







HIGHLIGHTS 2022

EDQM
annual report

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
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2022 HIGHLIGHTS
EDQM ANNUAL REPORT

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

Council of Europe, EDQM

French edition

Les points forts de 2022 – Rapport annuel de l'EDQM

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

7, allée Kastner
CS 30026
F-67081 Strasbourg – France
Tel.: +33 (0)3 88 41 30 30
Fax: +33 (0)3 88 41 27 71
https://go.edqm.eu/HDpubs

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Message from the Director

In 2022, the EDQM's ability to change, benefit from transition and adapt to new circumstances was crucial to the success of its activities. We became a Major Administrative Entity within the Council of Europe organisational structure, reporting directly to the Secretary General. Changes in key management personnel were made. The transition to the 11th Edition of the European Pharmacopoeia was marked by a milestone conference held in September in hybrid format. The war in Ukraine resulted in the exclusion of the Russian Federation from the Council of Europe and the suspension of the Russian Federation and Belarus as an EDQM observer to the European Pharmacopoeia Commission. All this took place against a backdrop of new global challenges in almost all areas of life during the post-pandemic period, where uncertainty is inevitable.

Old truths have been replaced with new concerns, risks and dangers. Not least of these are the widespread supply chain issues affecting medicines, which raise serious questions regarding resilience, sustainability and independence in our societies. We are already responding to this difficulty, contributing to our broader mission to protect public health by engaging with a global community of experts and stakeholders. Resolving and preventing drug shortages in collaboration with European and international partners will continue to be one of our most important areas of work for the foreseeable future, as this matter falls squarely within the EDQM's mandate.

The EDQM is therefore looking resolutely forward. On the strength of past successes and keenly aware that uncertain times require a plan for the future, we are devising a roadmap, the "EDQM 2030" strategic initiative, to future-proof our operations and activities.

To inform our planning process for the next mid-term strategy, we conducted surveys and targeted consultations, and analysed the results of past strategies. Our goal is to devise a new strategic framework that comprises the EDQM's vision, mission, and principles and is based on the fundamental values of the Council of Europe, our mother organisation.

At this early stage it is already clear that stakeholder engagement must have a priority role in this and all future undertakings. Cohesion within our organisation and engagement with external stakeholders are key to achieving our goals and will contribute to coping with an unpredictable future.

In conclusion, our ability to work together, both internally and externally, will be a determining factor in the success of the EDQM's endeavours. Our people, our teams and our organisational culture are essential to achieving our shared objectives. We remain committed to increasing our global outreach and impact by enhancing stakeholder engagement, modernising our working methods and by increasing the quality and efficiency of our contribution to public health. As we move forward, we will continue to be guided by our core values of integrity, respect and professionalism, striving for a world where better health protection for everyone is just a stepping stone to better health for all.

Thank you for your continued support and partnership in this important work.

Petra Doerr, PhD
Director, EDQM, Council of Europe

2022 at a glance

Outreach

26 events organised

10 000+ attendees from over **100** countries

7 200+ views of recorded sessions

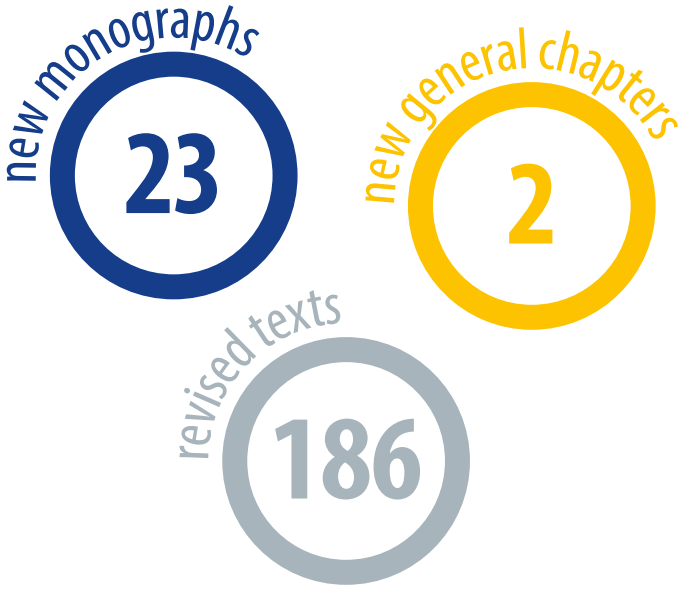
11 new publications

European Pharmacopoeia Commission members and observers (2022)

