

## Part 1b

# Annexes to the agreement on the trade in duty-free pharmaceutical substances

**Annex I:** List of International Non-proprietary Names (INNs), provided for pharmaceutical substances by the World Health Organization (WHO), which are free of duty.

**Annex II:** List of prefixes and suffixes which, in combination with the INNs of Annex I, describe the salts, esters or hydrates of INNs; these salts, esters and hydrates are free of duty, on condition that they are classifiable in the same 6-digit HS-heading as the corresponding INN.

**Annex III:** Salts, esters and hydrates which are not classified in the same HS-heading as the corresponding INNs and which are admitted free of duty.

**Annex IV:** List of pharmaceutical intermediates, i.e. compounds used for the manufacture of finished pharmaceutical substances, which are free of duty.

### Abbreviations:

#### INN:

(= International **N**on-proprietary **N**ame). Item appearing on the list of "International Non-proprietary Names for Pharmaceutical Substances" published by the World Health Organization (WHO).

#### CAS RN:

(= **C**hemical **A**bstracts **S**ervice **R**egistration **N**umber). This number, assigned by the "Chemical Abstracts Service" (a division of the American Chemical Society) is used to identify chemical products.

Where a product does not have a CAS registration number, that number is replaced by zeros.

### Explanatory notes

- a) Duty-free customs treatment is granted automatically in respect of the goods mentioned in Annexes I, III and IV, and of the salts, esters and hydrates specified by the combination of an INN of Annex I and the prefixes or suffixes of Annex II classified in the same 6-digit HS subheading as the corresponding INN.
- b) Duty-free customs treatment is likewise granted to salts and esters obtained by the combination of two INNs of Annex I, provided that such products are classified in the same 6-digit HS subheading as one of the corresponding INNs.
- c) Where the INN is a specific isomer, only that isomer and its salts, esters and hydrates specified by the combination of an INN of Annex I and the prefixes or suffixes of Annex II fall within the scope of the Agreement. For example,  
"phenylalanine (INN)" corresponds to "L-phenylalanine" (CAS RN 63-91-2)  
"D-phenylalanine" (CAS RN 673-06-3) and "DL-phenylalanine" (CAS RN 150-30-1) fall outside the scope of the Agreement.
- d) Where the INN does not specify stereochemistry, all stereoisomers and their salts, esters and hydrates specified by the combination of an INN of Annex I and prefixes or suffixes of Annex II shall be taken as falling within the scope of the Agreement.
- e) A double derivative (for example, a derivative which is a salt and ester of Annex II) of an INN of Annex I likewise falls within the scope of the Agreement. For example,  
"Roxatidine acetate, hydrochloride" (classified as "roxatidine") falls within the scope of the Agreement because "roxatidine" is an INN of Annex I and because "acetate" and "hydrochloride" are both suffixes listed in Annex II.
- f) Where the INN is a salt (or an ester), any other salt (or other ester) of the parent acid falls outside the scope of the Agreement. For example,  
"magnesium metamizole" falls outside the scope of the Agreement although "sodium metamizole" is an INN of Annex I and "magnesium" is listed in Annex II.