BT N 9207

Draft BT C61/2013

TECHNICAL BOARD

CEN/BT by correspondence

For vote	**Issue date:**	2013-05-08
Simultaneous circulation to CENELEC/BT ☐	**Deadline:**	2013-08-06

SUBJECT

Creation of a new CEN/TC "Project Committee- Services of Medical Doctors with additional qualification in Homeopathy"

BACKGROUND

On 6 May 2013, ASI submitted a Form A (see Annex 1) to CEN proposing the creation of a new CEN Project Committee in order to develop a European Standard on the services of medical doctors with an additional qualification in homeopathy.

Homeopathic medicine is a system of medicine requiring a distinct qualification in addition to the regular medical qualification. Medical doctors with an additional qualification in homeopathy provide their services all over Europe. However, there are no consistent standards of education, training and practice across Europe. There are also differences among medical doctors with additional qualifications in homeopathy within some member states.

The European Committee for Homeopathy (ECH) has identified the need to develop common standards and has already worked on developing voluntary standards. This work will serve as basis for European standardization.

The Form A envisages the development of a European Standard establishing minimum requirements in relation to the service provision, competences and training requirements of medical doctors with an additional qualification in homeopathy. Services provided by persons not being medical doctors and the preparation of homeopathic medicines are excluded from the scope. A first outline of the possible structure of the European Standards can be found in Annex 2.

It is envisaged that the proposed European standard would be a step towards increasing patient safety, providing safe and secure homeopathic medical services in Europe and creating a level playing field for medical doctors with an additional qualification in homeopathy.

By Resolution BT C75/2009, BT decided that both of the following criteria are to be met for acceptance of such a proposal for new work (in a new area):

- A two-thirds majority of the votes cast (abstentions not counted) are in favour of the proposal (or more);
- At least 5 members express commitment to participate.

As a consequence, BT Members are requested to state explicitly, by means of the commenting field provided in the BT-balloting tool, whether or not they are committed to participate in the work.

PROPOSAL(S)

BT,

- having considered the proposal for new work (Form A) submitted by ASI as included in BT N 9207;
- considering that the following members have expressed commitment to participate:
  - *<members>;*
- decides:
  - to create a new Project Committee, CEN/TC xxx 'Project Committee – Services of Medical Doctors with additional qualification in Homeopathy' in order to work on a European Standards on the services, competences and training of medical doctors with an additional qualification in homeopathy according to the specifications provided in BT N 9207;
  - to allocate the Secretariat of CEN/TC xxx to ASI;
  - to ask the new CEN/TC xxx to submit its programme of work for BT approval by February 2014.

This decision is applicable as from: <result release date>

2013-05-07– MO

FORM A

Proposal for a new project

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Title of project (shortened): ……

Service Provisions of Medical Doctors with additional Qualification in Homeopathy

CEN/TC: .....

Other: **Creation of a new CEN Project Committee**

(if applicable)

Name and address of the proposing organization:
Austrian Standards Institute
Heinestraße 38
1020 Vienna, Austria

Telephone No. : +43 1 213 00-714

Date : 2013-05-06

Information to be supplied by the proposer of the new project

1 Title (in full)

Services of Medical Doctors with additional Qualification in Homeopathy – Requirements for Healthcare Provision by Medical Doctors with additional Qualification in Homeopathy

The title should be unambiguous and as concise as possible. Where the proposal is for a new work item, the title should specify the subject to be covered and type of standard, e.g. terminology, method of test, performance requirements, etc.

2 Scope

Standardization of the requirements of Medical Doctors with additional qualification in Homeopathy and Standardization of specifications of their services.

NOTE Services provided by persons not being medical doctors and the preparation of homeopathic medicine are excluded from the scope.

The scope should define precisely the field of application. Where the new project relates to a new activity or a range of standards, the scope should begin with 'Standardization of...' or 'Standardization in the field of ...'

3 Justification and purpose

Why is standardization needed? Explain the economic, commercial/industrial, safety, consumer protection or other benefits of the proposal. If necessary, continue on a separate sheet.

Background context

Homeopathic medicine is a system of medicine requiring a distinct qualification in addition to the regular medical qualification, with medical doctors with additional qualification in homeopathy providing their services all over Europe. However, there are no consistent standards of education, training and practice across Europe. There are also differences among medical doctors with additional qualification in homeopathy within some member states.

