30.02 - Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products; cell cultures, whether or not modified. (+).

- Antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes :

3002.12 - - Antisera and other blood fractions

3002.13 - - Immunological products, unmixed, not put up in measured doses or in forms or packings for retail sale

3002.14 - - Immunological products, mixed, not put up in measured doses or in forms or packings for retail sale

3002.15 - - Immunological products, put up in measured doses or in forms or packings for retail sale

- Vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products :

3002.41 - - Vaccines for human medicine

3002.42 - - Vaccines for veterinary medicine

3002.49 - - Other

- Cell cultures, whether or not modified :

3002.51 - - Cell therapy products

3002.59 - - Other

3002.90 - Other

This heading covers :

(A) Human blood (e.g., human blood in sealed ampoules).

(B) Animal blood prepared for therapeutic, prophylactic or diagnostic uses.

Animal blood not prepared for such uses falls in heading 05.11.

(C) Antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes.

These products include :

(1) Antisera and other blood fractions, whether or not modified or obtained by means of biotechnological processes.

Sera are the fluid fractions separated from blood after clotting.

The heading covers, inter alia, the following products derived from blood (including vascular endothelial cells) : “normal” sera, human normal immunoglobulin, blood fractions and truncated variants (parts) thereof with enzymatic properties/activity, plasma, thrombin, fibrinogen, fibrin and other blood coagulation factors, thrombomodulin, blood globulins, serum globulins, and haemoglobin. This group also includes modified thrombomodulins and modified haemoglobins obtained by means of biotechnological processes, e.g., sothrombomodulin alfa (INN) and thrombomodulin alfa (INN), as well as cross-linked haemoglobins such as hemoglobin crosfumaril (INN), hemoglobin glutamer (INN) and hemoglobin raffimer (INN).

The heading further includes blood albumin (e.g., human albumin obtained by fractionating the plasma of whole human blood), prepared for therapeutic or prophylactic uses.

Antisera are obtained from the blood of humans or of animals which are immune or have been immunised against diseases or ailments, whether these are caused by pathogenic bacteria and viruses, toxins or allergic phenomena, etc. Antisera are used against diphtheria, dysentery, gangrene, meningitis, pneumonia, tetanus, staphylococcal or streptococcal infections, snake bite,

vegetable poisoning, allergic diseases, etc. Antisera are also used for diagnostic purposes, including in vitro tests. Specific immunoglobulins are purified preparations of antisera.

The heading does not cover blood albumin not prepared for therapeutic or prophylactic uses (heading 35.02) or globulins (other than blood globulins and serum globulins) (heading 35.04). The heading also excludes medicaments which are not separated from the blood but which in some countries are described as “sera” or “artificial sera”; they include isotonic solutions based on sodium chloride or other chemicals and suspensions of pollen which are used against allergic diseases.

(2) Immunological products, whether or not modified or obtained by means of biotechnological processes.

Products used for diagnostic or therapeutic purposes and for immunological tests are to be regarded as falling within this product group. They can be defined as follows :

(a) Monoclonal antibodies (MAB) - specific immunoglobulins from selected and cloned hybridoma cells cultured in a culture medium or ascites.

(b) Antibody fragments – active parts of an antibody protein obtained by means of e. g., specific enzymatic splitting. This group includes inter alia single-chain (scFv) antibodies.

(c) Antibody conjugates and antibody fragment conjugates – conjugates which contain at least one antibody or an antibody fragment. The simplest types are a combination of the following :

(i) antibody – antibody;

(ii) antibody fragment – antibody fragment;

(iii) antibody – antibody fragment;

(iv) antibody – other substance;

(v) antibody fragment – other substance.

Conjugates of types (iv) and (v) include, for example, enzymes (e.g., alkaline phosphatase, peroxidase or betagalactosidase) or dyes (fluorescin) covalently bound to the protein structure, which are used for straightforward detection reactions.

This heading also covers interleukins, interferons (IFN), chemokines and certain tumor necrosis factors (TNF), growth factors (GF), hematopoietins and colony stimulating factors (CSF).

(D) Vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products.

These products include :

(1) Vaccines.

The most typical vaccines are prophylactic preparations of microbial origin containing either viruses or bacteria suspended in saline solutions, oil (lipovaccines) or other media. These preparations have usually been treated to reduce their toxicity without destroying their immunizing properties.

