25 June 2026
EMADOC-1700519818-3223083
Committee for Medicinal Products for Human Use (CHMP)

CHMP List of questions

To be addressed by the marketing authorisation holders for Rifadin oral suspension and syrup, and associated names

Referral under Article 31 of Directive 2001/83/EC

Procedure number: EMA/REF/0000355053

INN/active substance: rifampicin

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1. Questions

The marketing authorisation holders (MAHs) are requested to address the following questions:

Question 1

Concerning your Rifadin oral suspension and syrup and associated names please provide in the annexed table:

a) Information on type of marketing authorisation, marketing and legal status.

b) Figures on sales and patient exposure for rifampicin oral suspension/syrup, by member state, indication and age. Data on the use in clinical practice including information on dose and duration of treatment.

c) Information included in the summary of product characteristics (SmPC) and package leaflet (PL) on indications and posology in the different indications, and information related to presence of diethanolamine (DEA). Please highlight the main differences between the product(s) information (PI) in the different EU member states.

d) An overview of the approved indication(s) of Rifadin oral suspension and syrup and associated names outside the EU.

Question 2

Please provide a review of all available preclinical and toxicological data related to the potential carcinogenic risk associated with oral exposure to DEA a) in general, and b) in Rifadin (and associated names) oral suspension and syrup. This detailed assessment should take into account the levels of DEA present in the product, the levels ingested daily in the different indications, the duration of use, and should be based primarily on available preclinical and toxicological data, including any evidence of carcinogenicity and the relevance of these findings to humans.

Question 3

Please discuss whether any clinical safety data, including from clinical trials, pharmaco-epidemiological studies, literature or post-marketing reporting, are available to inform the evaluation of the possible carcinogenic risk associated with DEA in Rifadin (and associated names) oral suspension and syrup. If such data are available, please provide a critical analysis of their relevance and limitations.

Question 4

Please provide a critical appraisal of the impact of the above data on the possible DEA-associated carcinogenic risk on the benefit-risk balance of Rifadin (and associated names) oral suspension and syrup in each of the approved indication(s) in the EU/EEA. This should specifically address aspects relating to age, dose and duration of treatment.

Question 5

Please provide justified proposals for potential reformulation strategies aimed at eliminating the presence of DEA in Rifadin (and associated names) oral suspension and syrup. Please discuss the feasibility of such approaches, including their potential impact on product quality, safety and efficacy, as well as how the implementation and outcomes of these strategies could be monitored and assessed.

Question 6

Please provide justified proposals for any other mitigation strategies which may improve benefit-risk balance of Rifadin (and associated names) oral suspension and syrup. Please discuss the feasibility of such approaches, including their potential impact on product quality, safety and efficacy, as well as how the implementation and outcomes of these strategies could be monitored and assessed.

Annex

Question 1

a) & b)

INN	Product name	Type of marketing authorisation	Marketing and legal status	Indications[1]	Pharmaceutical forms and strengths	Sales figures	Estimated patient exposure[2]	Doses (as approved and used in clinical practice)	Treatment duration (as approved and used in clinical practice)

[1]. <AT: company type 2> should clearly indicate for which country a specifically dedicated presentation has been granted for a particular indication
[2]. Expressed in patient years and stratified by Member State, by indication and by age (e.g. <12, 12-18 and adults). Reasonable efforts should be made to obtain this information; potential sources in addition to sales data include registries and healthcare databases. If no precise data is available an estimate can be provided.

c)

PI	SmPC	PL	Main differences in SmPCs/PLs between the different EU Member States (if relevant)
Posology (incl. max. daily dose)			
Information related to presence of DEA			