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Criteria, methodology and procedures for creating an Ecodification concerning substances used in Pharmaceutical compounding

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CEN WORKSHOP AGREEMENT

CWA 15914-1

January 2009

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English version

Criteria, methodology and procedures for creating an E-codification concerning substances used in Pharmaceutical compounding

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The present CWA sets forth criteria and methodologies, addressed to scientific editors, to be followed for the implementation of a databank concerning substances used by compounding pharmacists for preparing “Magistral Formula” and “Formula Officinalis”, as endorsed by the CEN/ISSS Workshop on Pharmaceutical Compounding E-codification Methodology (WS/PCEC), which was established on Oct 15th 2007

A list of the individuals and organizations which supported the technical consensus represented by this CEN Workshop Agreement is available to purchasers from the CEN/ISSS. The present CWA (CEN Workshop Agreement) has received the support of representatives of a variety of backgrounds: pharmacists, physicians, pharmacologists, representatives of European institutions in the pharmaceutical field, health informatics experts.

These specifications represent a first step into technical specifications concerning pharmaceutical compounding. The present CWA is a reference document for the competent working groups within the Joint Initiative ISO/CEN/HL7, for E-health and for regulatory agencies.

Within ISO TC 215 (Health Informatics) WG 6 work is ongoing on Identification of Medicinal Products - Product Information for Drug Dictionaries (MPID). ISO(-EN) standards is planned for the year 2010 - This CWA might need to be revised after the publication of the ISO(-EN) standard. The ISO/EN standard does not specifically address compounding pharmacy, the field of 'magistral formula' and “formula officinalis” as defined by Council Directive 83/2001, which is instead the focus of this CWA.

This CEN Workshop Agreement was endorsed electronically; the endorsement process ended on 20 September 2008. The Workshop was chaired by Alessandra Pastorino, consultant.

The following organizations have expressed support to the publication of the CWA

International Society of Pharmaceutical Compounding
Italian Society for Pharmacology
Pharmacy On Line Trade Sr.
SACCHI – Studio di Consulenza
Società Italiana Farmacisti Preparatori (SIFAP)

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Comments or suggestions from the users of the CEN Workshop Agreement are welcome and should be addressed to the CEN Management Centre.

1. Scope

The domain addressed by this CWA is the E-codification of substances used by compounding pharmacists in pharmaceutical compounding.

The present document specifies the technical requirements for creating the record structure and E-codification of the various substances supplied by commercial suppliers and used by the pharmacist in the pharmacy for preparing “Magistral Formula” and “Formula Officinalis” as defined by the European Directive 2001/83, Article 3, Paragraph 1) and 2).
The CWA includes a record of the supplier of substances.

“Magistral Formula” and “Formula Officinalis” are not themselves part of the present CWA

The users of the CWA are the editors of a databank. In this sense the CWA is not addressed to the final users of the databank but to the subjects which realize and implement the databank (the editors)

The purpose of the CWA is to define certain criteria the editors have to comply with, in realizing a databank in order to:
(i) allow an unique identification of the single substance in order to avoid any possible misunderstanding;
(ii) provides pharmacists and physicians with the basic information on each single substance and its administration (see paragraph 6.2, 6.4, 6.6, 6.8);
(iii) provides pharmacists and physicians with indication on the availability of the substance on the European and international market;

The CWA aims at setting forth the basis for establishing a unique language for compounding pharmacists, physicians and providers to the pharmacy of substances.

The CWA proposes to fill a gap, in terms of harmonization, that characterizes the pharmaceutical compounding. This shall allow:
(i) an increase in the sharing of scientific information concerning substances used in pharmaceutical compounding and basic pharmacological and administration information among physicians and pharmacists;
(ii) a development of the pharmacy compounding;
(iii) An increased in ADR reporting concerning substances used in pharmaceutical compounding by physicians, pharmacists and consumers.

Any authorized medicinal product is out of the scope of the present CWA.

The groups of substances which fall under the scope of the present document are the followings:

- **Synthetic substances**
- **Semi-synthetic substances**
- **Crude drug substances**

The above groups are listed with respect to origin.
See definitions on “substances” and “crude drug substances”.