

مجلس الصحة
لدول مجلس التعاون
Gulf Health Council



Guidance for Presenting the Labeling Information, SPC and PIL

Version 3.3

Date of issue	May 2011
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Version 3.3

Gulf Health Council

Registration and Licensing department

Central registration

What is New in version no. 3.3 ?

The following table shows the update to the previous version:

Section	Description of change
Section 4.2	<u>Addition</u> -For hazardous drugs, statements to indicate that it is a hazardous drug and to follow applicable special handling and disposal procedures in section 6.6
4.8.3 Post-marketing Experience	<u>Addition</u> - Decisions about whether to include an adverse event from spontaneous reports in the SPC are typically based on one or more of the following factors: (1) seriousness of the event, (2) number of
Section 6.6	<u>Addition</u> -For hazardous drugs, statements to indicate that it is a hazardous drug and special instructions for handling, manipulation (where applicable), and disposal procedures
6.Appendixes:	<u>Update</u> - Appendix 1 “Storage conditions are required to be translated into Arabic language for medicines used solely in hospitals”

1. INTRODUCTION

1.1. Objective

It is intended to guide applicants on the information required by the **Gulf Health Council** for:

- Labeling information
- Summary of Product Characteristics (SPC); and
- Patient Information Leaflet (PIL);

1.2. Scope

It is applicable to medicinal products intended for human use.

1.3. Related guidelines

This guidance should be read in conjunction with:

- **Drug Barcoding Specifications**
- **GCC Data Requirements for Human Drugs Submission**

2. GENERAL REQUIREMENTS

The SPC is the basis of information for health professionals on how to use the medicinal product safely and effectively. The Patient Information Leaflet (PIL) shall be drawn up in accordance with the SPC.

Applicants should maintain the integrity of each section of the document by only including information in each section, which is relevant to the section heading. However, some issues may

