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REPORT OF THE WORKING GROUP CONCERNING AMENDMENTS TO HEADING 29.37 AND
ITS EXPLANATORY NOTE

(Item II.1 on Agenda)

Reference documents :

- 37.740 (SSC/6)
- 37.886 (SSC/6)
- 37.906 (SSC/6)
- 37.900, Annex A/1 (SSC/6 - Report)
- 38.876 (SSC/8)
- 39.119 (SSC/8)
- 39.130, Annex A/15 (SSC/8 - Report)
- 39.206 (HSC/15)
- 39.400, Annex D/1 (HSC/15 - Report)
- 39.897 (SSC/10)
- 40.080, Annex A/7 (SSC/10 - Report)
- 40.037, (HSC/17)
- 40.260, Annex D (HSC/17 - Report)
- 40.204 (SSC/11)
- 40.299 (SSC/11)
- 40.460, Annex A/2 (SSC/11 - Report)
- 40.412, paragraphs 5 to 8 and paragraph 35 (HSC/18)
- 40.600, Annex D (HSC/18 - Report)
- 40.754 (SSC/12)
- 40.765 (SSC/12)
- 40.766 (SSC/12)
- 40.870, Annexes A/7 and A/8 (SSC/12 - Report)
- 41.138 (SSC/Working Group/June 1997)
- 41.139 (SSC/Working Group/June 1997)
- 41.167 (SSC/Working Group/June 1997)
- 41.150 (SSC/Working Group/June 1997 - Report)
- 41.345 (SSC/Working Group/June 1997 - Addendum to Doc. 41.150)

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I. BACKGROUND

1. An ad hoc Working Group met during 2-4 June 1997 to examine a draft new legal text and Explanatory Note to heading 29.37, concerning hormones. These texts, as amended by the Working Group, are set forth in Annex I to Doc. 41.150 (SSC/WG/June 1997 - Report).
2. On 7 August 1997, the Secretariat received comments from the Asociación Latinoamericana de Integración (ALADI), with suggestions for improving the texts finalised by the Working Group. These comments are summarized below. The numbers, items, paragraphs, etc., cited by ALADI refer to those in Doc. 41.150.

II. SUMMARY OF COMMENTS FROM ALADI

Page I/5. Item (V). Fourth line. (French version only).

3. The expression “une ressemblance naturelle” should read “une ressemblance structurelle”, in alignment with the English version.

Page I/7. Item (1). Fourth line. (French version only).

4. The expression “du lobe intérieur de l'hypophyse” should read “du lobe antérieur de l'hypophyse”, in alignment with the English version.

Page I/9. Part (B). Item (1).

5. ALADI points out that the first paragraph of item (1) indicates that corticosteroid hormones are secreted in the cortical zone of the adrenal glands, but that the examples given in subparagraphs (c), (d) and (f), i.e., prednisone, prednisolone and cortodoxone, respectively, are not secreted by the adrenal glands. ALADI also implies that the “effects” referred to in the last sentence of the paragraph are produced by mineralocorticoids, not by glucocorticoids. For these reasons, ALADI suggests two changes to Item (1) :

- (a) Change “**Corticosteroid hormones,**” to read “**Corticosteroid hormones, their analogues and derivatives.** Corticosteroid hormones,”.
- (b) In the penultimate line of the paragraph, change “These effects” to “The properties of mineralocorticoids”.

Page I/10. Item (2).

6. ALADI indicates that the text of this item does not clearly reflect the Subheading Explanatory Note to subheading 2937.22, which was adopted at the 19th Session of the Harmonized System Committee (see HSC/19 Report, Doc. 41.100, Annex K/2).

Page I/10. Item (3). Subparagraphs (d) and (e).

7. ALADI points out that the second paragraph of Item (3) describes oestrogens as naturally secreted substances, but that the examples in subparagraphs (d) and (e) are not naturally secreted. For this reason, ALADI suggests that subparagraphs (d) and (e) be replaced by the following :

“As examples of derivatives or analogues, we can mention :

- (a) **Ethinyl estradiol** (INN). [remainder unchanged]
- (b) **Mestranol** (INN). [remainder unchanged]”.

Page I/18. Part (C). Item (1).

8. ALADI indicates that epinephrine is not “(-)-adrenaline” and that racepinephrine is not “(+)-adrenaline”. According to ALADI, the denominations “epinephrine” (US Pharmacopeia (USP)) and “adrenaline” (British Approved Name (BAN)) are synonymous and already imply the compound’s levorotatory form, i.e., (-)-3,4-dihydroxy- α -[(methylamino)methyl]benzyl alcohol. Racepinephrine (USP) is the racemic mixture, expressed as (\pm)-3,4-dihydroxy- α -[(methylamino)methyl]benzyl alcohol. These chemical names appear in the Merck Index (12th Ed.) and the USAN.

