



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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GMP/GDP IWG

Concept paper on storage conditions during transport

Agreed by GMP/GDP Inspectors Working Group	March 2010
Agreed by QWP	May 2010
BWP consulted	September 2010
Agreement by GMP/GDP IWG for release for consultation	September 2010
End of consultation (deadline for comments)	28 February 2011

The proposal will create new GDP and GMP guidance and may lead to the need to revise guideline: CPMP/QWP/609/96/Rev2 – ‘Guideline on Declaration of Storage Conditions: A: In the Product Information of Medicinal Products B: For Active Substances’ and other relevant guidance including veterinary guidance

Comments should be provided using this [template](#). The completed comments form should be sent to ADM-GMDP@ema.europa.eu



1. Introduction

The globalisation of the manufacture of human and veterinary medicinal products has brought both benefits and a wide range of challenges. This paper is concerned with challenges related to the maintenance of appropriate transit conditions during transport as products move through all stages of the manufacturing and wholesale distribution system from active substance through the wholesale distribution system to ensure that patients and animals receive safe and efficacious medicinal products. The current guidance (CPMP/QWP/609/96/Rev2) was written in 1996 and revised in 2003, during this time significant changes continued to occur in the globalisation of manufacture with a consequent increase in the complexity and vulnerability in the supply chain.

2. Problem statement

There is a lack of clear guidance on the regulatory expectations for ensuring that medicinal products and APIs are not damaged during transportation. In order that products are fit for their intended purpose, including the ability to tolerate the range of expected storage conditions during use by patients or use in animals, simple and risk-based guidance is required for the transport. Such guidance needs to cover cold chain and non-cold chain products and all of the different stages of manufacture, importation and distribution.

3. Discussion

From a product's perspective, transport is a mobile form of storage but where there are weaker controls than storage in fixed sites – therefore similar levels of controls should exist. Compliance at all stages of manufacture and distribution becomes more important as the number of transport stages increase, including transport (i.e. import) into the EU. Several examples have been seen where sea-freight significantly exceeds 30 days. Any increases in the length of time and/or the climatic challenge at each stage will also impact on compliance. It is also increasingly difficult to be aware of and to assess the cumulative effects of adverse incidents at different stages.

Many sites of manufacture are now located in tropical zones and/or where transport infrastructure may be difficult. Therefore the challenges arising from transport between such sites and from these sites to the EU may take finished products, or their earlier stages of manufacture, outside of the conditions defined in the EU Marketing Authorisation for storage of the product. Also, the risk of freezing during transport and the effects on the products should be considered.

It is important to understand the susceptibility of different products at the different stages and whilst the principles of quality risk management would be applied on a product by product basis at each stage of manufacture and transport would be expected, the reality is that different products and different product stages are frequently co-shipped. It is therefore evident that a simple set of readily understood general rules should apply to transit conditions to reduce this complexity and risk of error. Although widely acknowledged, there is no explicit requirement for the need to conduct transport studies under worst case conditions and no requirement for routine monitoring during transport.

4. Recommendation

Whilst aligning, where possible, requirements with other key guidance documents (e.g. WHO, USP), the following are recommended:

1. Conduct the procedure by a linked parallel process under QWP, BWP and GMP/GDP IWG.
2. Consider the need to revise the QWP guidance.
3. Align with the text in the GDP guidance (under revision) and GMP Chapters 5, 6 and 7, Annex 15 (all currently under revision), Annex 16 and create new FAQs.

5. Proposed timetable

Approval of Concept Paper by GMP/GDP IWG in March, by QWP in May 2010 and by BWP in September 2010.

Release the Concept Paper for a 3 month consultation in October 2010, deadline for comments by January 2011. Produce initial GMP Q&As.

Review comments and revise relevant texts for initial discussion at QWP, BWP and GMP/GDP IWG by February 2010.

GMP/GDP IWG - Release draft text in June 2011 for 3 month consultation, deadline for comments September 2011.

- Re-discussion and agreement at GMP/GDP IWG November 2011. Finalise Q&As.

QWP/BWP - The need for new or revised complementary guidance falling under the responsibility of QWP or BWP will be subject to specific Concept Papers with their own timelines as needed.

6. Resource requirements for preparation

There will be 1 rapporteur for each of GMP/GDP IWG and QWP, documents will be submitted to 2 working party meetings, 2 drafting group meetings are anticipated.

7. Impact assessment

It is anticipated that public and animal health will benefit by the maintenance of the assurance of the quality of products with continued globalisation in manufacture. For industry and regulatory authorities there will be greater clarity in the transport condition requirements. There will be no net increase in resource requirements for regulatory authorities. It is likely that there will be some alteration to some types of transport currently used and some additional costs for monitoring shipments.

8. Interested parties

EMA – GMP/GDP IWG, QWP, BWP.

Industry – manufacturers and brokers of API, bulk and finished products, Transport service providers and logistics providers

9. References to literature, guidelines

1. CPMP/QWP/609/96/Rev2 – ‘Guideline on Declaration of Storage Conditions: A: In the Product Information of Medicinal Products B: For Active Substances
2. World Health Organization – ‘Proposal For Revision of WHO Good Distribution Practices for Pharmaceutical Products’.
3. USP 1079 “Good Storage and Shipping Practices”.