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	SEPTANEST / SEPTANEST FORTE and associated names *See Annex I*
Active substance(s)	Articaine (hydrochloride) /Adrenaline (tartrate)
Pharmaceutical form(s)	Solution for injection Solution for injection in cartridge
Strength(s)	40 mg/ml + 0.005 mg/ml 40 mg/ml + 0.01 mg/ml
Route(s) of administration	Dental use Oromucosal use Submucosal use Infiltration and perineural use Periodontal use
Presentations	1.8-ml glass cartridges 1.7-ml glass cartridges 1.0-ml glass cartridges
Marketing Authorisation Holder	SEPTODONT group of companies and associated companies *See Annex I*

Harmonisation of Summary of Product Characteristics (SmPC) for SEPTANEST / SEPTANEST FORTE and associated names:

The medicinal products concerned by the Referral procedure are authorised across European Union Member States (MS), Iceland and Norway in the form of 57 marketing authorisations (MAs): 39 purely national MAs, divided into 19 MAs for SEPTANEST and 20 MAs for SEPTANEST FORTE, and one Mutual Recognition Procedure (MRP) involving 9 MS where both products are registered.
The MAs were granted at different periods (between 1988 and 2017), with an uneven level of information registered, and were then the subject of a number of lifecycle management activities (variations, renewals, validation) which may have led to divergent decisions by the National Competent Authorities. As a consequence, discrepancies have been introduced both in the current versions of the Product Information and the Quality data (Module 3) between the Member States. This led to the decision to initiate a Referral procedure under Article 30(1), to resolve the divergences between the MS and achieve full harmonisation of the marketing authorisations granted for these medicinal products.

The Marketing Authorisation Holder carried out the task of identifying the divergences between the available SmPCs for these products and has come to the conclusion that the above-mentioned medicinal products SEPTANEST / SEPTANEST FORTE and associated names do not have the same Summary of Product Characteristics (SmPC) across all EU Member States and Norway with respect to posology, contra-indications, special warnings, use during fertility, pregnancy and lactation, undesirable effects, as well as Quality data in the Pharmaceutical dossier (Module 3).

The following examples constitute a non-exhaustive list.

Product Information

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

4.3 Contraindications /4.4 Special warnings and precautions for use
Divergences in the layout of the information provided and in the content (relevance of information, wording)

4.6 Fertility, pregnancy and lactation
Divergences in the layout of the information provided and in the content (rational, wording)

4.8 Undesirable effects
Divergences in the layout of the undesirable events

Discrepancies between Member States also exist regarding other sections including 4.5 Interactions, 4.9 Overdose, 5.1 Pharmacodynamics properties, 5.2 Pharmacokinetics properties and 5.3 Preclinical safety data.

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,
- Divergences in the specifications of the actives substances regarding the biological tests.

Part 3.2.P - Drug Product
- Divergences in the nominal filling volume of the cartridges,
- Divergences in the marketing presentations,
- Divergences in the batch sizes,
- 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 concerning the authorisations of the above-mentioned products, SEPTODONT 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 data for the above-mentioned products and thus achieve harmonisation of the divergent marketing authorisation dossiers across the EU.

Signed [redacted] Date: 04/06/2018

[redacted]hole range of names, pharmaceutical forms, strengths, routes of [redacted]medicinal product in all EU Member States (Iceland and Norway, if [redacted]