The European Directorate for the Quality of Medicines & HealthCare (EDQM) is a directorate of the Council of Europe, the oldest European institution which, today, has 47 member states, representing 800 million citizens across Europe.

The activities of the Council of Europe are focused on human rights, democracy, and the rule of law. The EDQM is based on the Council of Europe convention on the elaboration of a European Pharmacopoeia, signed by 8 Council of Europe member states in 1964. Today, this partial agreement has 37 signatory parties, 36 member states of the Council of Europe and the European Union. It also has 23 observers (in 2009, 22 countries from all continents and the World Health Organisation), which shows that our activities attract considerable interest in the rest of the world.

Up to 2009, the EDQM published its annual report for the previous year in the April edition of Pharmeuropa, our quarterly forum. Following internal reflection on how to further improve the information we provide to our stakeholders, we have decided to take a new route and to publish the annual report in a new format and separately. We very much hope you will find that the report in its new format is informative and serves your needs.

In 2009, the EDQM successfully continued its work in establishing standards for the quality of medicines in the form of pharmacopoeial texts and reference standards. At the international level, co-operation with the Japanese and United States Pharmacopoeias continued in the Pharmacopoeial Discussion Group (PDG), an informal initiative aimed at international harmonisation of pharmacopoeial requirements, run in parallel to the International Conference on Harmonisation (ICH). In addition, the EDQM and the United States Pharmacopeia, in close collaboration with industrial counterparts, jointly initiated a bilateral pilot project on prospective harmonisation of active pharmaceutical ingredient (API) monographs, which so far have been outside the scope of PDG activities.

The procedure for the Certification of Suitability to the Monographs of the European Pharmacopoeia saw yet another increase in applications received, which shows that the EDQM’s...
certification scheme is well accepted amongst API manufacturers, finished product manufacturers and regulatory authorities worldwide. A number of inspections conducted in the context of certification again demonstrated the need for more oversight of API manufacturers and led to the suspension or withdrawal of a number of certificates and the blocking of certain applications. In December 2009, the EDQM was ISO 9001 certified for its activities in the certification of suitability procedure, covering both assessment and inspections.

As part of the work done by the EDQM in co-ordinating the activities of the European network of Official Medicines Control Laboratories (OMCLs), databases for information sharing between authorities were further developed and updated. Overall, 2009 saw increased participation of OMCLs in activities that are aimed at building trust and confidence between member states to further strengthen mutual recognition of test results and make the best use of scarce resources.

In the field of blood transfusion and organ transplantation, further recommendations to ensure the quality of material and practices were elaborated and existing guides were revised and updated. The EDQM contributed to the world-wide fight against counterfeiting of medical products by organising multi-sectorial training sessions for government representatives. It also contributed to the Council of Europe’s efforts to support the finalisation of an international convention on combating counterfeit medical products and similar crimes posing a risk to public health (MEDICRIME convention), which is scheduled to be adopted by the Committee of Ministers, the Council of Europe’s governing body, in 2010. The MEDICRIME convention, an international treaty, will be open to participation by governments worldwide. Last but not least, the EDQM’s portfolio of activities saw another addition: since January 2009, the EDQM has been responsible for the Council of Europe’s activities in the field of cosmetics and food contact materials.

At the international level, the EDQM concluded bilateral confidentiality agreements with the US Food and Drug Administration and the Australian Therapeutic Goods Administration. These agreements enable the respective partners to share non-public information regarding inspections of active pharmaceutical ingredients and manufacturers of excipients. At the December session of the European Pharmacopoeia Commission, the EDQM invited its 23 observers to a special meeting, intended as a platform for exchanging information and better understanding of mutual needs.

The year 2009 also saw a number of changes within the EDQM. Professor John Miller, the long-time Head of the Laboratory Department, retired in March and was succeeded by Dr. Andrea Lodi, previously the Deputy Head of Department. In this context, working procedures were reviewed and the organisation of the Department was modified. Ms. Cathie Vielle, the Head of the European Pharmacopoeia Department and Secretary to the European Pharmacopoeia Commission, arrived in May to complete the EDQM management team. Throughout the year, the EDQM continued its work in modernising its IT infrastructure and systems. The development and implementation of an Enterprise Resource Planning System (ERP), an Electronic Document and Records Management System (EDRMS) and a Laboratory Information Management System (LIMS) will ensure that the organisation is fully prepared for the years to come.

However, the EDQM would not have been successful without the support and dedication of the numerous experts appointed by the 36 States that have signed the Convention on the Elaboration of a European Pharmacopoeia. Their expertise and contributions are crucial for the work of the European Pharmacopoeia Commission and its Groups of Experts and Working Parties, the Committees and Expert Groups in the areas of Blood Transfusion, Organ Transplantation, Pharmaceuticals and Pharmaceutical Care, Consumer Protection, the OMCL Network as well as assessment and inspections for the Certification Scheme. I would like to take this opportunity to express our sincere gratitude to all of them.

Susanne Keitel
Director
"THE EDQM AT A GLANCE": values, aims, activities

The European Directorate for the Quality of Medicines & HealthCare – a Directorate of the Council of Europe

The primary aim of the Council of Europe is to create a common democratic and legal area throughout the whole of the continent, ensuring respect for its fundamental values: human rights, democracy and the rule of law.

Human Rights… Democracy… Rule of Law

These values are the foundations of a tolerant and civilised society and indispensable for European stability, economic growth and social cohesion. On the basis of these fundamental values, we try to find shared solutions to major problems such as terrorism, organised crime and corruption, cybercrime, bioethics and cloning, violence against children and women, and trafficking in human beings. Co-operation between all member states is the only way to solve the major problems facing society today.

Objectives:

• To protect human rights, pluralist democracy and the rule of law
• To promote awareness and encourage the development of Europe’s cultural identity and diversity
• To find common solutions to the challenges facing European society
• To consolidate democratic stability in Europe by backing political, legislative and constitutional reform.

The mission of the EDQM

The mission of the EDQM is to contribute to the basic human right of access to good quality medicines and health-care, to promote and protect human and animal health by:

• establishing and providing official standards which apply to the manufacture and quality control of medicines in all the signatory states of the Convention for the elaboration of a European Pharmacopoeia and beyond,
• ensuring the application of these official standards to substances used for the production of medicines,
• co-ordinating a network of Official Medicines Control Laboratories to collaborate and share expertise between member states and effectively use limited resources,
• establishing quality standards and promoting ethical practices:
  - for the collection, preparation, storage and use of blood components concerning transfusion medicine,
  - for organ transplantation including tissues and cells,
• collaborating with national and international organisations in efforts to eliminate illegal and counterfeit medicinal and medical products,
• providing policies and model approaches for the safe use of medicines in Europe, including guidelines on pharma-

The European Directorate for the Quality of Medicines & HealthCare (EDQM)

The EDQM, whose origins date back to 1964, has over the years become an administrative directorate of the Council of Europe. In 2009 the EDQM employed 200 full-time staff members and was structured into 9 administrative entities.