* EU: European Union; TFDA: Taiwan Food and Drug Administration; WHO: World Health Organization

Quality and use of medicines

European Pharmacopoeia activities



Selected European Pharmacopoeia texts adopted in 2022

One new general chapter: *5.26. Implementation of pharmacopoeial procedures*

One harmonised general chapter: *2.2.46. Chromatographic separation techniques*

Two revised general monographs: *Substances for pharmaceutical use (2034)* and *Pharmaceutical preparations (2619)*

Two revised harmonised monographs: *Paraffin, white soft (1799)* and *Paraffin, yellow soft (1554)*

Biological Standardisation Programme achievements

Total number of projects	20
Concluded projects	1
Projects still running	19

Standard Terms Database Key figures

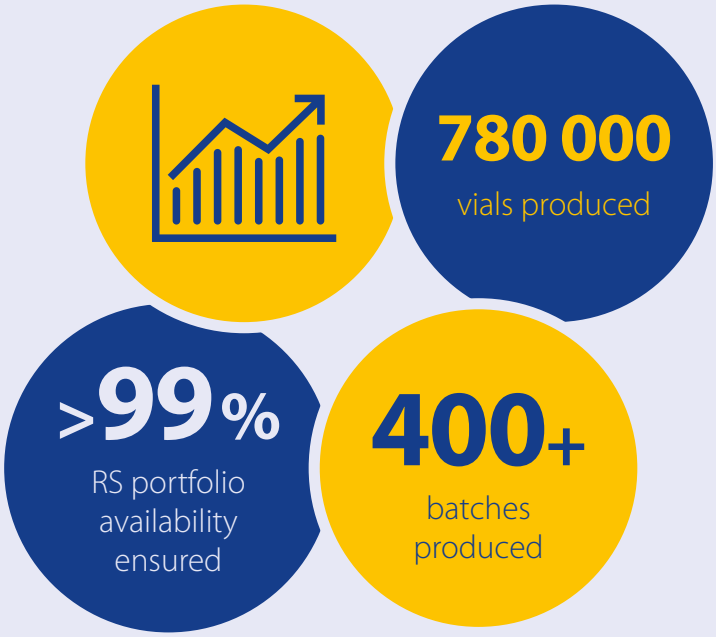
Registered users	40 000
Individual standard terms concepts	1 048
Entries	31 000
Languages	35

European Paediatric Formulary

PaedForm Online Platform

New users	Registered users
442	1 368

Reference standards (RSs)



Batches of Ph. Eur. RSs adopted in 2022

New RSs
48

Replacement RS batches adopted
288

Countries to which the EDQM distributed RSs directly
131

RSs available
3151

Certification of suitability to the European Pharmacopoeia monographs (CEP)

Total valid and issued CEPs in 2022

New certificates
459

Revised certificates
1532

Valid certificates
5997

Official Medicines Control Laboratories (OMCLs)

The OMCL Network general activities

Mutual Joint Audits (MJAs) conducted **16**

Proficiency Testing Scheme (PTS) studies carried out **10**

Market Surveillance Studies (MSSs) launched **2**

Substances of human origin

Organs, tissues and cells

Network of National Focal Points on Travel for Transplantation (NETTA)

35
designated national focal points (NFPs)

Information from almost
800
patients included in the Registry of International Travel for Transplantation Activity (RITTA)

Blood transfusion

7
B-PTS studies conducted

55
participating laboratories (on average, per study)

Nucleic Amplification Technique (NAT)
B-PTS062 HBV/HCV/HIV NAT
B-PTS044 HEV NAT

Serology
B-PTS063 anti-HCV
B-PTS064 HBsAg/Anti-HBc
B-PTS065 anti-Treponema
B-PTS066 anti-HIV/p24

Immuno-haematology
B-PTS067 ABO, Rhesus, extended phenotyping and irregular antibodies

Pharmaceuticals and pharmaceutical care

37
recommendations on the classification of medicines and their supply conditions (prescription and non-prescription status) established by CD-P-PH/PHO and entered into the Melclass database

Cosmetics

COS PTS studies

2 completed **1** running

COS MSS

1 running **1** initiated

Quality management system (QMS)

The EDQM continued to invest in its QMS as a priority matter in 2022, with a specific focus on European Pharmacopoeia reference standards. The EDQM also worked to improve its ISO 9001 governance, with the audit by the certification body — postponed from December 2021 to February 2022 — resulting in the renewal of the EDQM's ISO 9001:2015 certificate. The EDQM accreditation certificate according to ISO 17025:2017, covering 21 tests including nuclear magnetic resonance spectroscopy (NMR) and quantitative nuclear magnetic resonance spectroscopy (qNMR), was also confirmed after an audit by the relevant bodies. The EDQM's customers and interested parties can therefore have faith in the consistent quality of the goods and services provided by the EDQM, as well as its commitment not only to maintain, but also to continually improve quality standards for all its activities.