Other vaccines include recombinant vaccines, peptide vaccines and carbohydrate vaccines. These vaccines generally contain an antigen, a recognised part of an antigen or a gene coding for a recognised part of an antigen (peptides, recombinants or conjugates of protein and others). The “recognised part of an antigen” is the part of an antigen which triggers the immunological response in the organism. Many of these vaccines target a specific virus or bacterium. These vaccines are used for prophylactic or therapeutic purposes.

In addition, the heading covers nucleic acid vaccines. Some examples include DNA plasmid vaccines and messenger RNA (mRNA) vaccines. DNA plasmid vaccines carry protein encoding genes from the pathogen of interest while the mRNA encodes for a specific protein of the pathogen. Both DNA plasmid and mRNA either replicate within the body or signal the body to replicate the desired antigens which results in an immune response.

The heading also covers mixtures consisting of vaccines or toxoids (such as Diphtheria, Tetanus and Pertussis (DPT) vaccine).

The heading excludes vaccines put up in kits for recognized clinical trials (heading 30.06), whether as the vaccine to be tested or as the control substance (sometimes called “placebos”) against which another vaccine is being tested in the trial.

(2) Toxins (poisons), toxoids, crypto-toxins, protoxins (e.g., topsalysin (INN)) and antitoxins. Toxins of this heading are peptides or proteins. These toxins do not include alkaloids (heading 29.39).

(3) Cultures of micro-organisms (excluding yeasts). These include ferments such as lactic ferments used in the preparation of milk derivatives (kephir, yogurt, lactic acid) and acetic ferments for making vinegar; moulds for the manufacture of penicillin and other antibiotics; and cultures of micro-organisms for technical purposes (e.g., for aiding plant growth).

Milk or whey containing small quantities of lactic ferments is classifiable in Chapter 4.

(4) Virus, human, animal and vegetable and anti-virus.

(5) Bacteriophage.

The heading also includes products used for diagnostic purposes of microbial origin, other than those provided for in Note 4 (d) to this Chapter (heading 30.06) and those of heading 38.22. The heading does not cover enzymes (rennet, amylase, etc.) even if of microbial origin (streptokinase, streptodornase, etc.) (heading 35.07). The heading also excludes dead single-cell micro-organisms (other than vaccines) (heading 21.02).

(E) Cell cultures, whether or not modified

Cell cultures are cells which have been grown under controlled conditions, generally outside their natural environment. In this context, cell cultures refer to cell cultures derived from multicellular organisms, especially human or animal cells. Cultures of micro-organisms (excluding yeasts) are classified in subheading 3002.49.

Cell therapy products are cellular material which has been modified by manipulation of the cells and intended for injection, grafting or implanting into a patient.

Cell therapy has applications in a large number of disorders. The most important are diseases of the nervous system and cancer. Other applications include inter alia : cardiac disorders (myocardial infarction and heart failure), diabetes mellitus, diseases of bones and joints, genetic disorders, and wounds of the skin and soft tissues.

Cell therapy products include stem cells and stem cell derived products, such as those from hematopoietic, mesenchymal, embryonic, and umbilical cord blood, cancer vaccines and immunotherapies, such as dendritic cell vaccines, activated T or B lymphocytes, monocytes, and modified or unmodified cancer cells, allogeneic pancreatic islet cells, chondrocytes for cartilage repair, keratinocytes, fibroblasts, and hepatocytes.

The products of this heading remain classified here whether or not in measured doses or put up for retail sale and whether in bulk or in small packings.

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Subheading Explanatory Notes.

Subheading 3002.13

The unmixed immunological products of subheading 3002.13 may contain impurities. The term “impurities” applies exclusively to substances whose presence in the products results solely and directly from the manufacturing process (including purification). These substances may result from any of the factors involved in the process and are principally the following :

(a) Unconverted starting materials.

(b) Impurities present in the starting materials.

(c) Reagents used in the manufacturing process (including purification).

(d) By-products.

Subheading 3002.51

For the purposes of subheading 3002.51, “cell therapy products” are living cells whose biological characteristics have been substantially altered through manipulation (in an ex vivo procedure(s) that selectively removes, enriches, expands, or functionally alters the cells) and are intended for use in the body to achieve a therapeutic or prophylactic result for the recipient. Cellular therapy products can include cells sourced from humans or animals.

Subheading 3002.51 does not include cells which have not been manipulated or which have undergone minimal manipulation which does not alter the relevant biological characteristics of the cells.