WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTE

Reset | Verify

Request for an international nonproprietary name (INN)
Demande de dénomination commune internationale (DCI)
Fee: US$ 12000 (for details see overleaf)

Applicant *Demandeur* ☑ | Authority *Autorité* ☐

Applicant Name

Other
First Name of responsible officer / Prenom du responsable
Family name of responsible officer / Nom du responsable

Address / *adresse:*
Street
Zip Code
City - State
Select country

Organization name | Department name
Telephone No/No. de téléphone | Fax No./No. de fax
Email Address

We hereby request the World Health Organization to establish a free and unrestricted INN for the pharmaceutical substance described below.
L'OMS est priée de bien vouloir établir une DCI à usage libre pour la substance pharmaceutique en question.

For completion by WHO
A remplir par l'OMS

Request No:
Date:
Copies forwarded:

Date:

Payment received:

Date of cheque:

Acknowledged:

SUGGESTED NAMES (in order of preference):
DENOMINATIONS PROPOSEES (par ordre de préférence)

1. First suggested name
2. Second suggested name
3. Third suggested name
4. Fourth suggested name
5. Fifth suggested name
6. Sixth suggested name

☐ Biological

CHEMICAL NAME OR DESCRIPTION (INCLUDING STEREOCHEMICAL INFORMATION):
NOM OU DESCRIPTION CHIMIQUE (Y COMPRIS L'INFORMATION SUR LA STÉRÉOCHIMIE)

Chemical Name

GRAPHIC FORMULA (INCLUDING AMINO ACID OR DNA SEQUENCES IN ELECTRONIC FORMAT) :
FORMULE GRAPHIQUE (Y COMPRIS LES SÉQUENCES D'ACIDES AMINÉS OU D'ADN EN FORMAT ÉLECTRONIQUE):

Add BMP Strucuture Image

MOLECULAR FORMULA:
FORMULE BRUTE

Molecular Formula

CHEMICAL ABSTRACTS SERVICE (CAS) REGISTRY NUMBER:
NUMERO DU REGISTRE CAS

CAS Registry Number

TRADE NAME (known or contemplated):
NOM COMMERCIAL (connu ou envisagé)

Trade Name

ANY OTHER NAME OR CODE:
AUTRE NOM OU CODE

Manufacturer Code

PRINCIPAL THERAPEUTIC USES AND POSOLOGY; PHARMACOLOGICAL ACTION:
UTILITE THÉRAPEUTIQUE ET POSOLOGIE; ACTION PHARMACOLOGIQUE

Pharmacological Action

Additional Files:

Official CAS confirmation file (MANDATORY) | Add
Proof of Payment (MANDATORY) | Add

Additional information may be given overleaf/Toute information complémentaire à fournir au verso.
Conditions and Explanatory Notes overleaf/Conditions et notes explicatives au verso.

1. The process of selecting an INN should be initiated during that period of investigation when the compound is undergoing clinical study in human subjects. **Please indicate the date when clinical trials began**: (Phase 1) 1900-12-31

   La procédure de sélection d'une DCI débute pendant la période d'investigation au cours de laquelle la substance fait l'objet d'études cliniques sur des sujets humains. ***Veuillez indiquer à quelle date ont débuté les essais cliniques***:

2. This proposal is made on the understanding that insofar as is known, none of the suggested names is either registered or pending registration.
   En présentant cette proposition, le signataire déclare qu'à sa connaissance aucune des dénominations suggérées n'a été déposée ou n'est sur le point de l'être.

3. Permission is granted to the WHO Secretariat to include a Chemical Abstract Name and registry number for the compound, its corresponding free acid, base or alcohol. **N.B.: A letter from Chemical Abstracts Service confirming the CAS Registry Number and the CA Index Name needs to be submitted by originators of requests together with the INN application form.**
   L'autorisation est accordée à l'OMS, par la présente, d'inclure le nom et le numéro attribués par le Chemical Abstracts Service à la substance faisant l'objet de la demande ou à l'acide libre, base ou alcool correspondant· ***N.B.: Une lettre du Chemical Abstracts Service confirmant le numéro de registre du CAS et le nom du CAS doit être présentée par le requérant pour chaque demande de DCI en même temps que la soumission de la demande.***

ADDITIONAL COMMENTS:

REMARQUES

Date 2018-12-05 ***Signature*** .....

ADDITIONAL INFORMATION TO BE PROVIDED (Please note that incomplete requests will not be considered)

→Cell therapies:
- Name/Code designation
- Characterization/description
- Cell source
- List and description of manipulations (culture conditions included)
- If genetic manipulation: the detailed description of the vector and insert should be provided.