The European Committee for Homeopathy (ECH – www.homeopathyeurope.org) has identified the need to develop common standards and already has worked on developing voluntary standards. This work will serve as a basis to establish a European standard for the provision of homeopathic medical services. The Medical Homeopathic Education Standard presents the educational objectives of a programme of education and training in homeopathic medicine for doctors, agreed by the European Committee for Homeopathy and the Liga Medicorum Homoeopathica Internationalis (LMHI, www.lmhi.net). The document presents the minimum standards of education and training in homeopathic medicine for medical doctors agreed by the European Committee for Homeopathy (ECH) and the Liga Medicorum Homoeopathica Internationalis (LMHI). The ECH and the LMHI represent organisations responsible for the teaching of homeopathic medicine in the member states of the European Union and worldwide that are committed to using the programme. The document sets out the essential core elements – knowledge, understanding, skills and attitudes – of this commonly agreed curriculum. It provides a consensus framework of training requirements for a safe and effective practice of medical homeopathy (the practice of homeopathic medicine by medical doctors), and outlines the syllabus for examinations leading to a qualification in homeopathic medicine conferred by the organisations represented in the ECH and LMHI. The document also provides a basis for the accreditation by the ECH and LMHI of courses for medical doctors taught by organisations affiliated to the ECH and LMHI, should such accreditation be formally required in the future. The curriculum found in this document reflects standards which are considered a minimum to be a safe and knowledgeable medical doctor with additional qualification in homeopathy. There are countries where professional and registering organisations surpass these standards and set standards to reflect the practice of homeopathy by medical doctors.

It shall be recognized that in some member states homeopathic medicine is also practised by individuals without a full medical education. This particular standard is meant as an additional qualification for individuals with a full medical education.

In 2009 the World Health Organisation WHO has published its report on *Safety Issues in the Preparation of Homeopathic Medicines* (www.who.int/medicines/areas/traditional/Homeopathy.pdf). The proposed European Standard will focus on education, training and practice but will not deal with the preparation of homeopathic medicines.

Single market context

In some member states, homeopathic medicine is a recognised additional qualification for medical doctors (e.g. Austria, Germany, Italy, the UK), while in other member states this is not the case. In a few countries diplomas for doctors who have taken a full course of homeopathic medicine are issued and recognised by the national medical associations/chambers/ councils. However, there is no mutual recognition of diplomas among the various member states, which impedes the free movement of medical doctors with additional qualification in homeopathy.

Council Directive 2005/36/EC facilitates the mutual recognition of conventional medical qualifications (basic training, additional training as general practitioners or medical specialists, if applicable), but not their additional qualifications in particular CAM therapies (Complementary and Alternative Medicine such as Homeopathy or Acupuncture).

A European Standard can streamline the provision of homeopathic medical services and may pave the way for the inclusion of this additional qualification under Council Directive 2005/36/EC.

Patient safety and consumer well being

Successful homeopathic medical service provisions must fulfil certain safety and quality levels. Defining these requirements and levels – before, during and after homeopathic intervention – is essential for providing a safe environment for patients. This also gives patients and the public the information they need to know what to expect from treatment (see WHO Guidelines on Developing

Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine, http://apps.who.int/medicinedocs/pdf/s5525e/s5525e.pdf).

As such, a European Standard contributes to patient safety and the wellbeing of European citizens. This European Standard also contributes to and supports the Commission communication on patient safety (COM (2008) 836 Final) as well as Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

National provisions and regulations

Homeopathic medicine as a distinct system of medicine is recognised by law in Belgium (in June 2013), Bulgaria, Germany, Hungary, Italy, Latvia, Portugal, Romania and the United Kingdom. The laws in Belgium (future law), Bulgaria, Hungary, Italy, Latvia and Romania explicitly allow the practice of homeopathic medicine to medical doctors only. In Portugal the law does not exclude non-medical practitioners, but has not yet been implemented (see CAMbrella: Insights into the Current Situation of CAM in Europe. Major Findings of the EU Project CAMbrella, http://www.cambrella.eu/home.php).

In some countries where the government has delegated the tasks of authorisation, registration and supervision of medical doctors to the national medical associations, statutory regulation has been introduced by the national medical associations, e.g. in Austria, Germany, Hungary, Romania, Switzerland (subspeciality for General Practitioners GPs, paediatricians and internists). In Latvia the medical council/chamber has recognized homeopathic medicine as a medical specialty. The national medical association in France has recognized homeopathic medicine as a distinctive medical therapy and called on the government to provide the necessary legislation.

In Austria, Germany and Switzerland the diplomas of medical doctors with additional qualification in homeopathy are issued by the national medical council/chamber, and in other countries usually by the national association/faculty/school of medical doctors with additional qualification in homeopathy. Diplomas issued by the national association of medical doctors with additional qualification in homeopathy are officially approved by the government in Latvia and Romania and are recognized by the national medical council/chamber in Romania.

Most other member states do not have any legislation or regulation for homeopathic medicine.

The European Standard cannot harmonize national legislation on homeopathic medicine. But it can complement existing legislation and fill gaps where there is no regulation or standard in existence.

