

**CEN/ISSS Workshop “Pharmaceutical Compounding
E-Codification Methodology” (WS/PCEC)**

Draft Business Plan v.0.3

1 Title of proposed Workshop

Workshop on “Pharmaceutical Compounding E-Codification Methodology”
(WS/PCEC)

2 Status of this Business Plan

For comment

3 Background

Drug errors are common. The National Institute of Medicine reports that every year, more than 1.5 million patients in medical settings are injured or die as a result of mistakes with medication.

Pharmacy Compounding is the long-standing pharmacy practice that allows doctors to treat their patients’ individual needs without being restricted to off-the-shelf medicines or devices. Prescription compounding is a rapidly growing component of many physicians’ practices.

Pharmacists and physicians require precise and current data regarding all substances used in the formulation of compound preparations. Over the last decade, compounding resurgence has largely benefited from advances in technology, quality control and research methodology.

Current pharmacopoeias, formularies and monographs do not reflect all available values to the compounding pharmacist. There is no centralized information source which includes data for both chemical substances and herbal substances.

The use of Information and Communication Technologies (ICT) in the healthcare sector, including pharmaceuticals and medical devices increased in the last years. ICT is a tool to reduce medical errors in prescriptions.

The European Commission' Action Plan in eHealth¹ proposes a number of actions to be carried out at European level to enhance use of ICT in the healthcare sector.

The Pharmaceutical Industry has recently launched a new initiative, the Innovative Medicine Initiative (IMI)² to address biomedical research and development in Europe.

4 Origin of the workshop proposal and targeted participants

The Workshop is proposed by Pharmacy on line SrL³, an Italian publishing company specializing in E-databanks in the pharmaceutical sector.

Participation in the Workshop is open to any interested party interested in the subject. It is therefore expected that the Workshop will interest a large number of different market players, and it is hoped to secure representation from the following organizations:

- universities/research centres in Europe specialized in compounding;
- compounding pharmacists associations in Europe and internationally;
- compounding producers and manufacturers;
- experts in coding and databases.

5 Objectives of the Workshop

The domain addressed by this Workshop proposal is the E-codification of chemical and herbal substances used by compounding pharmacists.

The Workshop aims at providing criteria, methodology and procedures for creating a codified classification concerning both chemical and herbal substances used by compound pharmacists and physicians. The purpose is to establish a unique language for compounding pharmacist and doctors in accordance with directives and assurance of data consistency which facilitates the exchange of information.

The Workshop deliverable will be a CEN Workshop Agreement (CWA) describing criteria, procedures and methodology and for the implementation of an electronic databank of all the substances available for compounding.

¹ URL: http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf

² <http://www.imi-europe.org/>

³ <http://www.polweb.it>

The databank should become a reference for compounding pharmacists, doctors, producers, universities, and chemical industries. The information system architecture will allow all players to operate directly on the same databanks site through intuitional database.

The pharmaceutical substances taken into consideration are:

- Synthetic and semi-synthetic pharmaceutical substances
 - Drugs
 - Vitamins
 - Amino acids
 - Minerals
 - Hormones
- Herbal and animal substances
 - Herbal medicines
 - Natural pharmaceutical substances
- Excipients
- Cosmetic substances
 - Functional substances
 - Excipients

5 Work Programme

A dedicated CEN/ISSS Workshop will be set up to deal with this subject. The Workshop is proposed to last six months.

The following timetable is proposed:

Activity	Date	Who
Workshop kick-off meeting (appointment Chair and Secretariat, setting up of drafting working group)	15 October 2007	CEN
First draft CWA	Mid January 2008	Editors
WS comments on first draft	Mid Feb 2008	WS Members
Final draft CWA**	Mid March. 2008	Editors
WS approval of final draft CWA (2nd Workshop plenary meeting)	End March 2008	WS Members
Publication in CEN	May/June 2008	CEN

** In case the Workshop decides to have public comments on the draft CWA, this draft will be put on the CEN web site for comments for a period of 60 days. The final draft, taking due account of relevant comments, will be available at end of May. The final plenary meeting will then take place in June 2008.

The decision whether to opt for public comments on the draft CWA will be taken at the Workshop kick-off meeting.

6 CEN Workshop Structure and Resource Requirements

6.1 Secretariat

The Workshop Secretariat will be provided by a CEN member.

The role of the Secretariat is to co-ordinate the administrative duties involved in the organisation of the Workshop including:

- Maintaining the meeting schedules and arranging the physical meeting locations
- Distributing the agenda and other documents for the Plenary Sessions (2)
- Preparing draft minutes of the Plenary Sessions
- Maintenance of Web Site for posting work materials
- Final production (formatting according to CEN Style Guide) of the final CWA.

UNINFO, Associated Body of UNI the Italian standards body, is proposed to support the Workshop Secretariat.

6.2 Workshop Chair

The responsibility of the Workshop Chair is the following:

- To preside at Workshop plenary meetings.
- To ensure that the Workshop delivers in line with its Business Plan.
- To manage the consensus building process.
- To interface with the CEN/CMC regarding strategic directions, problems arising, external relationships, etc.

The Workshop Chair will work on a voluntary basis. A Chair will be nominated in advance of the Kick-Off meeting by the Workshop proposers.

The Workshop Chair and Secretariat shall formally be appointed at the Kick-Off meeting.

General characteristics of CEN Workshops to be followed are documented at <http://www.cen.eu/cenorm/businessdomains/technicalcommitteesworkshops/workshops/index.asp>

6.3 Resources

Sponsorship will be provided by Pharmacy On Line Srl to support the Workshop Secretariat operations.

The Editor(s) will work on a voluntary basis.

6 External Liaisons

The Workshop will liaise with:

- CEN TC 251 (Health Informatics)

The Workshop will take due account of relevant european, national or regional projects.

8 Contact Points

Workshop Chair: to be appointed at the Workshop kick-off meeting

Workshop Secretariat:
Massimo Actis Dato
UNINFO (subject to confirmation at kick-off meeting)
c.so Galileo Ferraris, 93
10128 TORINO
Tel. + 39 011 501027
Fax + 39 011 501837
e-mail: uninfo@uninfo.polito.it

CEN CMC contact person:
Barbara Gatti
Programme Manager Workshops and Focus Groups
CEN Pre Standards
Rue de Stassart, 36
B-1050 Brussels
Tel +32 2 5500834
Fax +32 2 5500966
Email : Barbara.gatti@cen.eu