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HARMONIZED SYSTEM
COMMITTEE
-
23rd Session
-

NC0023E1
(+ Annex)
O. Eng.

H9-3

Brussels, 7 April 1999.

CLASSIFICATION OPINIONS AND AMENDMENTS TO THE EXPLANATORY NOTES ARISING FROM THE CLASSIFICATION OF CERTAIN TRANSDERMAL ADMINISTRATION SYSTEMS

(Item VII.6 on Agenda)

Reference documents :

40.082 (HSC/17)
40.260, Annex IJ/12 (HSC/17 - Report)
40.455 (HSC/18)
40.561 (HSC/18)
40.626 (HSC/18)
40.749 (HSC/18)
41.185 (HSC/19)
41.100, Annex G/5 (HSC/19 - Report)
41.282 (HSC/20)
41.600, Annexes D, E/7, IJ/10, K/10 and L/9 (HSC/20 – Report)
42.428 (HSC/22)
42.750, Annex G/3 (HSC/22 - Report)

I. BACKGROUND

1. At its19th Session (April 1997), the Harmonized System Committee classified four products put up in the form of transdermal administration systems, as follows :

"Estraderm® TTS" (active ingredient - 17β-estradiol) in subheading 3004.39
"Climaderm®" (active ingredient - 17β-estradiol) in subheading 3004.39
"Nitroderm® TTS" (active ingredient - nitroglycerol) in subheading 3004.90
"Nicotinell® TTS" (active ingredient – nicotine) in subheading 3824.90

The Secretariat was instructed to prepare Classification Opinions to reflect these decisions. Further, it was agreed that proposals by Switzerland and Argentina to amend the Nomenclature in this regard should be referred to the Review Sub-Committee for examination.

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2. On 27 June 1997, the Brazilian Administration notified the Secretariat that it was entering a formal objection to the classification of "Estraderm® TTS", "Climaderm®" and "Nitroderm® TTS" and, pursuant to Article 8 of the HS Convention, asked that the classification of these products be re-examined by the HSC.

3. At its 16th Session (September 1997), the Review Sub-Committee examined Argentinean and Swiss proposals to amend the Nomenclature and Explanatory Notes concerning transdermal administration systems. Though the Delegate of Brazil noted that his Administration had entered a reservation against the HSC's classification decisions, the Sub-Committee agreed that the proposed amendments were for future application, whereas the Brazilian reservation was relevant only to the present classification of these products.

4. The Harmonized System Committee, at its 20th Session (November 1997), provisionally adopted legal text and Explanatory Note amendments in this regard under the Article 16 procedure (see Doc. 41.600, HSC/20 Report, Annexes D, K/10 and L/9). However, in the light of the Brazilian reservation, and given that Classification Opinions applied to the present Harmonized System, the Committee adopted a Classification Opinion only for "Nicotinell® TTS", the classification of which was not disputed by Brazil (Doc. 41.600, Annexes E/7 and IJ/10). Classification Opinions for the other three products were held in abeyance, pending the outcome of the Brazilian reservation.

5. At its 22nd Session (November 1998), the Harmonized System Committee, by 20 votes to 9, confirmed its previous decision that "Estraderm® TTS", "Climaderm®" and "Nitroderm® TTS" were classifiable in heading 30.04. At the request of the Swiss Administration, the Committee asked the Secretariat to prepare draft Classification Opinions for these products. The Committee also agreed to an EC request for amendments to the Explanatory Notes to clarify the classification of products of this nature, in particular, for a specific inclusion in the Explanatory Note to heading 30.04 and an exclusion in the Explanatory Note to heading 30.05.

II. SECRETARIAT COMMENTS

6. In accordance with the decisions by the Harmonized System Committee, the Secretariat has prepared draft Classification Opinions and Explanatory Note amendments. These drafts are set out in the Annex to this document. It should be noted that the draft texts are largely based on that adopted by the Committee (20th Session) for the Classification Opinion for "Nicotinell® TTS" (see Annex IJ/10 to Doc. 41.600).

III. CONCLUSION

7. The Committee is invited to approve the proposed amendments to the Compendium of Classification Opinions and to the Explanatory Notes, as set out in the Annex, once they have been finalized by the presessional Working Party.

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x x

Annexe au Doc. NC0023B1
Annex to

(CSH/23/mai 99)
(HSC/23/May 99)

ANNEXE

MODIFICATIONS DU RECUEIL DES AVIS DE CLASSEMENT
ET DES NOTES EXPLICATIVES SUITE AU CLASSEMENT DE CERTAINS PRODUITS
DESTINES A ETRE ADMINISTRES PAR VOIE PERCUTANEE

(Point V.7 de l'ordre du jour)

ANNEX

AMENDMENTS TO THE COMPENDIUM OF CLASSIFICATION OPINIONS
AND EXPLANATORY NOTES ARISING FROM THE CLASSIFICATION OF CERTAIN
TRANSDERMAL ADMINISTRATION SYSTEMS

(Item V.7 on Agenda)

Annexe au doc. NC0023B1
(CSH/23/mai 99)

A. MODIFICATIONS DU RECUEIL DES AVIS DE CLASSEMENT

Page 9a.