It was set up by virtue of article 9 of the Convention on the Elaboration of a European Pharmacopoeia, which was signed by 8 member states of the Council of Europe in 1964 with the vision of creating a common European Pharmacopoeia. Known for many years as the “European Pharmacopoeia Secretariat”, this administrative entity of the Council of Europe has undergone successive name changes, each time to reflect the new missions assigned to it.
1. CORE ACTIVITIES

1.1 The European Pharmacopoeia

Purpose

The main goal of the European Pharmacopoeia (Ph. Eur.) is to provide common, harmonised quality standards in Europe for the control of substances used to manufacture medicines for human and veterinary use. Monographs describing individual quality standards (i.e., a set of controls applying to one ingredient) and general standards applying to groups of ingredients or dosage forms compose the European Pharmacopoeia.

An official reference to serve public health

European Pharmacopoeia quality standards are not only part of the requirements for marketing authorisation of a medicinal product but are legally binding throughout the entire life-cycle of the product. They become mandatory on the same date in all member states of the European Pharmacopoeia Convention. They guarantee a single common quality for medicines throughout Europe.

A large scope to cover all public health issues

The scope of the Ph. Eur. extends far beyond the “classical” chemical medicines as it also provides quality standards on, for example, herbal, homoeopathy, ethnic medicines such as traditional Chinese medicines, vaccines for human and veterinary use and biologicals.

Officially adopted and implemented by all member states

All standards of the Ph. Eur. are adopted by consensus at the European Pharmacopoeia Commission consisting of delegates from the 36 member states. The 23 observers from all continents (e.g. Algeria, Australia, Brazil, Canada, Syria, USA) are welcome to participate in the deliberations of the Commission and its Groups of Experts and Working Parties.

An on-going process to add and to revise existing quality standards

The Ph. Eur. is maintained by the European Pharmacopoeia Department, composed of scientific officers who act as secretaries to groups of experts and working parties that establish the texts of the Ph. Eur. (more than 60 groups of experts and working parties with more than 800 experts from all over Europe). Translators in the European Pharmacopoeia Department ensure that the Ph. Eur. is translated into English and French, the two official languages of the Council of Europe. The European Pharmacopoeia is also progressively translated into Spanish in co-operation with the Spanish authorities. Translations into other national languages of member states of the Convention are performed under the responsibility of the member states, e.g. German, Hungarian, Polish. A Russian translation of the first volume is underway in co-operation with a Russian contract partner.

International Harmonisation- the Pharmacopoeial Discussion Group

With the Japanese (JP) and United States Pharmacopoeia (USP), the Ph. Eur. participates in the Pharmacopoeial Discussion Group (PDG) with the aim of harmonising pharmacopoeial requirements worldwide. Originally set up in 1990, the PDG is an informal forum between the three pharmacopoeias, which meets in parallel to the International Conference on Harmonisation (ICH). The work of the PDG includes harmonisation of the general methods covered by the ICH Guideline Q6A “Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products”, other general methods of high relevance for the pharmaceutical industry, and excipient monographs. In 2009, PDG meetings took place in Yokohama, Japan (June) and St. Louis, USA (November). With representatives of its sister organisations, the Ph. Eur. will also participate as an observer in ICH Expert Working Group Q3C, Metal Impurities, newly set up in 2009.

Key figures for 2009

During its three sessions, the European Pharmacopoeia Commission adopted:

- 34 general chapters including:

  - 4 new chapters on microbiological quality of herbal medicinal products for oral use, on monocyte activation tests, on dissolution testing and on glycan analysis.
  - 5 general methods included in Ph. Eur. chapter 5.8 Pharmacopoeial harmonisation, which brings to 15 the number of methods published in this section of the Pharmacopoeia. This chapter refers to texts harmonised between the European, Japanese and United States Pharmacopoeias through the PDG and provides assistance to users of the methods in the three regions as regards their equivalence.

- 255 individual quality standards for ingredients, including 6 standards on active substances, recently authorised in medicinal products in Europe and still under patent at the time of their adoption (Pramoxyle dihydrochloride (2416), Tiotropium bromide (2420) Monohydrate entacapone (2574), Levetriracetam (2535), Meropenem (2234) and Ziprasidone hydrochloride (2421). The latter were elaborated in close collaboration with the respective industrial counterparts, using the P4 procedure dedicated to substances still under patent.

- 4 new working parties were set up to better cover new public health challenges (Heavy Metals, Cell Therapy Products, Degree of hydration & INN modified names, and Rules of Procedure).
Achievements in Biological Standardisation

The Biological Standardisation Programme (BSP) pursues the following goals in the area of standardisation of biologicals: development and validation of new analytical methods and validation of alternative methods based on the 3R concept (i.e. the Refinement, Reduction and Replacement of animal experiments).

To this end, collaborative studies are performed involving all interested partners (e.g. Official Medicines Control Laboratories (OMCLs) and manufacturers). Since the programme’s start in 1992, 112 BSP projects have been initiated and in the year 2009, a number of projects were pursued in different fields:

- vaccines for human use: 8 projects
- vaccines for veterinary use: 1 project
- plasma-derived products: 8 projects
- biotechnology products: 4 projects

Amongst these, 5 projects were devoted to the establishment of alternatives to animal experiments, and 14 projects concerned the establishment of Biological Reference Preparations (BRPs).

In the field of vaccines for human use, a collaborative study was completed for the second phase of a project aimed at a better standardisation of the serological methods used for clinical evaluation of influenza vaccines during the annual licensing procedure according to the European Medicines Agency’s Committee for Human Medicinal Products (CHMP) guidelines. This project had been requested by the CHMP Biologics Working Party (BWP). The results of the study will be presented to the relevant committees in 2010.

The strong efforts to apply the 3R concept to the field of quality control of biologicals were continued in 2009. Three projects were concluded and proposals were made to the relevant Ph. Eur. group of experts for revision of the monographs. The monographs concerned are now being revised to incorporate the 3R methods:

- Tetanus immunoglobulin: replacement of the in vivo challenge assay by two different in vitro assays,
- Acellular pertussis vaccine: replacement of the in vivo challenge by a serological assay as batch potency assay. After completion of this project it will be possible to determine the potency of tetanus, diphtheria and acellular pertussis components of combined vaccines using a single assay instead of three different assays,
- Acellular pertussis vaccine: standardisation of the histamine sensitising test for the presence of pertussis toxin with the goal of reducing the number of animals used for this test.

Contribution of the European Pharmacopoeia Commission to the reduction of animal testing

As part of the Commission’s continuous efforts to reduce animal testing in the European Pharmacopoeia, a set of quality standards concerning human blood products was revised to introduce a provision for the use of an in vitro method as a preferred alternative to the pyrogen test in rabbits, and a new general chapter was adopted on monocyte activation tests, which provide in vitro alternatives to the rabbit pyrogen test.
1.2 Pharmaceutical Reference Standards

Why have reference standards?

The use of reference standards (samples of pure and carefully calibrated substances intended for quality control) is required in most of the tests and assays prescribed by the European Pharmacopoeia. The production and distribution of these standards therefore constitute an essential activity of the EDQM for the users of the European Pharmacopoeia.