As such, it is a step towards increasing patient safety, towards providing safe and secure homeopathic medical services in Europe and towards creating a level playing field for medical doctors with additional qualification in homeopathy.

Relevant stakeholders:

- Associations, authorities or societies competent for homeopathy
- Representative bodies of medical doctors with additional qualification in homeopathy
- Educational institutions for medical doctors with additional qualification in homeopathy
- Patient and consumer organisations
- Health ministries
- Public health authorities

4 Is the standard required as a reference document for use in an EU Directive?

YES ☐ NO ☒

(This question should only be answered when the European Commission is responsible for the proposal)

4.1 What Directorate General is responsible? Give details.

.....

.....

4.2 If so, what is (are) the specific aim(s) of the Directive e.g.?

	YES	NO		YES	NO
Abolition of barriers	☐	☐	Health	☐	☐
What barriers to trade can be identified ?			Safety	☐	☐
Do they hamper :			Environment	☐	☐
Commerce	☐	☐	Other aims	☐	☐
Production	☐	☐	(please specify)		
Exchange of services	☐	☐	.....		
Free circulation of goods	☐	☐	.....		

5 Is the proposed standard likely to be suitable for certification purposes?

YES ☒ NO ☐

6 Priority category

Indicate to which, if any, of the following categories the project belongs :

Category A : Subject of mandates from the Commission of the EU and/or EFTA for tasks requested by these two organizations for rapid completion ☐

Category B : Drafts relating to the harmonized application of ISO standards ☐

Category C : Existing or new subjects for which CEN offers an acceptance procedure for drafts established by European professional standardizing bodies having safeguard of constitution and effectiveness comparable with that of a CEN technical committee and where no ISO work already exists ☐

An explanation should be provided by the originator of any proposal for a new project which does not fall within the priorities defined here.

7 Programme of work

7.1 What are the objectives of the project?

	YES	NO		YES	NO
Safety, health, protection of the environment, energy conservation	☒	☐	Variety control	☐	☐
			Others (specify)	☐	☐
Interface, interchangeability	☐	☐	.....		
Performance, function, quality	☒	☐	.....		

7.2 Which of the following aspects are to be standardized?

	YES	NO		YES	NO
1) Terminology	☒	☐	3) Marketing, labelling, packaging, transport	☐	☐
Symbols/Signs Designation	☐	☐			
2) Characteristics :			4) Sampling	☐	☐
Dimensions	☐	☐			
Mechanical	☐	☐	5) Methods of test	☐	☐

Chemical	☐	☐			
Acoustical	☐	☐	6) Performance	☒	☐
Thermal	☐	☐	requirements		
Electrical*	☐	☐			
Other physical	☐	☐	7) Others	☐	☐
Non-physical, i. e. logical	☐	☐	(Please specify)		

** Necessary contact with CENELEC*

7.3 What is your estimation of the time needed for the technical project up to the completion of the draft EN/HD for the CEN enquiry? 20 months after WI adoption

7.4 What is the proposed deadline for submission of the draft EN/HD to the CEN formal vote? 30 months after WI adoption

7.5 What is the latest date by which the standard should be published? .....

8 Standards or other documents on which it is intended to base the European Standard

8.1 List of standards or other documents (please give titles, reference and date):

- Medical Homeopathic Education Standards for LMHI and ECH Allied Schools, version 2008 (http://www.homeopathyeurope.org/publications/professional-standards/medical-homeopathic-education-standard)
- HomQM – das QM System des DZVhÄ für die homöopathische Praxis (https://www.dzvhae.de/homoeopathie-fuer-aerzte/dzvhae-qualitaetsmodul-homqm-termine-fuer-online-schulung.html)
  HomQM - the QM System of the DZVhÄ for the Homeopathic Practice (DZVhÄ - Deutscher Zentralverein homöopathischer Ärzte - *German Association of Homeopathic Doctors*)
- Dokumentationsstandard: erarbeitet im Rahmen von drei Konsensus-Konferenzen von DZVhÄ und InHom (2002, 2004 und 2008, http://www.wisshom.de)
  Documentation Standard: developed during 3 consensus conferences of DZVhÄ and InHom(2002, 2004 and 2008, http://www.wisshom.de)
- CAMbrella: Insights into the Current Situation of CAM in Europe. Major Findings of the EU Project CAMbrella (http://www.cambrella.eu/home.php)
- Safety Issues in the Preparation of Homeopathic Medicines (www.who.int/medicines/areas/traditional/Homeopathy.pdf)
- Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine (http://apps.who.int/medicinedocs/pdf/s5525e/s5525e.pdf)
- Homeopathic Thesaurus. Keyterms to be used in Homeopathy. Tree structure and alphabetical list. English, German, French, Italian. Third Multilingual Edition, 1.2007. (http://www.homeopathyeurope.org/publications/thesaurus)
- Swayne J, Editor: The International Dictionary of Homeopathy. Churchill Livingstone, 2000. ISBN-13: 978-0443060090

8.2 Is there an existing International Standard? YES ☐ NO ☒

If 'YES',
a) give details :
b) is it suitable for harmonization? YES ☐ NO ☐
If 'NO', give reasons: .....

