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

Proteins and Peptides:

- The **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
- The **positions of the disulfide bridges (at least a prediction)** (for a monoclonal antibody: both, intra-chain and inter-chains) and all **post-translational modifications** listed after the amino acid sequence
- If available, the three dimensional structure in Protein Data Bank format or the Protein Data Bank accession code
- ***Additional,*** *for any recombinant DNA protein:*
  1) The **expression system (the cell type and the clone name used for the expression)**

2) The complete **precursor nucleotide sequence** with spaces between codons and **translation (including the stop codon in 5')** and with numbers per line, and **in a format that can be copied for analysis** (Word or in the text of an e-mail)

3) If relevant, **amino acid differences** with the native sequence (for a monoclonal antibody: constant region amino acid changes by comparison with the closer genomic C gene and allele)

- ***Additional,*** *only for a glycoprotein/glycopeptide*:

  The **glycosylation profile** (the types of sugar, the location of glycosylation site(s), etc.); if the cell line in which the protein/peptide is produced is engineered, detailed information **if the glycosylation pattern is affected**.

- ***Additional,*** *only for a conjugated protein*:

  The **ratio**: the mean numbers of molecules of the conjugated part (indicated by a range, thus integer numbers) per molecule of protein

- ***Additional,*** *only for a monoclonal antibody:*

  1) **IG class and subclass**; **IG format**; **species or Taxonomy Related structure** (chimeric, humanized, synthetic construct); **source** (e.g., hybridoma, EBV immortalization, transgenic mice, phage display library) (for each chain, if different); **CDR-IMGT** (e.g., VH [8.7.11], V-KAPPA [12.3.9]) and the closer genomic (human or other species) **V, J and C genes and alleles**.

  2) **Name/structure** of the antigen against which the monoclonal antibody is directed

  3) Laboratory **code name(s)**

  4) 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 post-translational modification clipping)

Please be aware that sequence information will be published either electronically (Mednet) or in both print and electronic format, depending on the size of the structure.

Examples can be found in published INN lists:
http://www.who.int/medicines/publications/druginformation/innlists/en/