Objective: guarantee at all times that 98% of the collection of standards is available

Careful planning of the production of standards (473 batches produced in 2009) made it possible to go beyond this objective and guarantee that over 98% of the standards were available to users at all times.

A collection of 2200 standards

This collection of reference standards is indispensable for the quality control of medicines according to the specifications of the European Pharmacopoeia. New standards were added to our collection in 2009:

Number of standards available

Use outside Europe

European Pharmacopoeia standards are used outside Europe; they are increasingly being used in certain geographical areas / countries (such as India and China) to ensure compliance with European quality specifications.

User demand for standards remains high.

Number of shipments

Achievements in the field of Biological Reference Preparations (BRPs)

In 2009 the international collaborative studies performed in the field of the Biological Standardisation Programme led to the adoption of 4 BRPs by the European Pharmacopoeia Commission: Diphtheria vaccine BRP batch 4, Hepatitis A vaccine (non-adsorbed) BRP batch 1, Varicella vaccine BRP batch 1 and Pertussis toxin BRP batch 1 (recalibrated in IU).

EDQM activities as WHO custodian laboratory for antibiotics

Since May 2006 the EDQM has been the custodian laboratory for the WHO International Standards for Antibiotics (ISA). At the same time, the EDQM took over the responsibility for the establishment, storage and distribution of ISA from the National Institute for Biological Standards and Control (NIBSC). Batches that were held and distributed by NIBSC are now being distributed by the EDQM.

The ISA are essential for the standardisation and quality control of antibiotic drug substances and pharmaceutical drug products. They are supplied for use in the microbiological assays performed for quality control.

In 2009, work began for the establishment of a number of replacement batches.
1.3 Laboratory activities

New management

2009 was a year of change for the EDQM Laboratory. A new head of Department and a new deputy head were appointed, and four new scientific programme officers and two new technicians were recruited.

New organisation

The Department now consists of two organisational units: Analytical Chemistry Division and Biology Section. The working structure is now aligned with groups of experts/initiative. For each group/initiative, a Laboratory representative is accountable for the activities performed for that particular group/initiative.

New synergies put in place internally

A new integrated establishment process was progressively put in place, allowing timely adoption of reference standards.

Contribution to the work of the European Pharmacopoeia

The Department contributed to the development of Ph. Eur. monographs by participating in meetings of the groups of experts and working parties as well as reporting the analytical experimental work carried out upon request. A Laboratory contribution that deserves to be singled out concerns the quality standards for heparins (test for related substances). The close collaboration with the industrial counterparts for chemically defined substances still under patent (P4 procedure) continued to be successful and more and more manufacturers opted for it, resulting in a growing workload for the Laboratory, consisting not only of experimental work but also of contributions to the assessment of the manufacturers’ dossier and the first draft of the monograph. The procedure is now being extended to biologicals and the Laboratory has been heavily involved in the first project (Factor VII A).

Involvement in the International Harmonisation process

In terms of harmonisation of quality standards at the worldwide level, the Laboratory actively participated in 2009 in two projects involving the European and United States pharmacopoeias:

a) establishment of four quality standards for active ingredients still under patent in a bilateral pilot project with the United States Pharmacopeia on prospective harmonisation of active substance monographs,

b) establishment of a common reference substance for glucagon.

International co-operation

In terms of co-operation with international stakeholders, the Laboratory carried out a quality survey of anti-tuberculosis medicines in Eastern Europe on behalf of the WHO. The quality of 53 batches of Ofloxacin tablets/solutions for infusion and 67 batches of Kanamycin powder for injection was assessed.

New developments

In terms of laboratory equipment three new techniques were introduced (LC-MS/MS, GC/MS, Ion-chromatography). Quantitative Nuclear Magnetic Resonance is becoming key for the characterisation of CRS.
1.4 Certification of Suitability to the Monographs of the European Pharmacopoeia

Purpose of the Certification procedure
The Certification of Suitability to the Monographs of the European Pharmacopoeia (CEP) procedure was established in 1994 and is aimed at:

• ensuring that the quality of substances used in the production of medicines complies with Ph. Eur. standards and hence the requirements of the European Union’s pharmaceutical legislation;
• contributing to keeping the Ph. Eur. continuously up-to-date by assessing whether its quality standards still reflect the quality of substances on the market. The information on the different routes of synthesis and impurity profiles is used to constantly improve the quality of Ph. Eur. standards. This synergy with Certification activities is of the highest importance for the Ph. Eur., as it ensures that Ph. Eur. standards are up to date with respect to the products currently on the world market;
• facilitating at the European level the management of Marketing Authorisation Applications by a centralised assessment that reduces the workload in all the member states.

Which substances are covered by the Certification procedure?
Under the official procedure described in Resolution AP-CSP (07) 1 and referred to in European Union Directives 2001/83/EC as amended, 2001/82/EC and 2003/63/EC, manufacturers or suppliers of active pharmaceutical ingredients or excipients, or of herbal products used in the production or preparation of pharmaceutical products, covered by a Ph. Eur. monograph or any substance with a risk of transmissible spongiform encephalopathy (TSE), can apply for a certificate.

The assessment of the quality documentation submitted to the EDQM for certification is complemented by an inspection programme. This EDQM inspection programme has been set up to check compliance with both the Certificate of Suitability (CEP) application submitted to the EDQM, and Good Manufacturing Practices (GMP as laid down in Vol 4 of the Rules Governing Medicinal Products in the European Union) on the manufacturing/distribution sites covered by CEPs. The EDQM Certification Division is responsible for organising the inspections and their follow-up, including taking any subsequent action regarding related CEPs or CEP applications and communicating with the authorities concerned. The annual inspection programme is based on priorities recommended by the EMA/EU and it is adopted by the Certification Steering Committee, following consultation with member states’ authorities and the GMDP Inspectors Working Group of the European Medicines Agency.

Key figures
The Certification Division has been receiving an increasing number of applications for certificates of suitability (CEPs) in recent years. In 2009, more than 400 new applications and 835 requests for revision were received, in addition to the regular updates following the publication of revised quality standards in the supplements of the Ph. Eur. It should be noted that even though the procedure was extended to herbal drugs and herbal drug preparations several years ago, the first applications for these were only received in 2009.

Cumulative number of new applications received

In 2009, more than 1250 CEPs were granted (new or revised CEPs), and there are currently more than 2500 valid certificates.

New certificates granted per year

In 2009, the Certification of Substances Division focused on streamlining the management of applications for CEPs (new applications and revisions), which included both a stricter monitoring of applications as well as the development of risk-based assessment principles in the evaluation of the dossiers. This led to a significant reduction of processing times.

The programme for inspection of manufacturing sites covered by CEPs is an important tool to supplement the evaluation of the quality of substances for pharmaceutical use. 29 on-site inspections were performed, mainly in Asia, with the participation of inspectors from different national agencies, whilst another 32 sites were covered by sharing information with inspectorates of member states and partners participating in the EU/USA/Australia pilot project for collaboration on GMP inspections of APIs.
A number of these inspections led to the suspension or withdrawal of CEPs and the blocking of CEP applications due to non-compliance of the manufacturing sites with GMP or major deviations from the dossier submitted to obtain the CEP. Since the beginning of the EDQM inspection programme, almost 200 inspections have been performed, covering more than 150 different manufacturing sites.

