# Explanatory Notes to the Combined Nomenclature of the European Union

(2019/C 248/03)

Pursuant to Article 9(1)(a) of Council Regulation (EEC) No 2658/87 [1], the Explanatory Notes to the Combined Nomenclature of the European Union [2] are hereby amended as follows:

*On page 169, in the Explanatory Note to heading* ***'3004 Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale'****, the following text is added:*

'This heading includes, inter alia, hormone, co-enzyme and co-factors preparations. These preparations are based on hormones of heading 2937, on enzyme co-factors and mixtures thereof. Such preparations contain a sufficient quantity of active substances to provide therapeutic or prophylactic effect against a specific disease or ailment. The daily dose is recommended on the label, packaging or on the accompanying user directions.

The index of Anatomical Therapeutic Chemicals (WHO ATC-DDD index) (https://www.whocc.no/atc_ddd_index/), developed by the World Health Organisation (WHO), indicates the Defined Daily Dose (DDD) providing therapeutic or prophylactic effect when applied in quantities equal to or exceeding the amounts listed in that index.

The following table shows the DDD for α-lipoic acid and melatonin:

| Name of the active substance | Defined Daily Dose | Unit | Administration route |
|---|---|---|---|
| α-lipoic acid or thioctic acid | 0,6 | g | oral |
| | 0,6 | g | parenteral |
| Melatonin | 2 | mg | oral' |

[1] Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

[2] OJ C 119, 29.3.2019, p. 1.