WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTÉ
WELTGESUNDHEITSORGANISATION
ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ

REGIONAL OFFICE FOR EUROPE
BUREAU RÉGIONAL DE L'EUROPE
REGIONALBÜRO FÜR EUROPA
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

Date: 6 June 2005

Professor Rainer Seitz
The Paul-Ehrlich-Institut (PEI)
Paul Ehrlich Str. 51-59
D-63225 Langen
Germany

FAX : Fax: +49 6103 77 1250

Our reference:
Notre référence:
Unser Zeichen:
См. наш номер: Langen-Seitz-DEU

Your reference:
Votre référence:
Ihr Zeichen:
На Ваш номер:

Dear Professor Seitz,

WHO Collaborating Centre for
Quality Assurance of Blood Products and in vitro Diagnostic Devices

I have pleasure in informing you that the World Health Organization, after consultation with your Government, has designated the Paul-Ehrlich-Institut (PEI), Langen, as a WHO Collaborating Centre for Quality Assurance of Blood Products and in vitro Diagnostic Devices. It is understood that you will be Head of the centre.

A copy of the terms of reference for your centre is enclosed with this letter. Should there be any changes in the future that might affect this arrangement, I should be grateful if you would inform the Regional Office without delay.

You will kindly note from the enclosed document entitled "Guidelines for institutions wishing to collaborate with WHO" that annual reports of activities undertaken as part of the agreed plan of work should be submitted to this office.

The designation of the centre will be effective for a period of four years as from the date of this letter. Unless a redesignation has been officially approved and notified before that date, the designation of the Institute as a WHO Collaborating Centre will automatically lapse. It is in this context that I invite you to contact the WHO Department with which you collaborate to discuss a potential redesignation. It is important to note that the redesignation process should commence at least six months prior to the end of the designation period. Either party may revoke the designation in any year by giving notice of its intention to do so three months before the end of that year.

Copy for information:
Herrn Udo Scholten, Unterabteilungsleiter, Internationale Gesundheits- und Sozialpolitik, Bundesministerium für Gesundheit und Soziale Sicherung, Am Propsthof 78a , D-53121 Bonn , Germany

Enclosures: as mentioned

8, Scherfigsvej
DK-2100 Copenhagen Ø
Denmark

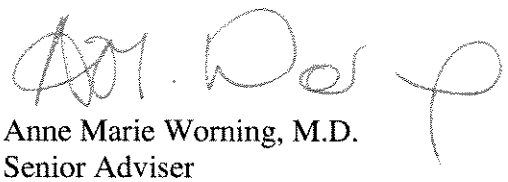
Telephone: +45 39 17 17 17
Fax: +45 39 17 18 18
Telex: 12000 dk

E-mail: postmaster@euro.who.int
Web site: http://www.euro.who.int

For your information, the HQ website http://whocc.who.int provides you with general information on WHO Collaborating Centres, as well as information on other collaborating centres working in your specific area or related areas which could be of interest to your work. Also enclosed is an extract of the WHO Manual concerning the use of the WHO emblem in letterheads and use of the WHO flag for the mentioned period of designation.

I look forward to our successful cooperation.

Yours sincerely,



Anne Marie Worning, M.D.
Senior Adviser
Programme Management and Implementation

WHO Collaborating Centre for Quality Assurance of Blood Products and in vitro Diagnostic Devices

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Web: www.pei.de

Responsible Officer (based in HQ): Dr Ana Padilla, QSD

Terms of Reference

1. Support to WHO in the organization of training courses and meetings covering the following fields of activity:
    a. GMP inspections of blood establishments and plasma fractionation facilities
    b. Review of production protocols and laboratory control of batches, including testing of viral markers
    c. Regulatory control systems for blood components and plasma derivatives, covering:
        i. Assessment of quality
        ii. Administrative procedures
    d. In vitro diagnostic devices
        i. Validation of assays
        ii. Evaluation of performance of IVDs
        iii. Control and batch release of IVDs
        iv. Evaluation of viral safety of blood derived products:
            - Plasma pool testing by nucleic acid amplification techniques (NAT)
            - Plasma pool testing by serological methods
            - Safety evaluation of plasma derivatives
        v. Evaluation of pathogen inactivation/removal procedures
2. Laboratory studies and standardization exercises
    a. Active contribution in design and organization of collaborative studies in order to establish international standard preparations and reference panels
    b. Experimental research, particularly into the development of improved test methods
    c. Quality control of blood and plasma derived medicinal products and in vitro diagnostic devices
3. Contributing to the development of guideleines and recommendations
    a. Sharing long standing and broad experience due to invovlement in several national and international committees, including the EMEA working parties and expert groups of the Euroepan Pharmacopoeia
    b. Active contribution to keeeping updated WHO guidance documents (e.g. Technical Report Series, No 840).