ISO certification
Following a three-day audit performed by Afnor Certification, the French standardisation body, the EDQM became certified as meeting the requirements of ISO 9001:2008 for the following activities:

“Evaluation of applications for certificates of suitability to the monographs of the Ph. Eur. (initial, revisions and renewals), granting of certificates, and management of the inspection programme of manufacturing sites and associated brokers” (for more information, see Chapter 2.2).

Exchanges and collaboration at the international level
In the field of international collaboration, the EDQM actively participated in a pilot project of collaboration and information-sharing between Europe, Australia and the USA for the inspection of manufacturing sites of active substances. In this context, bilateral confidentiality agreements were signed with the US FDA and the Australian TGA in order to share non-public information regarding inspections. Additionally, the EDQM interacted with the PIC/S.

Finally, the Certification Division also took part in meetings with relevant Trade Associations (CEFIC/APIC, EFPIA, EGA), and also in international conferences and workshops on the quality of pharmaceutical substances. The procedure is applicable to manufacturers of substances for pharmaceutical use, independently of their geographical origin. The distribution of manufacturing sites covered by valid chemical CEPs is shown above.
1.5 Official Medicines Control Laboratory (OMCL) Network

The network of Official Medicines Control Laboratories (OMCLs), which was established in 1994, is open to all countries that have signed the European Pharmacopoeia Convention as well as to observers of the European Pharmacopoeia Commission, provided that the criteria of the network are fulfilled (e.g. independence, public funding, implementation of the Ph. Eur. as common standard, implementation of the ISO/IEC 17025 standard).

‘Networking’ means sharing of know-how within a pool of experts, work sharing and mutual recognition of test results based on commonly agreed procedures, and consequently saving of resources and costs in the testing of medicinal products.

Quality Management Systems

Under the Quality Assurance (QA) programme of the OMCL Network, co-ordinated by the EDQM, the following activities were carried out in 2009:

Mutual Joint Audits and Mutual Joint Visits

During 2009, 7 Mutual Joint Audits (MJAs) and 2 Mutual Joint Visits (MJVs) were carried out on OMCL sites. One Training Visit was organised by the EDQM to provide technical training on physico-chemical laboratory methods.

Training courses for the OMCL Network

In 2009, 2 training courses on the use of CombiStats™ were organised.

OMCL Network Quality Assurance Guidelines

A new OMCL Network guideline was issued on the “Validation of computerised systems”, including 3 annexes dedicated to the practical validation of 3 different types of computerised systems. The guideline was adopted at the OMCL Network annual meeting in May 2009.

The 6th annex of the OMCL guideline “Qualification of equipment”, dedicated to the qualification of pipettes, is under preparation and will be issued in June 2010.

Key QA documents and guidelines are available on the EDQM website.

Mutual Recognition Procedure (MRP)/Decentralised Procedure (DCP) product testing programme

The 5th regular programme for the market surveillance of medicinal products authorised in the European Economic Area (EEA) via the MRP or DCP procedure conducted in 2009 saw the highest number of OMCLs ever participating in the testing scheme and the highest number of projects registered with respect to a testing year in the database, which evidences the increasing acceptance of the EDQM programme throughout the EEA member states.

On 13 and 14 October 2009, training for OMCL users of the database was organised at the EDQM with the goal of further improving the competency of “read-write” users of the IT tool and the quality of data entries. 35 trainees from 30 OMCLs representing 24 member states followed this training, which was structured in 4 sessions.

In 2009, a total of 24 database amendments were implemented, initiated both by the OMCL users of the system and the EDQM Secretariat.

Since August 2009 the database has also been open to National Competent Authority (NCA) members from licensing departments, GMP inspectorates and pharmacovigilance units.

Meanwhile, the database plays an important role in the discussions on improvements in the collaboration between assessors, inspectors and OMCLs which are currently going on at the level of the Heads of Medicines Agencies Working Group on Product Testing (HMA WGPT).

Reflection Group on Quality Monitoring of Stockpiled Medicines

The group, which was established in summer 2008, developed between October 2008 and April 2009 a position paper entitled “Stockpiling of Medicines – Monitoring – General Considerations”. It highlights the contributions of OMCLs in the national programmes for the extension of the use of stockpiled medicines beyond their re-test period or officially authorised expiry date in case of emergency such as pandemic situations. Following its official adoption by the Network, the document was distributed in September 2009 to the members of the European Union (EU) Health Security Committee and the Heads of Medicines Agencies (HMAs) of EU member states with the intention of raising the key stakeholders’ awareness of the role and contribution of OMCLs in questions of quality monitoring of stockpiled medicines.

During 2009 two face-to-face meetings of the reflection group took place on 13 March and 7 October.

OMCL Annual Meeting – General Session / Policy documents

During the General Session of the Annual Meeting of the General European OMCL Network (GEON), which is open to OMCLs from all Ph. Eur. member states and observers fulfilling the requirements, the following general (new or revised) documents were adopted:

- Terms of Reference for the GEON of the Council of Europe – revised document
- Annex 1 to GEON Terms of Reference: Definition of an OMCL – revised document
- Annex 3 to GEON Terms of Reference: List of members – new document
- Terms of Reference for the GEON Advisory Group –
revised document

• Questionnaire to query the OMCL status of present and future members of the GEON – revised document

The decision has been taken to make the “Terms of Reference document” of the GEON and its three Annexes accessible to the public. For this purpose, the documents in question have been placed on the EDQM website (www.edqm.eu).

Proficiency testing scheme studies (PTS)

Over the years, the proficiency testing scheme (PTS) studies have become a regular programme within the Network. In 2009, 5 studies were organised in the physico-chemical field, with an average participation of 46 national control laboratories and 30 other pharmaceutical-control laboratories, the private sector, industry and hospitals, while in the biological area 4 studies were organised, involving an average of 23 laboratories (12 OMCLs and 11 laboratories from the private sector).

In 2009, the 4th PTS agreement with the WHO was finalised and the 5th PTS agreement covering the period from January 2010 to December 2012 was signed. On average 60 governmental control laboratories belonging to the 6 different WHO world regions (Africa, Americas, Eastern Mediterranean, Europe, South-East Asia and Western Pacific) will participate in these studies.

General studies on market surveillance

In 2009, market surveillance studies (MSSs) aimed at screening the quality of medicinal products on the European market were finalised for the following products: lisinopril dihydrate tablets; intramammary suspensions (veterinary use) containing amoxicillin, clavulanic acid and prednisolone; omeprazole gastro-resistant tablets and capsules; a study on levothyroxine tablets was also initiated. The studies on simvastatin tablets, modified release oral opioid medicinal products and acetylsalicylic acid are still in the preparatory stage and the testing phase will only take place in 2010. Such a testing campaign provides an overall picture of the quality of products available on the European market for a given class of products. Where pertinent, the results of these studies will also support the revision of the relevant monographs and/or general chapters and methods of the Ph. Eur. as well as specific actions by the licensing and supervision authorities.

