Ministry of Health, Welfare and Sport

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Subject	Enclosure(s)	Your reference
Public consultation on the draft detailed guideline on GCP specific to ATMPs'	1	

To whom this may concern,

The Netherlands has the pleasure to send you herewith the response to the Public consultation on the draft detailed guideline on good clinical practice specific to advanced therapy medicinal products.

Yours sincerely,

The director of the Department of Pharmaceutical Affairs
and Medical Technology,

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PUBLIC CONSULTATION PAPER
"DRAFT DETAILED GUIDELINE ON GOOD CLINICAL PRACTICE SPECIFIC TO ADVANCED THERAPY MEDICINAL PRODUCTS"
Version: 2 July 2008

The proposed guideline is endorsed by The Netherlands. The requirements are considered rational and also in line with requirements generally accepted in bloodtransfusion and for plasmaproducts. This is relevant since Advanced Therapy Medicinal Products (ATMPs) comprise a wide variety of medicinal products with hazards comparable to those with blood transfusion and plasma products. It is therefore important that the principles and standards applied in those cases with respect to donor selection, donor testing and traceability are also implemented in guidelines for ATMPs. Interested parties in Advanced Therapy Investigational Medicinal Products (ATIMPs), like sponsors, investigators and Ethics Committees, will perhaps not always be familiar with these principles and standards yet and this Guideline will lead to a more general awareness of these principles.

It can be expected that some aspects of the guideline, for instance the requirements for long term follow-up and the extended period for record-keeping, will be considered very demanding, especially by small and medium sized enterprises. Therefore, the proposed approach for long term follow-up based on an ongoing risk analysis is endorsed since it enables a case-by-case approach.

Finally, an addition is proposed to the examples of "Unexpected reactions" (2.4.1. Notification of Adverse Events and Reactions; page 8): "changing of the biological properties of a viral vector, e.g. generation of replication competent viruses".
