

***Notes from the fusion protein Working Group***

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***Programme on International Nonproprietary Names (INN)***

***Technologies Standards and Norms (TSN)***

***Regulation of Medicines and other Health Technologies (RHT)***

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## Notes from the fusion protein Working Group

### Substances to include in the *-fusp* nomenclature scheme:

For the purposes of the *-fusp* scheme, a fusion protein is defined as a multifunctional protein derived from a single nucleotide sequence, which may contain two or more genes, or portions of genes, with or without amino acid linker sequences. The genes should originally code for separate proteins, with at least two of them endowed with a pharmacological action (e.g. action and targeting).

In addition to the suffix *-fusp*, a syllable formed from a one consonant and one vowel will be added before the suffix to indicate: (a) consonant – the pharmaceutical action; and (b) vowel – the targeting. The meanings of these infix letters are given in Table 1.

### Further specifications/caveats:

The *-fusp* naming scheme is not designed to give comprehensive information about the substance in the name, but rather to indicate that it is a fusion protein and its type. It is reasoned that the description at the level of publication will provide more extensive information about the precise content and action of the fusion protein.

All components must be endowed with a pharmacological activity. In a bifunctional fusion protein, if one component has a purely stabilizing function (e.g. to increase half-life), no “*-fusp*” will be assigned. For instance, if the component is a stabilizing Fc fragment, the “*ef-*” prefix should be used, not *-fusp*. In a multifunctional fusion protein that has more than one pharmacological action, but also contains a stabilizing Fc fragment, both *ef-* and *-fusp* should be used.

If both components of the fusion protein have a targeting action, and one of them is derived from a monoclonal antibody (mAb) or from a mAb fragment, when assigning the identifying infix letters, the “*-a-*” for *antibody* takes priority. For instance, a fusion of a receptor with an antibody will be *-ra-* (where *r* stands for *receptor* and *a* for *antibody*) not *-be-* (where *b* stands for *binding protein* and *e* for *receptor*).

The infix letters will not distinguish between mAb or mAb fragments, in all these cases the letter “*a*” will be selected.

Multiple mAb or mAb fragments will be named using the *-mab* nomenclature scheme, not the *-fusp* scheme.

If more than two components are present, the two infix letters will still be used to represent the different action/targeting by class: e.g. if a fusion protein is composed by two mAbs and one receptor, the INN will end in *-rafusp*.



Table 1 - Infix letters and their meaning

Action		Targeting	
Letter	Meaning	Letter	Meaning
b	Binding protein	a	Antibody
c	Encapsulation protein	e	Receptor
d		i	Antigen
f	Hormone	o	Other
g	Antigen	u	Untargeted
k	Cytokine		
l			
m	Membrane protein		
n	Enzyme		
p	Apoptosis		
r	Receptor		
s			
t	T-cell receptor		
v	Multiple actions/proteins		
x	Toxin		
z			

*v* → will be used when a multifunctional fusion protein has multiple and not related actions;

*o* → will be used when some other targeting mechanism (i.e. not antibody, receptor or antigen) is used in a bifunctional fusion protein or in a multifunctional fusion protein with multiple unrelated targeting;

*u* → will be used when a fusion protein has multiple actions and no targeting;

*h, j, q, w, y* → these consonants were excluded to facilitate the translation.