CombiStats™

In 1999, the EDQM initiated the development of a computer program for the statistical evaluation of biological dilution assays in accordance with chapter 5.3 of the Ph. Eur. At that time, most laboratories of the OMCL network used their own in-house-developed software, which led to a strong demand for a common program to harmonise the presentation of assay data and the analysis thereof. The lack of availability of suitable commercial software resulted in the development of CombiStats™, which has been used to the general satisfaction of the net-

work since 2000.

Initially the software was only available to OMCLs, but as of November 2005, non-OMCL laboratories can also obtain a user licence. Three training courses were organised in 2009; the last training course was also open to industry and private sector participants.

By the end of 2009, a significant number of licences had been issued, 21.8% of which were to OMCL laboratories in 23 countries and 78.2% to non-OMCL users in 33 countries. On 9 December 2009, CombiStats™ was used in 18 countries of the EU and 20 countries outside the EU, including non-European countries such as Argentina, Australia, Brazil, Canada, China, India, Israel, Japan, Mexico, South Africa, South Korea, Taiwan, Uruguay and the USA. CombiStats™ has thus evolved into a common internationally agreed reference in its domain and contributes to mutual recognition of data and results by all interested parties.

CombiStats™ licences per category of users (in%)

![CombiStats™ licences per category of users](image-url)
EU/EEA - Specific activities

Official Control Authority Batch Release (OCABR) of Biologicals for Human Use

The Network’s goal remains to provide a harmonised platform for application of Article 114 of EC Directive 2001/83/EC as amended, maximising work sharing and ensuring active and relevant coverage of batches on the market with a focus on reducing animal testing through development and application of procedures and guidelines and providing fora for exchange.

Major highlights

More than 69 participants from 22 member states attended the annual meeting in Vienna of OMCLs to review activities and determine strategies. Guidelines concerning the establishment of memoranda of understanding for the exchange of information with countries outside the EC/EEA and 2 revised general procedures as well as 1 new and 6 revised guidelines for vaccines were finalised in 2009. A special meeting was convened in June to help ensure the network was prepared for its critical role in the timely supply of vaccines for pandemic influenza.

In October the OCABR Batch Database was launched at the EDQM to allow real-time traceability of batches on the market for authorities. Meetings were organised in December with representatives from the European Vaccine Manufacturers’ association (EVM) to address issues specifically relevant to them. A practical workshop for OMCLs involved in testing of oral poliomyelitis vaccine monovalent bulks was also held in December at NIBSC.

All adopted product-specific guidelines and administrative procedures are available in a book published by the EDQM at the end of December 2008. They can also be downloaded in their entirety from the EDQM website.

Official Control Authority Batch Release (OCABR) of Immunological Veterinary Medicinal Products (IVMPs) – Veterinary Batch Release Network (VBRN)

During the veterinary session of the 2009 annual meeting, member states provided a summary of their activities over the reporting period and their progress in application of the Article 81 and Article 82 procedures.

New terms of reference were adopted for the Veterinary Batch Release Network (VBRN). As a result elections will be held at the 2010 annual meeting to create an advisory group.

A successful training session on protocol review in the context of the Article 81 and Article 82 Procedures was held in December to foster common practice and support member states getting started in the activity and thus reinforce mutual recognition.

All the adopted documents can be downloaded from the EDQM website.

Market Surveillance for products with a centralised marketing authorisation (CAP)

The programme for sampling and testing of Centrally Authorised Products (CAP) was successfully continued in 2009 and entered its 11th consecutive year. The programme is run on the basis of a contract between the European Medicines Agency (EMA), which is the sponsor and has the overall responsibility, and the EDQM, which coordinates the sampling and testing operations using the information provided by the Marketing Authorisation Holders upon request from the EMA. The findings of the sampling (performed by national inspection services) and testing operations (performed by the OMCLs of the EU/EEA OMCL Network) are evaluated at the EDQM and transmitted to the EMA with proposals for follow-up actions where necessary.

The CAP programme covers medicinal products for both human and veterinary use. On average, 40 to 45 products are sampled and tested per year. Additional information on the CAP programme can be found on the EDQM as well as on the EMA website.
Within the context of intergovernmental co-operation in the field of health, the Council of Europe has consistently selected ethical problems for study. One of the most important ethical issues relates to the non-commercialisation of human substances, i.e. blood, organs and tissues.

The preparation of the 15th edition of the 'Guide to the preparation, use and quality assurance of blood components' progressed substantially. The guide represents a key milestone in defining the “standard” for blood transfusion services and forms the basis for many national regulators in Europe and beyond. This guide is of great interest to blood transfusion centres, regulators, health professionals and to all those working in the field of transfusion medicine.

The follow-up of the reporting from Council of Europe member states on the collection, testing and use of blood components was organised, and the 2004 survey was completed and published. Reports and publications on the next surveys and on trend analysis on data from the years 2001-2007 are currently under preparation.

Organ transplantation activities

The Steering Committee on Organ Transplantation held one meeting in October 2009. The 3rd edition of the “Guide to safety and quality assurance for organs, tissues and cells” with an addendum on “Criteria for Preventing the Transmission of Neoplastic Diseases in Organ Donation” was published.

International surveys on critical issues (e.g. transplant tourism, transplantation to non-residents) and drafting of state-of-the-art position papers (e.g. on international organ exchanges) were continued or initiated.

With regard to blood transfusion, co-operation amongst member states started in the 1950s. From the outset, the activities were inspired by the following guiding principles: promotion of voluntary, non-remunerated blood donation; mutual assistance of member states (e.g. in the exchange of blood-typing reagents and access to rare blood donations); optimal use of blood and blood products; and protection of the donor and the recipient.

Later, activities in the field of organ transplantation were initiated according to the leading principles of ensuring the dignity of the human being, maintaining and promoting human rights and fundamental freedom, non-commercialisation of substances of human origin and protection of donors and recipients.

Around its first agreements in the 1950s and 1970s, the Council of Europe has established pan-European programmes on blood transfusion and transplantation. Since February 2007, these programmes have been run by the EDQM under the aegis of 2 new steering committees (the European Committee on Blood Transfusion and the European Committee on Organ Transplantation that were created by the Council of Europe).

Blood transfusion activities

The Steering Committee on Blood Transfusion held one meeting in November 2009.
1.7 Pharmaceutical Care

Thematic workshops and new publications

The European Committee on Pharmaceuticals and Pharmaceutical Care organised the expert workshop “Assessing the quality of patient-centred pharmaceutical care in Europe – where do we stand, where should we go?” on 19 November 2009. Fifty-four participants made proposals on how to promote pharmaceutical care as a successful strategy to improve outcomes for patients receiving medicinal therapy in Europe and to develop indicators for the quality of pharmaceutical care in Europe with relevant stakeholders in the context of a project co-ordinated by the EDQM. The survey report (2009) “Pharmaceutical care: where do we stand – where should we go?” giving key concepts in pharmaceutical care, quality assessment of pharmaceutical care in Europe, sources of information was released and will serve as a basis for the project mentioned above.

