NOTIFICATION TO THE CHMP/EMA SECRETARIAT OF A REFERRAL UNDER ARTICLE 30 OF DIRECTIVE 2001/83/EC

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This notification is a referral under Article 30 of Directive 2001/83/EC to the CHMP made by the Marketing Authorisation Holder (MAH).
SEPTODONT

Product name	SCANDONEST and associated names *See Annex I*
Active substance(s)	Mepivacaine hydrochloride
Pharmaceutical form(s)	Solution for injection
Strength(s)	30 mg/ml
Route of administration(s)	Dental use Perineural use Submucosal use *See Annex I*
Presentations	Cartridge 1.7 ml / Box of 50 Cartridge 1.7 ml / 4 Boxes of 50 Cartridge 1.7 ml / 8 Boxes of 50 Cartridge 1.8 ml / Box of 50 Cartridge 2.2 ml / Box of 50
Marketing Authorisation Holder(s)	SEPTODONT group of companies and associated companies *See Annex I*

Harmonisation of Summary of Product Characteristics (SmPC) for SCANDONEST 30 mg/ml solution for injection (and associated names):

The medicinal product concerned by the referral is authorised across European Union (EU) Member States, Iceland and Norway in the form of 22 national marketing authorisations (MAs) and one MRP involving 5 MS. The national MAs were granted between 1966 and 2017 and were then subject to a number of lifecycle activities (variations, renewals, validation) over the following years. The different granting time of MAs, the long submission period of variations, the disparities in the level of information registered, and the consequent divergent opinions delivered by the national competent authorities, all triggered current versions of Product Information that are non-harmonized between MS and discrepancies in the Quality part (module 3) across national MAs.

The MAH carried out the task of identifying the divergences between the available SmPCs for this product and has come to the conclusion that the above-mentioned medicinal product SCANDONEST 30 mg/ml solution for injection (and associated names), does not have the same Summary of Product Characteristics (SmPC) across all EU Member States, Iceland and Norway with respect to indications, posology, contra-indications, special warnings and precautions for use, undesirable effects as well as Quality aspects in the Pharmaceutical dossier (module 3).

The following examples constitute a non-exhaustive list.

Product Information

4.1 Indications
Consistency in the primary indication (dental indication) and divergence on secondary indication for chiropody procedures.

4.2 Posology
Divergences in the expression of the dose recommendations (i.e. average dose, maximum recommended dose, with quantities expressed in cartridges, weight of active substance per kg of body weight or volume of solution).

4.3 Contraindications /4.4 Special warnings and precautions for use
Divergences in the layout of the information provided and in the content.

4.8 Undesirable effects
Divergences in the layout of the undesirable events (SOCs, frequencies, description).

Discrepancies between Member States also exist regarding other sections in particular with divergences but for which no detailed overview is provided above.

Quality part

The pharmaceutical dossier (module 3) has been restructured into CTD format and updated according to current scientific guidelines in force.

Part 3.2.S - Drug Substance
Divergences in the registered active substance manufacturers and the related pharmaceutical documentation.

Part 3.2.P - Drug Product
- Divergences in the nominal filling volume of the cartridges (from 1.8 ml to 1.7 ml),
- Divergences in the In-Process Controls limits,
- Divergences regarding the control of excipients,
- Divergences in release and end-of-shelf life specifications in order to follow state of the art and current guidelines in force,
- Divergences in the registered information regarding the quality of the container closure system,
- Divergences in storage recommendations and labelling statements according to current scientific guidelines in force and Quality Review Document (QRD) template.

Discrepancies between Member States also exist regarding some other sections with divergences but for which no detailed overview is provided above.

Due to the divergent national decisions taken by Member States as part of the authorisations of the above-mentioned product, SEPTODONT hereby notifies the Agency of an official referral under Article 30 of Directive 2001/83/EC in order to resolve divergences amongst the nationally authorised SmPCs and the Quality module and thus to harmonise its divergent SmPC and module 3 across the EU.

Signed

Date: 25/08/2017

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EU Regulatory Affairs Manager