Insérer l'Avis de classement suivant :

"**3004.39** 1. **Produit destiné à être administré par voie percutanée**, utilisé dans le traitement des déficiences hormonales pendant la ménopause. Le produit comprend 1°) une enveloppe extérieure ou pellicule protectrice en matière plastique transparente qui permet d'éviter l'épanchement de la substance active, à savoir le 17*ß*-estradiol; 2°) une petite poche à partir de laquelle le 17*ß*-estradiol est diffusé par absorption au travers de la peau dans le système circulatoire; 3°) une membrane de contrôle (perméable à la substance active) permettant une diffusion continue et constante de 17*ß*-estradiol dans le corps; 4°) un adhésif perméable à la substance active qui permet à la peau d'absorber le produit dès son application; et 5°) une enveloppe protectrice à retirer au moment de l'utilisation qui permet de conserver le produit clos et intact jusqu'au moment de son application.".

Page 10.

Insérer l'Avis de classement suivant :

"**3004.90** 1. **Produit destiné à être administré par voie percutanée**, utilisé par les patients atteints d'angine de poitrine pour régulariser le battement de coeur. Le produit comprend 1°) une enveloppe extérieure ou pellicule protectrice en matière plastique transparente qui permet d'éviter l'épanchement de la substance active, à savoir le nitroglycérol; 2°) une petite poche à partir de laquelle le nitroglycérol est diffusé par absorption au travers de la peau dans le système circulatoire; 3°) une membrane de contrôle (perméable à la substance active) permettant une diffusion continue et constante de glycérol dans le corps; 4°) un adhésif perméable à la substance active qui permet à la peau d'absorber le produit dès son application; et 5°) une enveloppe protectrice à retirer au moment de l'utilisation qui permet de conserver le produit clos et intact jusqu'au moment de son application.".

A. AMENDMENTS TO THE COMPENDIUM OF CLASSIFICATION OPINIONS

Page 9a.

Insert the following Classification Opinion :

"**3004.39** 1. **Transdermal administration system**, used for treating hormone deficiency during menopause, comprising (i) a transparent, external protective film of plastics to prevent leakage of the active substance (17*ß*-estradiol); (ii) a small reservoir from which 17*ß*-estradiol is released by absorption through the skin into the circulatory system; (iii) a control membrane (permeable to the active substance) to permit a continuous and controlled release of 17*ß*-estradiol entering the body; (iv) an adhesive contact permeable to the active substance, enabling absorption to start at the moment of application; and (v) a removable protective film which keeps the system closed and intact until the time of application.".

Page 10.

Insert the following Classification Opinion :

"**3004.90** 1. **Transdermal administration system**, used by angina patients for regulating the heartbeat, comprising (i) a transparent, external protective film of plastics to prevent leakage of the active substance (nitroglycerol); (ii) a small reservoir from which nitrogycerol is released by absorption through the skin into the circulatory system; (iii) a control membrane (permeable to the active substance) to permit a continuous and controlled release of nitroglycerol entering the body; (iv) an adhesive contact permeable to the active substance, enabling absorption to start at the moment of application; and (v) a removable protective film which keeps the system closed and intact until the time of application.".

Page 52.

Insérer les références suivantes :

Colonne 1	Colonne 2	Colonne 3	Colonne 4
"**3004.39**	1	(*)	**"Estraderm® TTS"** **"Climaderm®"**
"**3004.90**	1	(*)	**"Nitroderm® TTS""**.

B. MODIFICATIONS AUX NOTES EXPLICATIVES

PAR VOIE DE CORRIGENDUM

CHAPITRE 30

Page 468. N° 30.04. Premier paragraphe. Alinéa a). Nouveau deuxième paragraphe.

Insérer le nouveau deuxième paragraphe suivant :

> "Cette position comprend également des médicaments **sous forme de doses destinés à être administrés par voie percutanée**. Ces produits comprennent une enveloppe extérieure ou pellicule protectrice en matière plastique transparente qui permet d'éviter l'épanchement de la substance active; une petite poche à partir de laquelle la substance active est diffusée par absorption au travers de la peau dans le système circulatoire; une membrane de contrôle (perméable à la substance active) permettant une diffusion continue et constante de médicament dans le corps; un adhésif perméable à la substance active qui permet à la peau d'absorber le produit dès son application; et une pellicule protectrice à retirer au moment de l'utilisation qui permet de conserver le produit clos et intact jusqu'au moment de son application.".

Page 471. N° 30.05. Exclusions.

Insérer la nouvelle exclusion b) suivante :

"b) Les médicaments sous forme de doses destinés à être administrés par voie percutanée (**n° 30.04**)."

Les exclusions b) et c) actuelles deviennent c) et d), respectivement.

(*) Insérer la référence du rapport appropriée.

Page 52.

Insert the following references :

Column 1	Column 2	Column 3	Column 4
"**3004.39**	1	(*)	**"Estraderm® TTS"** **"Climaderm®"**
"**3004.90**	1	(*)	**"Nitroderm® TTS"**

B. AMENDMENTS TO THE EXPLANATORY NOTES

TO BE MADE BY BY CORRIGENDUM

CHAPTER 30

Page 468. Heading 30.04. First paragraph. Item (a). New second paragraph.

Insert the following new second paragraph under Item (a) :

> "The heading also includes measured doses in the form of **transdermal administration systems**, comprising : a transparent, external protective film of plastics to prevent leakage of the active substance; a small reservoir from which the active substance (medicament) is released by absorption through the skin into the circulatory system; a control membrane (permeable to the active substance) to permit a continuous and controlled release of the active substance entering the body; an adhesive contact permeable to the active substance, enabling absorption to start at the moment of application; and a removable protective film which keeps the system closed and intact until the time of application.".

Page 471. Heading 30.05. Exclusions.

Insert the following new exclusion (b) :

"(b) Medicaments put up in the form of transdermal administration systems (**heading 30.04**).".

Redesignate present exclusions (b) and (c) as (c) and (d), respectively.

(*) Insert the appropriate Report reference.