



**GMP/GDP INSPECTORS WORKING GROUP
(GMP/GDP IWG)**

**CONCEPT PAPER ON REVISION OF THE EU GUIDELINE ON GOOD DISTRIBUTION
PRACTICE (GDP)**

AGREED BY GMP/GDP IWG	February 2009
DEADLINE FOR COMMENTS	31 May 2009

The proposed guideline will replace the Guideline on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03).

While strictly not necessary, but in the interests of transparency, this Concept Paper also describes the other work related to wholesale distribution that will arise from the legal proposals aimed at combating counterfeit medicinal products once these are finally adopted.

Comments should be provided to GMP@emea.europa.eu and entr-gmp@ec.europa.eu

KEYWORDS	<i>GDP, Wholesale distribution, Supply of medicinal products</i>
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1. INTRODUCTION

This concept paper addresses the need to update the Guideline on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03). This Guideline was originally adopted in 1994.

Current distribution activities and operations have changed since this time and become more complex. The scope of the Guidelines are somewhat limited and do not reflect the emerging changes to the distribution industry. In addition the Guidelines do not provide industry and regulatory bodies with clear guidance/policy on a number of issues.

In December 2008 the European Commission adopted a legal proposal to combat counterfeit medicinal products which would amend Directive 2001/83/EC. In view of the proposed amendments to the Directive, it is reasonable to review the GDP Guidelines to bring them up to date with current practices within the wholesale distribution sector and to consider any new requirements established by the new proposed EU legislation related to wholesale distribution.

2. PROBLEM STATEMENT

As a result of changes to business operations in the wholesale distribution environment, the scope and content of the EU Guideline on Good Distribution Practice is no longer adequate to meet the needs of either the industry or inspectors.

3. DISCUSSION

Today's distribution network for medicinal products has become increasingly complex and involves many players which are not necessarily wholesale distributors as defined in Directive 2001/83/EC. This has led to inconsistencies throughout Member States with regards to management and licensing of activities such as virtual wholesaling and trading/brokering of medicinal products, total or partial outsourcing of the distribution and transportation of medicinal products.

There is a need for harmonisation of GDP requirements with respect to a number of areas such as supplier qualification. In addition, new legislative requirements arising from the recent Commission proposal on "counterfeit" medicinal products (e.g. identification of GDP requirements and obligations for traders and minimum requirements to be met for accreditation for third party GDP auditors) need to be developed and incorporated into the GDP Guideline.

At a Community level there is also a lack of harmonised procedures and formats relating to GDP (e.g. procedure for inspection of wholesale distributors, qualifications and training of GDP inspectors, format of an inspection report and of a wholesaler's authorisation etc.)

4. RECOMMENDATION

The Working Group recommends to revise the Guideline on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03) and to develop other documents required to implement the new proposals in the Community legislation related to wholesale distribution.

Two work streams are envisaged.

One stream will focus on review of the GDP Guideline and its restructure including a review of World Health Organisation (WHO) documentation; Working Group of Enforcement Officers (WGEO) recommendations; European Association of Pharmaceutical Full-Line Wholesalers (GIRP) position paper; European Association of Euro-Pharmaceutical Companies (EAEPC) guidelines and the Pharmaceutical Inspectors Cooperation Scheme (PIC/S) 2008 seminar output. Existing standards of

relevance will be identified and certain topics such as transportation and computerised systems will be considered.

The second work stream will develop wholesale authorisation formats, certificate templates and procedures (similar to the existing Compilation of Community Procedures) relevant to GDP (inspection, report writing, training of inspectors).

Further work will be initiated at a later stage pending further legal proposals. These include: obligations and requirements for wholesalers distributing to third countries; inspection procedures for traders of medicinal products and accreditation requirements for third party auditors.

The guidelines are intended to apply to medicinal products already authorised and on the market.

5. PROPOSED TIMETABLE

It is anticipated that draft documents from the initial work streams will be presented to the GMDP IWG in September 2009. It is expected that the guidelines could be available 1 year after publication of this concept paper. The draft GDP guideline would then be released for 6 months external consultation before its finalisation within another six months after the expiration of the public consultation period.

The other documents to be developed will follow the appropriate adoption processes, which may, or may not, involve public consultation depending on the nature of the documents themselves.

6. RESOURCE REQUIREMENTS FOR PREPARATION

The review and update to the Guideline on Good Distribution Practice of Medicinal Products for Human Use and the drafting of templates and procedures relevant to GDP will be carried out by the GDP Drafting Group. This Group consists of ten experts from Member States and a representative from the Directorate-General of Enterprise and Industry. It is chaired by the EMEA.

While the entire Drafting Group will be involved in both work streams, two rapporteurs were appointed to instigate the different work plans.

Work already done by the PIC/S GDP Working Group will be taken into account. The group will work mainly by written correspondence but if necessary meetings will be arranged.

7. IMPACT ASSESSMENT

The new guidelines will clarify requirements for industry and regulators and are not expected to add to the changes resulting from the legislative proposals on combating counterfeits which have already been assessed as part of the process for adopting those proposals.

8. INTERESTED PARTIES

Member States' National Competent Authorities, EFPIA, EGA, AESGP, EAEPIC, GIRP, GMDP IWG, WHO, WGEO, PIC/S.

9. REFERENCES TO LITERATURE, GUIDELINES ETC

1. Guideline on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03)
2. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.22.2001, p.67)
3. Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry in to the legal supply chain of medicinal products which are falsified in relation to their identity, history or source. (COM (2008) 668).