

**Nucleic acid-based substances:
Mandatory information for INN selection and publication**

ANNEX TO INN APPLICATION FORM

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Programme on International Nonproprietary Names (INN)

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Mandatory information for INN selection and publication for nucleic-acid based substances including gene therapy substances

Annex to INN application form

(Please note that incomplete requests will not be considered)

Nucleic Acid-based substances (e.g. oligonucleotides, gene therapy substances):

- 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 in a format that can be copied (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 **table of features** providing an overview of the relevant parts of the sequence (*not required for short oligonucleotides*). The table should contain the annotation, a description of the annotation, the position and the colour code used in the sequence. Where a new vector is derived from an existing one, a sequence alignment and table of comparison should be provided.
- A **schematic map** of the entire nucleic acid showing inserted/deleted gene(s) and relevant functional parts (*not required for short oligonucleotides*).

For **cell-based gene therapy** substances, please consult the “Cell-based therapies” information sheet.

For pegylated nucleic acid-based 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 conjugated nucleic acid-based substances:

The mean numbers of molecules of the conjugated part, and if known, positions where the conjugate is attached.

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/>