Health Care Inspectorate
Ministry of Health, Welfare and Sport

European Commission
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Subject **Public consultations on Good Manufacturing Practice for Investigational Medicinal Products for human use and inspection procedures (GL on GMP for IMP)**

Our reference final comments IGZ GL on GMP for IMP 1nov15

Your reference GL on GMP for IMP

Dear Sir/ Madam

Member states were asked to provide comments on the public consultation document on detailed Commission guidelines on good manufacturing practice for investigational medicinal productss. Below an overview of the comments from the Dutch Health Care Inspectorate is provided:

Section	**Comment**
In general	Only references present to GMP Part 1, references to Part II and GMP annexes is missing
Section 2	
Line 125	Remove "also"
Line 151	Remove "anticipated"
Line 167-178	Remove refer to chapter 5 GMP
Line 183	Replace immediate"with "primary"
Line 229	Replace "of certification"with "for certification"
Line 245	Replace "storage, distribution conditions and storage conditions with "storage and distribution conditions"
Line 270	Add "at least "25 years
Line 319	Remove "so that blinding is maintained" or line 3198-319> No added value since this is an obvious fact to be able to maintain blinding
Line 325,326	Remove lines,no added value.Already stated that procedures are needed to minimize product mix up
Section 2.7.5	Role of QA/QP unclear in relabeling activities
Line 368	Typo "place" should be "placed"
Section 2.13	Definition transportation: "clarify unjustified periods of time "