TITLE OF CENTRE AND USE OF WHO'S EMBLEM AND FLAG

A WHO collaborating centre may use the name "WHO" or "World Health Organization" and the WHO emblem in its letterhead on the following conditions:

(a) solely for correspondence related to its activities as a collaborating centre;

(b) if the term "WHO" or "World Health Organization" is used in the letterhead, the characters of these terms should be the same size as those for the title of the centre;

(c) if the language used by the centre for its letterhead is a language other than the official languages of the World Health Assembly (Arabic, Chinese, English, French, Russian, Spanish) or other languages used officially by regional offices (English, French, German and Russian in the European Region), one of the latter should also be included;

(d) any letterhead using WHO's name should conform to the title under which the institute has been designated and which is contained in the official letter of designation.

(e) For other purposes (including web pages) and especially commercial purposes, the use of the WHO emblem must be authorized by the Director-General. Collaborating centres should contact their counterpart in WHO for permission to use the emblem under such circumstances.

A WHO flag can be obtained on request for use on the building housing the centre on certain occasions (World Health Day (7 April) and on the occasion of any official event which is related in some way to the World Health Organization), and provided it is displayed in conformity with the Flag Code (sent at the same time as the flag).

What is a WHO collaborating centre ?

A WHO collaborating centre is a national institution designated by the Director-General of the World Health Organization to form part of an international collaborative network carrying out activities in support of WHO's mandate for international health work and its programme priorities.

An entire institution, or a department or laboratory within an institution, or a group of facilities for reference, research or training belonging to different institutions, may be designated as a "WHO collaborating centre". When a WHO collaborating centre comprises several departments or institutions, only one of these acts for that centre in relation to WHO.

The use of the title, logo and official letterhead of "WHO collaborating centre" is strictly regulated and limited to matters directly related to WHO collaborative activities.

Role of WHO collaborating centres

WHO collaborating centres play a strategic role in helping the Organization meet two major needs:

1 they contribute to implementing WHO's programme priorities, in close coordination with the units concerned in WHO's six Regional Offices and at headquarters;

2 they strengthen institutional capacity in countries and regions.

Functions of WHO collaborating centres

Within this context, WHO collaborating centres may carry out one or several of the following functions:

- collection and dissemination of information;

- standardization of terminology and nomenclature, of technology, of diagnostic, therapeutic and prophylactic substances, and of methods and procedures;

- development, application and evaluation of appropriate technology;

- provision of reference substances and of services such as quality assurance;

- participation in collaborative research developed under WHO's leadership, including the planning, conduct, monitoring and evaluation of research, and the promotion of the application of its results;

- education and training, including research training;

- coordination of activities carried out by several institutions on a given subject;

- provision of information and advice on scientific, technical and policy issues.

Criteria for the selection of WHO collaborating centres

WHO collaborating centres are selected in fields that are relevant to WHO's activities. They should be able to fulfil one or several essential functions in support of WHO's programme priorities. More particularly, their collaboration should be linked to the objectives defined in WHO's programme budget. Particular attention will be given to institutions in less developed countries which can play a strategic role in strenghtening WHO's network in terms of geographical coverage and area of expertise for health development.

Other criteria for selection include the scientific and technical standing of the institution, its actual level of commitment at national, regional and international level, and its ability to strenghten national and regional capacity for health development. The institution must also have collaborated successfully with WHO for at least two years in carrying out jointly planned activities.

WHO collaborating centres must have the capacity and the institutional stability to develop relations with other

institutions through shared activities and networking. They should be willing and prepared to use their own resources to implement the collaborative activities proposed in their work plans.

Designation of WHO collaborating centres

The designation procedure is the same for all parts of the Organization. This ensures that the selection process is as objective and transparent as possible. The initiative for proposing institutions as WHO collaborating centres may come from institutions and governments or from WHO's regional offices and headquarters.

WHO collaborating centres are designated for a limited period of time (up to four years). Designation is based on technical considerations which include geographical and subject relevance. It can be renewed on the basis of review of performance and assessment of the continued relevance of collaboration, taking into consideration WHO's evolving needs and policy. Evaluation, for both designation and redesignation, is carried out through an open and collective process which involves WHO country representatives, Regional Offices and relevant units at headquarters, as well as the governments concerned. Final authority in designating a collaborating centre rests with WHO's Director-General.

Management of collaboration with the centres

Collaboration with the centres is managed by relevant units in that part of the Organization which initiated the designation process, whether at headquarters or in a region. WHO collaborating centres, however, maintain technical links with all parts of the Organization relevant to their agreed programme of work. The scope and objectives of the collaboration, including the terms of reference of the centre and its work plan for the four-year period of designation, are jointly defined by the Organization and the institution. On that basis, monitoring of collaboration is carried out annually and final evaluation after four years. The Organization commits its own staff time and related resources, although not necessarily direct financial support, to ensure that collaboration can develop in a useful manner - which implies frequency and intensity in the collaboration. WHO collaborating centres are encouraged to develop networks with other institutions and to hold regular meetings ither at country and regional level or on specific topics, to promote exchange of experience and collaboration.

The global database on WHO collaborating centres is being developed as an essential tool for enhancing communication and collaboration between institutions, networks and WHO and its constituents.