BOND VAN DE GENERIEKE
GENEESMIDDELENINDUSTRIE
NEDERLAND

May 31th 2012
Response of the Bogin, to the Public consultation: DRAFT TEMPLATE FOR THE WRITTEN CONFIRMATION FOR ACTIVE SUBSTANCES IMPORTED INTO THE EUROPEAN UNION FOR MEDICINAL PRODUCTS FOR HUMAN USE,
SANCO/D6/(2012)ddg1.d6.517666

The Bogin welcomes the use of the written confirmation.

At this point, we have two comments:

1- What is the legal implication of the statement 'at least equivalent to those of the EU' for authorities in 3rd countries? (e.g. maybe they do not have any reference to EU laws)

2- How will non-EU bulk API imported into the EU be handled (distinguished) by customs officers?

a) If it is intended for veterinary use? (vet medicines are outside the scope of FMD yet the same API might be used in both human and veterinary medicines)

b) If it is an atypical active? (for which the EU provides some flexibility as to GMP compliance)

c) If it is intended for research and laboratory purpose? (EU laws foresee that material should be GMP 'approvable' and not certified)

d) If the imported substance is an API yet that in this specific case it is an intermediate further processed into another API?

e) Other?

Could a specific label be affixed on drums or parcels to help sort this issue? Should these be part of a ticking exercise at the top of the written declaration (i.e. if not ticked, then written confirmation applies)?

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