8.3 Is any aspect detailed in 7.2 already referred to in existing :

		YES	NO			YES	NO
1)	International Standards*	☐	☒	3)	Other specifications or requirements*	☐	☒
2)	National Standards*	☐	☒	4)	Not known	☐	☐

** If 'YES', please identify on a separate sheet.*

8.4 Is any requirement included in the documents, and detailed in 7.2 considered to be of outstanding importance by the originator? YES ☒ NO ☐

If 'YES', give details .....

A European Standard which lays down the requirements for services of medical doctors with additional qualification in homeopathy, closes the existing gap between those countries with and without national requirements and enhances patient's safety.

9 **Are there any documents in the same field whose requirements must be taken into account during the technical work**? YES ☐ NO ☐ Not Known ☒

If 'YES', give brief details : .....

.....

10 **Will liaison with outside bodies be necessary?** YES ☒ NO ☐

ECH, European Committee for Homeopathy, www.homeopathyeurope.org

11 **Is there any existing national legislation which may be relevant to CEN Work in this area?**

YES ☒ NO ☐ Not Known ☐

Please specify such legislation and give details:

Homeopathic medicine as a distinct system of medicine is recognised by law in Belgium, Bulgaria, Germany, Hungary, Italy, Latvia, Portugal, Romania and the United Kingdom. The laws in Belgium and Portugal have not been implemented as yet.

12 **Is any aspect governed by the requirements of inspection bodies?**

YES ☐ NO ☐ Not Known ☒

Give brief details : .....

13 **Would any aspect conflict with known patented items?** YES ☐ NO ☒

(ISO Directives, Part 2 and CEN/CENELEC Guide n°8 refers)

If 'YES', provide full information on a separate sheet.

14 **Participation in work**

	YES	NO
14.1 Is the proposer prepared to participate diligently in the work?	☒	☐
14.2 Is the proposer, if a CEN member, prepared to undertake the Secretariat duties if a new CEN/TC is necessary?	☒	☐
14.3 Is the proposer prepared to undertake the preparatory work required for a new work item?	☒	☐

15 Documentation

All documentation previously referred to should accompany this proposal and be listed below.

Are any of the attached documents to be circulated to CEN members with the proposal?

YES ☒ NO ☐

Please send an electronic copy of these document(s) together with the proposal to CCMC.

Signed: .....……. Date : . 2013-05-06

Name : Dr. Karl Grün Position : Director Development

Concept for a draft structure for the proposed standard

In the drafting of this European Standard the following CEN Guides will be considered:

- *CEN Guide 14: Common policy guidance for addressing standardisation on qualification of professions and personnel*
- *CEN Guide 15: Guidance document for the development of service standards*

Title: Services of Medical Doctors with additional Qualification in Homeopathy – Requirements for Healthcare Provision by Medical Doctors with additional Qualification in Homeopathy

Foreword:

Introduction:
This European Standard provides a set of minimum requirements, which are essential for the service provision of medical doctors with additional qualification in homeopathy. Furthermore, recommendations for other aspects of good practice are provided.

Emphasis is placed on defining requirements for the quality of the service offered.

1. **Scope**

This European Standard specifies the requirements of medical doctors with additional qualification in homeopathy and the specifications of their services.

NOTE Services provided by persons not being medical doctors and the preparation of homeopathic medicine are excluded from the scope.

2. **Terms and definitions**
   2.X
   Homeopathy
   .....
3. **Service preconditions**
   3.1. Clinical practice
   3.2. Core competences
   3.3. …

4. **Education**
   4.1. Educational requirements
   4.2. Continued education and training

5. **Code of ethics**
   5.1. Relationship with patient
   5.2. Relationship with other medical professions
   5.3. Relationship with colleagues
   5.4. Advertising
   5.5. .....

6. **Organisation**
   6.1. Facility requirements
   6.2. Equipment requirements
   6.3. Quality assurance
   6.4. Insurance

6.5. ....

Annex A
(normative)

Minimum competencies and training requirements of Medical Doctors with additional qualification in homeopathy

A.1 Description of the competences
- A.1.1. General Competences
- A.1.2. specific competences

A.2 Clinical
A.3 ..
A.4 Recommended training programme
A.5.....

Annex B
(informative)

Patient records