Page I/18. Part (C). Item (2).

9. ALADI indicates that the minus sign “(-)” is not needed before the term “noradrenaline” (BAN).

Page I/19. Part (E). Item (1). Subparagraphs (a) to (c).

10. ALADI points out that the examples in subparagraphs (b) and (c) are synthetic analogues of prostaglandins and, therefore, should be listed separately from the example in subparagraph (a). Thus, ALADI suggests that subparagraph (a) become a new second paragraph (unnumbered) under Item (1) and that subparagraphs (b) and (c) be replaced by the following :

“As examples of derivatives or analogue products, we can mention :

- (a) **Alfaprostol** (INN). [remainder unchanged]
- (b) **Tilsuprost** (INN). [remainder unchanged]”.

III. SECRETARIAT COMMENTS

11. The Secretariat agrees with the editorial corrections to the French text proposed by ALADI for in paragraphs 3 and 4 above.

12. Regarding the amendments in paragraphs 5 (a), 7 and 10 above, the Secretariat reminds the Sub-Committee that derivatives and analogues of hormones are discussed in the general introduction on pages I/5 and I/6 (Items IV and V) of the draft Explanatory Note. Nevertheless, the amendments proposed by ALADI in this regard serve to improve the clarity of the Explanatory Note. If the Sub-Committee agrees, in principle, to incorporate these proposed changes, the Secretariat would suggest that the phrase "As examples of derivatives or analogue products we can mention : " be replaced by the expression "Derivatives or analogues :".

13. ALADI's proposal in subparagraph 5 (b) above appears to be appropriate. According to the Kirk-Othmer Encyclopedia of Chemical Technology (4th Ed. Vol. 16, p. 762), "the secretion of rennin stimulates the production of aldosterone [the most important mineralocorticoid] resulting in increased sodium retention and increased volume of cellular fluid.... Hyperkalemia [excess potassium] resulting in cardiac arrest is possible ... combined with inadequate kidney function. Faulty utilization of K^+ and/or Na^+ can lead to Addison's or Cushing's disease".

14. Concerning ALADI's comment in paragraph 6 above, the Secretariat reminds the Sub-Committee that the text adopted by the Harmonized System Committee for the Subheading Explanatory Note to subheading 2937.22 reads as follows :

"Halogenated derivatives of adrenal cortical hormones include derivatives of natural adrenal cortical hormones, or of those reproduced by synthesis, which are obtained by halogenation only or by halogenation in combination with one or more other chemical modifications (e.g., flucinolone acetonide)."

This text was adopted by corrigendum; since no objection was entered pursuant to Article 8(2) of the HS Convention, the text was deemed approved by the Council, effective as of the end of June 1997.

15. The Secretariat would agree that the substance of the Subheading Explanatory Note cited in paragraph 14 above is not exactly the same as that in the proposed new Explanatory Note. However, this is not inappropriate, since the proposed new scope of heading 29.37 would be broader than the present scope; thus it would not be desirable to limit the proposed new Explanatory Note (specifically, page I/10, Item (2)) to halogenated derivatives of hormones which are only natural or reproduced by synthesis. Further, in the Secretariat's view, the fact that such derivatives may be halogenated only or may be further modified (e.g., in the form of esters, acetonides, etc.) seems clear enough in the proposed new text. The Sub-Committee is requested to give its views on this point.

16. The comments by ALADI in paragraphs 8 and 9 above, concerning certain chemical synonyms, are supported by Merck and USAN. Therefore, the Secretariat would suggest that the following changes be made to page I/18, Part (C) :

(a) In Item (1), first line :

(i) change "((-)-adrenaline)" to "(adrenaline or (-)-3,4-dihydroxy- α -[(methylamino)methyl]benzyl alcohol)".

(ii) change "((+)-adrenaline)" to "((\pm)-3,4-dihydroxy- α -[(methylamino)methyl]benzyl alcohol)".

- (b) In Item (2), first line, change “(-)-noradrenaline” to “noradrenaline”.

IV. CONCLUSION

17. The Sub-Committee is requested to examine the draft Nomenclature and Explanatory Note texts in Annex I to Doc. 41.150. In so doing, it is asked to take into account the comments by ALADI in paragraphs 3 to 10 above and the Secretariat Comments in paragraphs 11 to 16 above.