Co-operation with international partners

The EDQM places high value on its co-operation with a range of international partners. None of its activities would be possible without the support of national pharmacopoeia authorities (NPAs), national competent authorities (NCAs), official medicines control laboratories (OMCLs), inspectorates and more than 2 000 experts in pharmaceutical sciences and practices, as well as specialists in healthcare issues such as blood transfusion, organ transplantation, pharmaceutical care and quality and safety of cosmetics and food contact materials, from around the globe. Similarly, as an integral part of the European regulatory network, the EDQM meets and collaborates regularly with national regulatory authorities and the European Commission, as well as its technical agencies, such as the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC).

Co-operation with national authorities

Representatives of NCAs are also members of the European Phamacopoeia Commission (EPC) and its expert groups and working parties (currently numbering just over 60). NCAs also take part in the work of the European Pharmacopoeia (Ph. Eur.) by submitting requests for revision and reviewing draft texts published in *Pharmeuropa* online.

The 2022 annual meeting of the NPAs, initially foreseen to take place in Helsinki, was replaced by a hybrid meeting. In addition, monthly virtual meetings were held (see "The European Pharmacopoeia", below).

The General European OMCL Network (GEON) Annual General Meeting was held on the premises of the Council of Europe, in Strasbourg, from 13 to 17 June 2022. Over 230 participants – from 36 countries and representing 60 OMCLs – attended, including representatives from the Malta Medicines Authority, participating in the meeting for the first time (see "The European Network of Medicines Control Laboratories", below).

Assessors and inspectors from NCAs contribute to the assessment of applications for Certificates of suitability (CEPs) and the associated inspection programme of manufacturing sites of active substances.

NCAs also represent their member states in the eight intergovernmental committees for which the EDQM ensures the secretariat, and in this capacity contributed in 2022 to the elaboration of the deliverables of these committees in the form of recommendations or resolutions adopted by the Committee of Ministers of the Council of Europe, or guidance documents.

The EDQM has observer status to the Heads of Medicines Agencies (HMA), the network of the heads of the NCAs whose organisations are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area (EEA). In particular, in 2022 the EDQM continued to work with the HMA Working Group of Enforcement Officers (HMA-WGEO) on the issue of falsified medicines. It attended the two meetings of the Working Group, at the levels of both OMCLs and the Committee of Experts on minimising the public health risks posed by falsified medical products and related crimes (CD-P-PH/CMED), where information was shared between health and law-enforcement authorities on cases involving the use of falsified medicines. The EDQM is also a member of the HMA Working Group of Quality Managers (WGQM) and maintains relations with the Non-Prescription Medicinal Products Task Force of the Co-ordination Group for Mutual Recognition and Decentralised Procedures-Human (CMDh) to explore convergence on the classification of medicines as regards their supply.

In the field of cosmetics, the EDQM is an observer to the Platform of European Market Surveillance Authorities for Cosmetics (PEMSAC) open sessions.

The EDQM is also an observer in the European Commission's working group on food contact materials and in the Joint Research Centre's Taskforce on testing conditions for kitchenware articles.

Involvement in international harmonisation

Globalisation and expansion in international trade have created a growing need to develop global quality standards for medicines. The EDQM has a long-established collaboration with sister pharmacopoeias to harmonise pharmacopoeial monographs. The most prominent example in this area is the Pharmacopoeial Discussion Group (PDG), jointly run with the United States Pharmacopeia (USP) and the Japanese Pharmacopoeia (JP), and to which the World Health Organization (WHO), with its International Pharmacopoeia, is an observer. The year 2022 saw the roll-out of a one-year pilot expansion project, in which the Indian Pharmacopoeia Commission was invited to participate in the PDG's activities as of October. It is hoped that this initiative will promote global convergence in pharmacopoeial standards.

In addition, the EDQM continues to play a crucial role in the WHO International Meeting of World Pharmacopoeias (IMWP).