The committee of experts organised the expert workshop “Promoting standards for the quality and safety assurance of pharmacy-prepared medicinal products for the needs of patients” with the support of scientific experts from the health authorities and professional associations on 24 September 2009. Forty-five participants from 21 member states identified criteria and key elements of good practices for the quality and safety assurance of non-industrial medicinal products prepared in pharmacies in Europe.

The committee of experts’ survey on quality and safety assurance standards for pharmacy preparations (2009) showed that regulations vary considerably in Europe for products prepared by healthcare establishments for special patients’ needs that cannot be covered by medicinal products with a marketing authorisation.

The committee of experts prepared in 2009 a compilation of information on the impact of traditional Chinese medicine on pharmaceutical practice in Europe with a view to organising an expert workshop in 2010 and discussing aspects relevant to public health.

Numerous practical training sessions were organised

The Committee of Experts on counterfeiting of medical products and related crimes is carrying out a practical programme of activities to help officials manage and prevent public health risks posed by counterfeit medicines and similar crimes. The EDQM is providing training sessions for multisectorial teams of member states’ officials on how to combat counterfeit medicines and to protect public health. On 16-17 June 2009, the 4th European basic training session was organised, hosted by the Italian Medicines Agency (AIFA). In total 90 officials from health, police and customs authorities from 35 member states have been trained since 2007.

Evaluation immediately, 3 and 6 months after training revealed not only improvement of the acceptance but increased consistency of the ratings between the different sectors. In order to foster sustainability and efficiency of the training effect, the training concept was adapted to be delivered to local and regional groups of trainees. The first local training session for 35 multisectorial officials was co-organised on 18-19 June 2009 by the AIFA. In 2009, the EDQM developed procedures to give assistance in a structured manner to member states organising local or regional training.

A new international Convention under elaboration to criminalise counterfeiting of medicines

Supported by intersecretariat co-operation between the EDQM and the Council of Europe, DG Human Rights and Legal Affairs, Criminal Law Division, and multidisciplinary expertise, the Council of Europe member states finalised and negotiated the Council of Europe draft convention on counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME convention). This convention is the first binding instrument in the criminal law field focused on public health protection. In 2010, the Council of Europe Committee of Ministers will be invited to formally adopt the above convention.

International co-operation with the United Nations

The workshop “Medicines on the net-risks and benefits” was co-organised by the EDQM and the Criminal Law Division with the support of international panellists at the 2009 Sharm El Sheikh UN Internet Governance Forum (IGF) on 16 November 2009. With an international audience, this workshop improved the visibility of the activities of the Council of Europe and its EDQM to combat counterfeiting of medical products, which are often marketed via the Internet, and to protect access to safe medicines irrespective of the dispensing pharmacy.
1.8 Cosmetics and Food Packaging

Since 1 January 2009, the EDQM has been engaged in efforts to improve consumer health protection in Europe. Our activities are aimed at the development of harmonised approaches to ensure product quality and safety in two areas:

- Cosmetic products including borderline products such as tattoos and permanent make-up
- Packaging materials for food and pharmaceutical products

In 2009, the committees of experts responsible for these activities held their inaugural meetings, which were attended by representatives of the EU commission, the European Food Safety Authority (EFSA) and Council of Europe member states.

During the 3-year period of their initial mandate, these committees will follow-up on specific topics.

In the field of cosmetics, preparatory work has started for a positive list of colourants for tattoo inks which should be compiled in co-operation with the safety evaluators of participating national authorities. Furthermore, previous work will be continued on safety monographs for active cosmetic ingredients. These monographs provide information on substance properties, general toxicity and their use in marketed products as well as expert opinion and experience in dealing with the substances to assist national regulatory and other health and safety professionals.

The committee of experts on cosmetic products designated rapporteurs for the following new topics: cosmetic products for newborn and young children, so-called “organic” or “natural” cosmetics”; exploring the creation of a pan-European network of official (or independent) laboratoires (similar to the Official Medicines Control Laboratories, OMCL) was also an objective to be set. For the purpose of this network, a European survey was initiated to collect information about national programmes and structures linked to cosmetics surveillance

Priority was given to the committee of experts on packaging materials for food and pharmaceutical products to work on metals and alloys that are used in food packaging and also in the manufacture of articles with food contact.

A general safety clause according to Framework Regulation 1935/2004/EC applies to these materials; however, no specifications have been established yet at the European level. Therefore, the objective of the current work is to set safe limits for the (unintentional) release of metallic elements from any such materials and to implement suitable analytical tests to check compliance of materials with the corresponding limits.

Paper and board, printing inks for packaging materials, coatings, elastomers such as silicons and rubber are amongst other non-regulated materials at the European level for which the Council of Europe has already established substance inventories and recommendations for migration testing. The Committee will assess the need to further update existing documentation and to implement procedures for the safety evaluation of relevant substances, principally collect and evaluate quality and safety data on packaging materials, especially, where materials are used for both foodstuffs and pharmaceuticals or where such use is technically feasible for pharmaceuticals in addition to foodstuffs. To this end, the Committee established contact with manufacturer associations and other stakeholders and open consultations will be organised as of 2010.
2. SUPPORT ACTIVITIES

2.1 Administration, finance: Key issues for 2009

The work of the Administration and Finance Division covers:
• preparing and monitoring the annual EDQM budget and verifying that financial transactions are in conformity with the financial regulations of the Council of Europe;
• ensuring all EDQM contracts established with third parties are in conformity with the requirements of the Council of Europe;
• administering and recruiting the EDQM’s staff and seconded personnel in collaboration with the Council of Europe’s Human Resources Directorate; and
• processing customer orders for EDQM products and dealing with related queries.

In 2009 the EDQM undertook a survey of 8700 EDQM customers (active during 2008) and some 800 customers replied – about 8% of the active client base. The survey was quite positive and some of the highlights related to the sales team are set out below:
- Satisfaction that telephone queries are dealt with quickly and efficiently 3.59/5.
- Satisfaction with the completeness of the replies provided on availability, open/recently dispatched orders and complaints via the Helpdesk 3.24/5.
- Satisfaction with the EDQM’s approach to e-mails at orders@edqm.eu 3.5/5.
- Satisfaction with the EDQM’s management of the client’s account 3.5/5.

-Satisfaction with the ordering process 3.7/5.

The survey also identified a number of areas for improvement, including:
- the information and layout of the web-site related to ordering and registration of products;
- the online shop in terms of functionality;
- the layout of order confirmation e-mails
- the ability to download invoices from the web or send them by e-mail
- having nominated account staff for specific customers.

Most of these issues will be dealt with as part of the EDQM’s ongoing implementation of an Enterprise Resource Planning System for sales and distribution in 2011. The EDQM will also continue to reflect on the feasibility of nominating dedicated account managers.

