to the EMA or NCA, to be dealt with as a scientific advice.”

QUESTION AND ANSWER SECTION

Question 1

Will the CMDh provide advice on questions raised by companies?

As written in the Rules of Procedure of the CMDh, it is the task of the CMDh to provide advice. Individual advice is given if the question is not already addressed in published papers or FAQ of the CMDh.
Question 2

What kind of advice is given by the CMDh?

The CMDh will provide procedural and regulatory advice in the framework of mutual recognition (MRP/DCP) at European level. Scientific advice for the development of a medicinal product is the task of either the national competent authorities (NCA) or the CHMP through the Scientific Advice Working Party.

Question 3

What is the procedure to get advice from the CMDh?

The CMDh encourage the applicant to address the question for advice in the first instance to the experts in the NCAs, preferably the future RMS. If it is not appropriate for the NCA to solve the question raised, the usual procedure is for the CMDh-Member of the respective MS to take forward the question for discussion to the CMDh. In exceptional cases, with the agreement of the Chairperson of the CMDh, the applicant may take forward the question for discussion to the CMDh. In both cases, a first discussion of the raised question will take place at the following CMDh Meeting, which is normally within 30 days after the question has been received by the CMDh Secretariat.

Question 4

How will I receive an answer from the CMDh?

Following the final discussion at the CMDh, the specific answer will be provided to the company by the CMDh-Secretariat or by the CMDh-member who has forwarded the question to the CMDh. If the CMDh is of the opinion that the subject is of general importance for other MAH/applicant/companies, the information/agreement will be published in an anonymous Q&A by the CMDh.

All questions discussed at the CMDh, as far as no confidential data is concerned, are published in the Agenda and the Minutes of the CMDh meeting in an anonymous way, as appropriate.