The EDQM continued to participate in the Innovative Medicines Initiative's (IMI) VAC2VAC ("vaccine batch to vaccine batch comparison by consistency testing") project by contributing to its Scientific and Ethics Advisory board. The overall objective of the project is to provide proof of concept of the consistency approach for batch release testing of established vaccines with the aim of replacing some of the *in vivo* methods still used to test human and veterinary vaccines. With the end of the VAC2VAC project in 2022, the *in vitro* methods developed and qualified/validated within the initiative may be further evaluated after their publication through their inclusion in the Biological Standardisation Programme (BSP) and ultimately included in the Ph. Eur., depending on the outcome of the BSP studies.

The EDQM also participates in another global international harmonisation effort aimed at finding alternatives to the use of animals to test biological products. This effort is led by the National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs, UK) on behalf of WHO, with a view to integrating the 3R principles into the guidelines published by the WHO Expert Committee on Biological Standardization (ECBS). The EDQM contributes to the NC3Rs working group and focus groups in order to promote the use of EDQM 3R achievements and ongoing 3R activities as a basis for further revisions of the WHO guidelines.

In addition, as an observer to the Assembly of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the EDQM continues to play an active role in international harmonisation and collaboration activities. EDQM scientists actively participate in the development and revision of ICH guidelines that are important for the quality of medicines, including Q3C, Q3D, Q3E, Q2/Q14, Q5A, Q9 and Q13, and are major contributors to ICH discussion forums such as the Quality Discussion Group (QDG) and the Generics Discussion Group (GDG).

Participating in the QDG is of particular strategic relevance for the EDQM as this group is a think-tank for matters related to the quality of medicines and associated harmonised guidance for the ICH.

The same holds true for the EDQM's engagement in the International Pharmaceutical Regulators Program (IPRP), where it is a member of the Management Committee, co-chairs the Quality Working Group and takes part in the Reliance discussion group.

The EDQM is also involved in the veterinary counterpart to the ICH, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Veterinary Use (VICH), and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) (see also "Certification of suitability to the Ph. Eur. monographs" and "Blood transfusion", below).

All the activities in the eight intergovernmental committees address public health concerns and, more specifically, focus on access to and rational use of high quality and safe health products through the elaboration of standards, guidelines and sharing of best practices. To enhance harmonisation of practices in the field of pharmaceutical care, efforts in 2022 included a survey involving seven countries of the South-eastern European Health Network (SEEHN) and collecting data on the implementation of pharmaceutical care and related services in hospital and community care settings, as described in Resolution CM/Res(2020)3.[1]

With their positive impact on the availability and use of good quality medicines and healthcare worldwide, these are obviously an important and valuable part of the EDQM's activities.

The EDQM works with internationally renowned experts to regularly review and update common technical standards in the field of substances of human origin (SoHO). These include the *Guide to the preparation, use and quality assurance of blood components* (commonly referred to as the "Blood Guide"; 20th Edition, 2020) and Good Practice Guidelines for blood establishments (GPGs for BEs), the *Guide to the quality and safety of organs for transplantation* (8th Edition, 2022) and the *Guide to the quality and safety of tissues and cells for human*

1. Resolution CM/Res(2020)3 on the implementation of pharmaceutical care for the benefit of patients and health services, https://go.edqm.eu/CMRes20203.

application (5th Edition, 2022). The GPGs are now referenced in Commission Directive 2016/1214, ensuring that BEs in all European Union/European Economic Area (EU/EEA) member states take into account the standards and specifications set out in the GPGs when implementing their quality systems.

These reference works are internationally recognised as gold standards in the field.

In addition, to ensure consistency in approaches, the EDQM plays an active role in the work of the United Nations Office on Drugs and Crime (UNODC) with regard to the fight against organ trafficking.

Co-operation with the EU and the EMA

The EDQM works closely with the European Commission, communicating regularly to share progress reports on work programmes and potential developments in EU legislation.

It is also a member of the European Union Network Data Board (EUNDB), created at the end of 2014 and co-chaired by the EMA and an NCA, and of the International Standards on Identification of Medicinal Products in the EU Task Force (EU ISO IDMP, created in 2015), including the corresponding subordinate groups.