2.2 Quality Assurance and Environment Management Systems

EDQM receives ISO 9001:2008 Certification

The EDQM continued to develop its Quality Management System based on the ISO 9001 standard (general administration), ISO 17025 (laboratory), ISO Guide 34 (Reference Standards) and ISO Guide 43-1 (Proficiency Testing Scheme) in order to guarantee an optimal service to its stakeholders whilst improving the efficiency of working methods.

This work led to official ISO 9001:2008 certification delivered by Afnor Certification (AFAQ) after a comprehensive three-day certification audit process.

The EDQM is now certified as meeting the requirements of ISO 9001:2008 for the following activities:
“Evaluation of applications for certificates of suitability to the monographs of the European Pharmacopoeia (initial, revisions and renewals), granting of certificates, and management of the inspection programme of manufacturing sites and associated brokers”.

This certification of compliance with ISO 9001:2008 recognises that the policies, practices and procedures of our organisation ensure consistent quality in the services and products we provide to our customers and stakeholders.

The EDQM is committed to extend the scope of its certification in the following years.

Review of safety data sheets

The EDQM continued and completed a full review of its 2400 safety data sheets (SDSs) in order to be compliant with the REACH regulation (1907/2006/EC) and introduced a new electronic system in order to deliver a better service to our users. It provides these SDSs in four European languages (English, French, German and Spanish). Other languages will be added in future.
2.3 Information technology (e.g. Internet, publishing, EDRMS)

A Website (www.edqm.eu) with additional content

In 2009 the EDQM continued to develop its website: www.edqm.eu. This website has become the EDQM’s main means of communication.

During the past year, the number of visitors and visits to the website continued to increase, reaching a monthly average of 22 000 visitors (+10%) and 69 000 visits (+11%, statistics obtained using AWSTATS software).

The content on the website was supplemented by information on activities in blood transfusion, organ transplantation and healthcare.

Dynamic publications activities

The Publications unit is mainly responsible for the technical and administrative aspects of the publication of the European Pharmacopoeia, the forum Pharmeuropa and related publications.

The last 3 supplements (6.6 to 6.8) of the 6th Edition of the European Pharmacopoeia were published in 2009, comprising 1090 pages for the English version and 1142 pages for the French version. The 6th edition (including supplement 6.8) therefore consists of 2117 monographs (including those on dosage forms) and 331 general texts (including general monographs and general methods of analysis).

The 4 issues of Pharmeuropa published in 2009 contained 158 texts for enquiry and for general information, comprising 640 pages for the English version and 666 pages for the French version. One issue of Pharmeuropa Scientific Notes containing 6 scientific articles in English was published in 2009, before this publication was merged with Pharmeuropa Bio. One issue of the new publication Pharmeuropa Bio & Scientific Notes containing 7 scientific articles in English was published.

The Publications unit also provides support for the publication of other documents of the EDQM. In 2009, documents were prepared in English on counterfeit medicines (Counterfeit Medicines: Facts and Cases Studies; Counterfeit Medicines: Practical Advice - Exercises; Counterfeit Medicines: Practical Advice - Cases Studies) and on pharmaceutical care (Pharmaceutical Care: Where Do We Stand, Where Should We Go). The document in English 'Biological Substances Submitted to the Official Control Authority Batch Release' and 2 issues of the catalogue of reference standards (now available only by downloading from the EDQM website) were also prepared in 2009.

In addition, the Publications Unit continued its work on the conversion of monographs to a more concise editorial style and maintained lists of data needed for the publication work.

The Spanish version of the European Pharmacopoeia now contains more than 2000 texts of the 6th Edition and its supplements and is available to subscribers to the current online version. New translations are put online on a monthly basis. The approval process by the competent national authority (AEMPS: Agencia Española de Medicamentos y Productos Sanitarios) has started.

An Archive version containing all previous editions of the European Pharmacopoeia is now available as a service to subscribers to the current online versions.
2.4 Communications, landmark events

Rapid and reactive communication to keep the EDQM’s partners better informed

The EDQM regularly publishes press releases on news items. Fourteen press releases were distributed electronically in 2009 to various media, authorities and partner associations all over the world.

An “EDQM Newsletter” was also published and distributed electronically to provide direct access to important information on the website. This newsletter is available free of charge to subscribers (8500 subscribers in 2009). Since 2007, users have been able to access RSS feeds through the “NEWS” page of the website. This is yet another means provided by the EDQM to help users keep up with the latest developments.

Regularly organised events on topical subjects

Various events took place on technical and scientific subjects related to the European Pharmacopoeia. A symposium was organised on herbal drugs and herbal drug preparations (Vienna, Austria, September 2009) to present the progress that had been made in analytical techniques used for the quality control of herbal drugs, new test methods and recent developments in this area. Other events were the organisation of two training sessions, in Strasbourg, France (July 2009) and in Sofia, Bulgaria (December 2009). These training sessions, which are always greatly appreciated by users of the European Pharmacopoeia, were supplemented by individual sessions with EDQM staff members for personalised interaction with the participants. To promote the Spanish version of the 6th Edition of the European Pharmacopoeia, the EDQM also participated in the ExpoPyBI 2009 (XII Exposición de la Farmacia y Bioquímica Industrial) organised by the Asociación Argentina de Farmacia y Bioquímica industrial (Buenos Aires, Argentina, October 2009).

In September 2009, the EDQM jointly organised a two-day conference, followed by tutorials, on the quality of API with WHO and DIA in India. This conference highlighted important aspects relevant for the quality of APIs, relevant for dossier assessment, inspections and pharmacopoeial requirements, and emphasised close collaboration of the European Pharmacopoeia and the EDQM’s Certification of Suitability procedure with European regulatory authorities and WHO.

As a corollary of inspection campaigns carried out in China for the procedure for Certification of Suitability to Monographs of the European Pharmacopoeia, a training session for representatives of Chinese manufacturers was organised (Shanghai, China, November 2009) in partnership with the China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE) and the Chinese Ministry of Commerce.

Other specific events were organised on subjects such as the batch release procedure for vaccines for human use and “CombiStats™ software”, developed by the EDQM to perform the calculations described in chapter 5.3 of the European Pharmacopoeia.

In 2009, communication and public relations efforts were reinforced as regards events for the general public such as the 14th World Blood Donor Day (14 June 2009) and the 11th European Day of Organ Donation and Transplantation (4 October 2009, Berlin, Germany) organised in collaboration with the Deutsche Stiftung Organtransplantation and the European Commission (EU). This event was an opportunity to strengthen European co-operation in the area of organ donation, increase the levels of awareness of the different issues, facilitate the exchange of information, and above all to celebrate and express thanks to all the donors and their families for their dedication, generosity and courage. The events for the general public were organised at the Brandenburg Gate in Berlin and were a huge success (250 000 visitors). They were well covered by the media (television, radio) and enhanced the visibility of the EDQM and the Council of Europe in the eyes of the general public.

In partnership with the Paul-Erhlich-Institut, a technical symposium on the Optimal Clinical Use of Blood Components was organised in Kreuth, Germany, in April 2009, and the EDQM participated for the first time in the Congress of the International Society of Blood Transfusion (ISBT, Cairo, Egypt, March 2009), which enabled it to promote the 14th Edition of the Guide to the Preparation, Use and Quality Assurance of Blood Components.

