25 February 2016
EMA/CHMP/147245/2016

CHMP List of questions

To be addressed by the marketing authorisation holders for dienogest/ethinylestradiol containing medicinal products indicated in acne

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1435

INN: dienogest/ethinylestradiol

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The marketing authorisation holders MAH(s) are requested to provide the following:

1. Concerning your dienogest/ethinylestradiol containing medicinal product(s) available on the EU market, please provide:

    - information on approved indication(s), doses, treatment duration, contraindications, warnings and precautions, information on pregnancy and lactation included in your Summary of Product Characteristics (SmPC). Please tabulate the main differences between the SmPCs in the different countries in the EU.
    - an overview of the approved indication(s) of dienogest/ethinylestradiol containing medicinal product(s) outside the EU
    - figures on patient exposure by product and by country, particularly for the indication in acne, if possible.

Efficacy

2. There are concerns with regard to the efficacy of dienogest/ethinylestradiol containing medicinal product(s) in the treatment of acne with moderate severity in women in whom topical treatment was ineffective. Please provide relevant pivotal and supportive evidence.

Safety

3. Provide a detailed analysis of the available safety data from clinical trials (both placebo-controlled and active-controlled) and new relevant safety data which has become available after the Article 31 outcome on combined hormonal contraceptives (EMEA/H/A-31/1356) (e.g. spontaneous reports, information on ongoing studies, published literature) with your dienogest/ethinylestradiol containing medicinal product(s), in particular the data related to the risk of venous thromboembolic events (VTE) and arterial thromboembolic events (ATE):

    - These analyses should provide – as far as possible - information on the risk factors of VTE and ATE according to relevant criteria, such as dose, duration of treatment, age, time to event onset, concomitant medications, concomitant illnesses or other factors. An assessment of causality should also be provided and possible risk factors discussed.

Risk-Benefit analysis for any changes proposed to the indication

4. Please provide proposals and justification with supportive evidence for any measures, including changes to the SmPC and package leaflet (PL), which could be taken in order to improve the benefit/risk of dienogest/ethinylestradiol containing medicinal product(s) for the indication in acne. A discussion of the benefit/risk assessment of dienogest/ethinylestradiol containing medicinal product(s) for any proposed changes to the indication of acne should be provided also taking into consideration other medicinal products authorised for this indication. Such a risk-benefit discussion should pay attention to different populations (women requiring contraception and those not requiring contraception), age groups (>18 years of age and adolescents,) and subgroups with other recognized risk factors (e.g. weight, smoking).