The EDQM works closely with the EMA and national authorities to ensure continued consistency of EDQM activities with the approaches of licensing authorities, for example regarding the Ph. Eur. and Certification activities. It has observer status with a number of EMA bodies, including the Committee for Advanced Therapies (CAT), the Herbal Medicinal Products Committee (HMPC), the joint CHMP/CVMP Quality Working Party (QWP), the Good Manufacturing and Distribution Practice Inspectors Working Group (GMDP IWG), the Biologics Working Party (BWP) and the Immunologicals Working Party (IWP). Members of EMA working groups (for which the EMA provides the secretariat) or of the EMA Secretariat itself are observers to some of the EPC groups of experts and working parties, for example 6B (human blood and blood products), 15 and 15V (vaccines and sera for human use and veterinary use), and the BSP Steering Committee.

The EDQM and the EMA communicate regularly on the Certification procedure: the EMA is a member of the Certification Steering Committee, and channels for regular communication are in place for the elaboration of technical documents as well as for the inspection programme and its outcomes. The two bodies also continue to work together on running a long-established Centrally Authorised Product (CAP) Sampling and Testing Programme for products for human and veterinary use (see also "The European Network of Medicines Control Laboratories", below).

The long-standing close technical collaboration with the European Commission continued in 2022, with the EDQM co-ordinating a number of SoHO activities (the Blood Quality Management [B-QM] and Blood Proficiency Testing Scheme [B-PTS] Programmes, the Blood Supply Contingency and Emergency Plan [B-SCEP] Project, the Quality Management and Serious Adverse Reactions and Events [SARE] training sessions in the field of tissues and cells and B-QM, the project on Harmonising Activity Data Collection Exercises in the Field of Tissues and Cells in Europe), and through its analysis of and reporting on EU SARE related to blood components and tissues and cells.

The draft proposal for a new EU regulation on the safety of blood, tissues and cells was published by the European Commission in July 2022. This draft contains the proposal to make the EDQM an expert body with, in particular, a cross reference to the EDQM's Blood and Tissues & Cells Guides in the legislative cascade.

In 2022, the EDQM actively participated and contributed to the impact assessment and stakeholder consultation organised by the European Commission, on the upcoming revision of the EU pharmaceutical legislation.

The EDQM continues to participate as an observer at meetings of the EU NCAs for blood, tissues and cells, and organs. National authorities also take part in the work of the European Steering Committee on Blood Transfusion (CD-P-TS) and the European Steering Committee on Organ Transplantation (CD-P-TO) through their participation as steering committee members and through their submissions in the consultation for the guides on blood, tissues and cells, and organs. In addition, to ensure consistency in approaches, the EDQM actively participates in the EMA work cluster on blood products.

On consumer health issues, the EDQM continues to participate as an observer in meetings of the EU Working Group on food contact materials, of the Taskforce on kitchenware articles of the Joint Research Centre, and of the PEMSAC. The year 2022 saw the start of a dialogue with the European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), focusing on market surveillance of cosmetics and the contribution of the European Network of Official Cosmetic Control Laboratories (OCCLs, whose secretariat is ensured by the EDQM).

Co-operation on inspections

In 2022, the EDQM's Certification Department continued its active involvement in the activities of the International Active Pharmaceutical Ingredients (API) Inspection Programme and the PIC/S including the Expert Circle on APIs.

The Organisation also participated in the PIC/S Expert Circle on Human Blood, Tissues and Cells in the context of the revision of the "PIC/S GMP Guide for Blood Establishments" and ensured that the revised document published by PIC/S was harmonised with the text of the GPGs for BEs.

As was the case for many supervisory authorities worldwide, the COVID-19 pandemic continued to affect the EDQM Good Manufacturing Practice (GMP) inspection programme for manufacturers of active substances, because on-site inspections could not be performed until late 2022. In response to this situation, the EDQM performed a number of real-time remote inspections (RTEMIS) in collaboration with national inspectorates.

Co-operation with WHO

The EDQM co-operates extensively with WHO in a number of joint meetings and consultations. WHO is an observer to the EPC, while the EDQM:

- is an observer to the WHO Programme on International Nonproprietary Names (INNs);
- takes part in the WHO ECBS, with WHO participating as an observer in the meetings of the EDQM BSP Steering Committee, thus guaranteeing a smooth exchange of information;
- participates in the WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) (see also "Reference standards", below);
- plays a role in the WHO drafting group (oral poliovirus vaccine) and the WHO working groups (mRNA vaccines, etc.) to provide expertise on related topics;
- shares data and carries out joint inspections relating to the API Certification process.

The EDQM is responsible for establishing, monitoring and distributing WHO International Standards for Antibiotics (ISAs) and International Chemical Reference Substances (ICRSs) (for more details, see "Reference standards", below).

