Health Care Inspectorate
Ministry of Health, Welfare and Sport

European Commission
DG Health and Food Safety
Unit D6 "Medicinal products – Quality, Safety and Efficacy"
B-1049 Brussels (Belgium)
SANTE-D6-DA-GMP-IMP@ec.europa.eu

T +31 88 120 50 00
F +31 88 120 50 01
www.igz.nl

Our reference comments IGZ DA on GMP

Your reference DA on GMP for IMP

Date 1 november 2015
Subject **Public consultations on Good Manufacturing Practice for Investigational Medicinal Products for human use and inspection procedures (DA on GMP for IMP)**

Dear Sir/ Madam

Member states were asked to provide comments on the public consultation of the Commission Delegated Act on principles and guidelines of good manufacturing practice for investigational medicinal products and on inspection procedures. Below an overview of the comments from the Dutch Health Care Inspectorate is provided:

Section	**Comment**
Section 1	
Lines 11-33	Reword these lines in the final version of this document
Lines 42-48	Reword these lines in the final version of this document
Section 2	
Line 53	Typo"human use"instead of human sue"
Line 91	Typo "initial"instead of "internal"
Line 93	Remove word "in " sentence should be including particular requirements
Question 1a	Yes, we agree that the introduction of the PSF a basic document required for release of IMP is usefull in the delegated act.
Question 1b	For the Netherlands PSFs are present for the manufacture of IMPs
Question 2	Our preferred option is at least 25 years after the end of the clinical trial to be in line with the retention period of the clinical trial master file
Line 157,158	The meaning of this sentence is unclear, please rephrase
Question 3	No, not feasible often when comparators are imported no CoA is provided.
Line 183	Finished pack should be "finished pack specification"
Question 4a	Already described in GMP guidelines
Question 4b	Already described in GMP guidelines
Question 5a-5b	No information can be provided
Line 227,231	Inconsistent use of terms "shall"and "must"
Line 233	Five years to be changed to 25 years following the timelines for trial master file
Line 270,271	And or preventive actions instead of or preventive action(s)
Line 277-284	Remove explanatory text
Section 3	
Line 308	Replace "lay" with "any"