→Nucleic Acid-based substances: (e.g. oligonucleotides, gene therapies)
- The full nucleotide sequence of the substance in the following format: 50 nucleotides per line, in blocks of 10, with numbering at the end of each line (Word or in the text of an e-mail)
- The nucleotide sequence should be annotated to delineate relevant parts of the sequence (e.g. coding regions, control regions)
- A schematic map of the entire nucleic acid showing inserted/deleted gene(s) and relevant functional parts (not required for short oligonucleotides)

→Pegylated substances:
- The details of pegylation: the end group and the polymer chain with the average number of repeat units (to 2 significant figures)
- The details of the linker (not the reagent used): where the linker is attached to the active moiety, and, ideally, if multiple sites are involved, in what proportion they are modified

→For all proteins (including monoclonal antibodies)
- complete mature amino acid sequence in a format that can be copied for analysis (Word or in the text of an e-mail), using the single-letter code for each amino acid with spaces between groups of ten characters, five groups per line and with a number indicating the position of the last amino acid at the end of each line
- complete precursor nucleotide sequence with spaces between codons and translation (including the stop codon) and with numbers per line, and in a format that can be copied for analysis (Word or in the text of an e-mail)
- if applicable, state and explain the purpose of having amino acid differences with the native sequence (for a monoclonal antibody: constant region amino acid changes by comparison with the closest genomic C gene and allele) (e.g. mutations introduced to alter receptor binding or change the isoelectric point, to prevent C1q binding, enhance FcRn binding, etc.)
- positions of all disulfide bridges (specify if they are determined or predicted)
- post-translational modifications (specify if they are determined or predicted)
- expression system (the cell type, specific strain and the clone name used for the expression)
- if available, the three-dimensional structure in Protein Data Bank format or the Protein Data Bank accession code
- if glycosylated, the glycosylation profile (the types of sugar, the location of glycosylation site(s), etc.); specify if they are determined or predicted; if the cell line in which the protein/peptide is produced is engineered, detailed information if the glycosylation pattern is affected
- if conjugated, the mean numbers of molecules of the conjugated part, and if known, positions where the conjugate is attached

→For monoclonal antibodies:
- IG class and subclass and light chain type.
- antibody format (e.g. complete antibody, Fab, scFv, etc.) For non-standard formats, including bispecifics, be as specific as possible (e.g. scFv fusion to the beginning of the VH domain, IgG format with two different light chains and two different heavy chains with electrostatic mutations...)
- source of the original antibody (or antibodies) that provided the binding affinity [e.g., hybridoma (including species origin such as mouse, rat, etc.), EBV immortalization of human B-cells, transgenic mice with human genes, artificial human phage display library, naive human phage display library, immunized human phage display library], be as specific as possible
- subsequent engineering of V domains. e.g. none, humanization by CDR grafting (specify the CDR definition that was used), humanization by resurfacing framework mutations, etc. This must be provided for each V domain, if different
- a graphic representation/drawing of the arrangement of the domains or linkage of the domains
- CDR-IMGT (sequence and residue range)
- CDR-Kabat (sequence and residue range)
- he closest genomic germline V, J and C genes and allele using IMGT germline names:
  - o For the V-domains, if the domains are nominally human (e.g. produced from human antibodies, EBV immortalization of human B-cells, human phage display libraries, transgenic mice with human V-domain genes, or similar), the closest human gene/allele should be given
  - o If the V-domains have been humanized by CDR-grafting onto a human framework, the closest human gene/allele to the parent human framework should be given
  - o Otherwise the closest germline (human or other species) should be given
- name/structure of the antigen against which the monoclonal antibody is directed and the official gene name that encodes the target. Where an antibody binds across two or more components of a hetero-multimer, gene names for all relevant components should be provided
- laboratory code name(s) and/or code name used in publications and clinical trials
- if the terminal lysine is absent in the heavy chain amino acid sequence, a statement of the fabricant confirming that indeed there is no lysine codon in the nucleotide sequence (if not the lysine should be added in the amino acid sequence mentioning the posttranslational modification clipping)

The processing of a request for an International Nonproprietary Name (INN) is subject to the payment of a fixed fee of **US$ 12000**. (No other currency is accepted and any bank charges/transaction fees/taxes should be covered by the applicant). Payment by bank transfer or by bankers certified cheque must be included with each request and should be made payable by:

Bank transfer: UBS AG
C.P. 2600
CH - 1211 Geneva 2, Switzerland

USD Account: 240 C0 169 920 3
USD Account IBAN: CH31 0024 0240 C01699203
Swift code: UBSWCHZH12A

Please send a copy of the bank transfer by fax to QSM (+41 22 791 4856/5853) , which will enable us to timely validate receipt of your payment. **Any bank fees/taxes should be covered by the applicant.**

Cheque payable to: World Health Organization
Avenue Appia
CH-1211 Geneva 27
Switzerland

To avoid delays in processing, the accompanying cheque should be sent by regular mail or special delivery to the **INN programme, c/o Quality Assurance & Safety: Medicines (HSS/EMP)** at the above address.

PLEASE ENSURE OUR REFERENCE NUMBER IS QUOTED ON PAYMENT:

EDM/INN26FT010000022

No request for an INN will be processed without payment having been received by WHO by the deadline.
The INN form (signed hard copy) must be received by the WHO INN Secretariat at least the week following the deadline.