

**GENERAL AGREEMENT
ON TARIFFS AND TRADE**

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TRADE IN PHARMACEUTICAL PRODUCTS

The following communication concerning trade in pharmaceutical products has been received from the delegations listed below:

RECORD OF DISCUSSION

In the course of the Uruguay Round negotiations, representatives of the following governments discussed the treatment of pharmaceutical products and came to the following conclusions:

Australia
Austria
Canada
Czech Republic
European Communities
Finland
Japan
Norway
Slovak Republic
Sweden
Switzerland
United States

Each government will eliminate customs duties on pharmaceutical products, as defined below, recognizing the objective of tariff elimination should not be frustrated by trade restrictive or trade distorting measures. Other governments are encouraged to do the same.

1. With respect to pharmaceutical products (as defined below), they will eliminate customs duties and all other duties and charges, as defined within the meaning of Article II.1 (b) of the General Agreement on Tariffs and Trade (1994), on **ALL** items in the following categories:

- (i) items classified (or classifiable) in Harmonized System Chapter 30;
- (ii) items classified (or classifiable) in HS headings 2936, 2937, 2939, and 2941, with the exception of dihydrostreptomycin and salts, esters, and hydrates thereof;
- (iii)* pharmaceutical active ingredients as designated in Annex I and that bear an "international non-proprietary name," (INN) from the World Health Organization;

- (iv) salts, esters, and hydrates of pharmaceutical products which are described by the combination of an INN active ingredient contained in Annex I with a prefix or suffix as designated in Annex II to this record, as long as such salt, ester, or hydrate is classified in the same HS 6-digit heading as the INN active ingredient;
- (v) salts, esters, and hydrates of INN active ingredients that are separately contained in Annex III to this record and that are not classified in the same HS 6-digit heading as the INN active ingredient;
- (vi) additional products used for the production and manufacture of finished pharmaceuticals as designated in Annex IV to this record.

In addition, to ensure transparency, each government will incorporate these measures into that government's schedule to the General Agreement on Tariffs and Trade (1994), and, in addition, at either its national tariff line level or the Harmonized System 6-digit level in either its national tariff or any other published versions of the tariff schedule, whichever is ordinarily used by importers and exporters.

Each government will fully implement the duty elimination on the date of entry into force of the World Trade Organization (WTO) agreement, for that government.

In incorporating the results described above, duty elimination can be achieved either by creating sub-headings at the national tariff line level, or attaching an Annex to the national tariff listing all products concerned or by a combination of the above methods, whereby duty-free treatment is provided for at national tariff line level for certain products.

In cases where it is not possible to designate an entire national tariff line for duty-free treatment, **EACH GOVERNMENT** will list the pharmaceutical products covered in an Annex to its national tariff, with a full concordance to the products listed in Annexes I, III, and IV at either the national tariff line level or the Harmonized System 6-digit level. Where some or all of the products are incorporated in such an Annex, each government will include appropriate footnotes (or other means of cross-referencing at the national tariff line level or the Harmonized System 6-digit level) either in the national tariff or in any other published version of the national tariff to indicate that bound duty-free treatment is provided for the products listed in the Annex.

2. In implementing these measures, each government's national customs authorities may require importers to provide one or more of the following types of information to certify that the imported chemical is included in this record:

- (i) Harmonized System 6-digit heading of the chemical;
- (ii) Chemical Description;
- (iii) International Non-proprietary Name (INN);
- (iv) Chemical Abstracts Service (CAS) Registry Number (RN);
- (v) Prefix or suffix of the salt/ester/hydrate (if applicable).

3. Representatives of the governments listed above will meet under the auspices of the Council for Trade in Goods of the WTO -- normally at least once every three years -- to review the product

coverage with a view to including, by consensus, additional pharmaceutical products for tariff elimination. They agreed to encourage autonomous elimination of duties prior to agreement to eliminate duties on a permanent and reciprocal basis, in accordance with their national procedures.

4. The positive list of products covered by these annexes has been deposited with the GATT Secretariat.

*Paracetamol, ibuprofen, dihydrostreptomycin, monosodium glutamate, and levomenthol have been excluded from the coverage of this record of discussion.