Training sessions were organised for persons involved in the fight against counterfeit medicines (police, customs, inspection authorities, etc.). A workshop on “Medicines on the net—risks and benefits” was co-organised by the EDQM and the Criminal Law Division of the Council of Europe, as part of the UN Internet Governance Forum (IGF), in Sharm El Sheikh, Egypt, November 2009).

Throughout 2009, the EDQM actively participated in celebrating the 60th anniversary of the Council of Europe, publicising the values and missions of the organisation at its meetings and events.

In keeping with its policy of openness and transparency, the EDQM welcomed various groups of visitors to its premises.
2.5 International collaboration

Exchanges and collaboration at the international level

In the field of international collaboration, the EDQM participated in or organised over 60 consultation meetings with European/international institutions and professional associations.

Two bilateral meetings were also held with national authorities (South Africa and the Russian Federation).

In December 2009, the EDQM organised for the first time a special meeting for observers to the Convention on the Elaboration of a European Pharmacopoeia. Observers can participate in the scientific work of the Commission to benefit from European experience in this area and to gain access to work on the quality control of medicines and the methods of analysis used and other activities of the EDQM. The objective of this meeting was to provide a forum for discussion, to exchange experiences and views and to identify areas of common interest. At the end of the meeting, participants agreed on a number of possibilities for a strengthened collaboration, for example, the elaboration of monographs, participation in PTS studies and other laboratory activities.

The EDQM is also actively participating in a pilot project of collaboration and information-sharing between Europe, Australia and the USA, for the inspection of manufacturing sites of active substances. In this context, bilateral confidentiality agreements have been signed with the US FDA and the Australian TGA in order to share non-public information regarding inspections. Additionally, the EDQM has interacted with the PIC/S.

Finally, EDQM staff participated in numerous international conferences and workshops in the fields of the quality of pharmaceutical substances, blood products, organ transplantation, combating counterfeit medical products and other EDQM activities.

Some of these events, of worldwide interest, were organised in partnership with other organisations such as the European Medicines Agency (EMA), the World Health Organization (WHO) and the professional pharmaceutical association, Drug Information Association (DIA). These events provided an opportunity to exchange scientific knowledge and promote quality control of medicines all over the world.
List of EDQM committees

- **THE EUROPEAN PHARMACOPOEIA COMMISSION**

The Commission was set up in 1964 in accordance with the Convention on the Elaboration of a European Pharmacopoeia. In 2010, its membership comprised 36 states and the European Union (EU). The Commission sets the work programme and defines the quality standards for all our medicines and their components by appointing national experts authorised to work on the elaboration of these standards. 19 permanent groups of experts and 46 “Ad hoc” working parties have been set up by the Commission to carry out the Ph. Eur. work programme. More than 2000 texts containing quality standards have already been elaborated, adopted and implemented. These texts are constantly being revised to keep pace with technical and scientific progress in production and quality control. The European Pharmacopoeia, which is now in its 6th Edition, is essential to the protection of public health; it is intended for professionals working in the area of medicines, who refer to it constantly.

- **THE BIOLOGICAL STANDARDISATION PROGRAMME (BSP) Steering Committee**

The BSP focuses on the standardisation of the methods and tools for the quality control of biologicals by establishing reference standards and validating new methods, in particular such methods where the use of animals is reduced, refined or replaced (3R initiative). The activities are supervised by the BSP Steering Committee.

- **NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES (OMCL)**

More than 40 European countries have been participating in the activities of the OMCL network since 1994; these activities are co-ordinated by the EDQM. The role of this network is to ensure the consistent quality of medicines marketed in the member states and to contribute to the mutual recognition of the results of quality control testing of medicines by these states. Major decisions are taken by the annual plenary meetings of the OMCL network. Advisory groups prepare and ensure the implementation of the annual work programme. There are two levels of collaboration within the network:

- general activities involving all of the member states of the Convention and the observer states; these general activities cover work in the area of quality management systems, such as audits and proficiency testing studies (PTS) as well as market surveillance studies (MSS). These activities are prepared and followed by the General OMCL Advisory Group (AdGEON);
- activities restricted to the European Union (EU) and the European Economic Area (EEA) concerning products with a centralised marketing authorisation (CAP), products authorised according to the mutual recognition or the decentralised procedure (MRP/DCP) and the Official Control Authority Batch Release (OCABR) system for biological products (human and veterinary). This latter activity also involves Switzerland. For the CAP and the OCABR activities advisory groups ensure the continuity of operation in the interval between annual meetings of each specific network. These activities involve the European and national authorities. The OMCL network also participates in investigations into fraudulent medicines.

- **CERTIFICATION OF SUITABILITY TO PH. EUR. MONOGRAPHS**

The activities associated with the procedure of Certification of suitability to Ph. Eur. monographs are guided by a Steering Committee and two Technical Advisory Boards (TAB). The three Cs (Consultation, Coordination, Cooperation) that characterise the procedure are implemented by a steering committee consisting of representatives of the authorities. The Steering Committee takes decisions on general policy, examines and comments on matters brought to its attention by the Technical Advisory Boards, adopts guidelines and the inspection programme and co-ordinates questions amongst the represented parties. It is also responsible for appointing assessors as well as the Technical Advisory Boards and their Chairs. A network of about 80 assessors and 30 national inspectors participate in the work required for the evaluation of files and the inspection of manufacturing sites.

- **EUROPEAN COMMITTEE ON BLOOD TRANSFUSION (CD-P-TS)**

This steering committee supervises the work of a number of individual projects and Working Groups, for example:

- European Database of Frozen Blood of Rare Groups,
- Blood Donor Management,
- Ad-hoc Working Group “Guide to the Preparation, Use and Quality Assurance of Blood Components”.

- **EUROPEAN COMMITTEE ON ORGAN TRANSPLANTATION (CD-P-TO)**

The Steering committee supervises the activities of the Ad-hoc Working Group “Guide to Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells” as well as of a number of individual projects on topics such “Non-heart-beating donors”, “Double listing on transplantation waiting lists” and “Cooperation of states from the Black Sea Area in organ transplantation”.

- **EUROPEAN COMMITTEE ON PHARMACEUTICALS AND PHARMACEUTICAL CARE (CD-P-PH)**

The Steering Committee supervises the programmes of activities of its subordinate committees:

- Committee of Experts on the classification of medicines as regards their supply (CD-P-PH/PHO),
- Committee of Experts on quality and safety standards for pharmaceutical practices and pharmaceutical care (CD-P-PH/PC),
- Committee of Experts on minimising public health risks posed by counterfeiting of medical products and related crimes (CD-P-PH/CMED).
CONSUMER HEALTH PROTECTION COMMITTEE (CD-P-SC)

The Committee is responsible for managing the work programme and decision-making. It has 2 subordinate bodies that examine health-related issues and evaluate the risks, draft reports and recommendations for regulatory approaches:

- Committee of Experts on Packaging Materials used for Food and Pharmaceutical Products (P-SC-EMB),
- Committee of Experts on Cosmetic Products (P-SC-COS).

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