The EDQM also contributed to the activities of the COVID-19 Vaccines Global Access (COVAX) Regulatory Advisory Group (RAG),[2] in particular by providing expertise on the testing of COVID-19 vaccines, linked to its activities in the field of Official Control Authority Batch Release (OCABR) and quality assurance in vaccine manufacturing and testing. The Coalition for Epidemic Preparedness Innovations (CEPI), Gavi and WHO co-lead COVAX, with the United Nations Children's Fund (Unicef) as a key delivery partner, to ensure equitable access to COVID-19 vaccines.

Finally, the EDQM also collaborates with WHO in the fields of pharmaceuticals, pharmaceutical care, anti-falsification, blood transfusion and organ transplantation.

Co-operation with manufacturers, industry associations and other stakeholders

Stakeholders are invited to regular exchanges with the intergovernmental committees, and are consulted during the elaboration of standards. The consultation process takes place either within drafting groups, in which stakeholders are represented by experts in a given field, or through survey-based consultations of targeted stakeholders, such as patient, healthcare professional and donor associations.

The EDQM continues to hold annual bilateral meetings with industry associations to promote exchanges on all aspects related to the work of the EDQM and to collect feedback on its activities. Since the beginning of the COVID-19 pandemic, the EDQM has also organised regular meetings with all European industry organisations to keep them informed about the EDQM's business continuity plan and operating framework, and to discuss how the EDQM can help the pharmaceutical industry ensure a continued supply of quality medicines and support developers of COVID-19-related vaccines and medicines.

2. See https://epi.tghn.org/covax-overview/regulatory-advisory-group.

Initiatives in the context of COVID-19

Availability of and access to safe, good quality medicines for patients is more important than ever in the context of the COVID-19 pandemic. This is why the EDQM has prioritised the continuous supply of its products and services to support public health protection.

Throughout this period, the EDQM has openly shared knowledge, thus demonstrating its commitment to supporting not only competent authorities, health professionals and manufacturers and developers of medicines and vaccines, but also universities and research centres contributing to the wider global effort to combat the virus.

COVID-19 vaccine guidance, standards, quality control and related training

The EDQM has provided support in the form of guidance documents, quality standards and training materials, among others, since efforts to develop vaccines for COVID-19 began.

Official Control Authority Batch Release

In 2022, the EDQM and the OCABR Network built on the foundations laid the previous year, which included:

- a recommendation document for manufacturers on early method transfer;
- an OMCL competency list based on control techniques for the different categories of COVID-19 vaccine candidates enabling manufacturers to identify OMCLs for OCABR;
- new OCABR guidelines for Pandemic COVID-19 vaccines.

A total of four full guidelines (test list for OMCLs plus manufacturers' protocols) were available by the end of 2022. During the year, the full guidelines for *Pandemic COVID-19 vaccine (recombinant spike protein)* and *Pandemic COVID-19 vaccine (inactivated)* were finalised, and existing guidelines revised to cover newly authorised vaccines and variations to existing vaccines. This allowed the release of more than 1740 batches in 2022, representing billions of doses.

The OCABR guidelines were published at an early stage for transparency and to help anticipate the launch of each vaccine, thus allowing OMCLs and manufacturers to take the necessary steps to prepare for OCABR and preventing delays while still ensuring the quality and safety of the vaccines released. EU OCABR certificates issued for compliant lots meant that patients in the EU/EEA and beyond could trust in the quality of the vaccines they received.

As part of its local outreach programme, the EDQM held a conference on how vaccine quality is guaranteed by the EDQM and regulatory authorities in Europe. The event was held in April 2022 at the Lieu d'Europe, Strasbourg, near the EDQM headquarters.

Quality and use of medicines

The European Pharmacopoeia

A year of renewal and innovation

Over two years since the beginning of the COVID-19 pandemic, 2022 saw the long-anticipated return of large-scale in-person meetings and a focus on a post-pandemic future. The pandemic has, indeed, brought in its wake a new normal: remote working, hybrid expert and other meetings and the rapid digital transformation of working methods, all of which have had a lasting impact on how and where we work. This new normal is global, and the European Pharmacopoeia has embraced it to ensure that its stakeholders (regulators, manufacturers and universities, for example, in Europe and of course beyond) continue to have timely access to legally binding and harmonised standards.

Over the course of 2022, 193 texts (new and revised) were published in issues 34.1 to 34.4 of *Pharmeuropa* (the Ph. Eur.'s online commenting platform) for public consultation, and a total of 23 new monographs, two new general chapters and 142 revised texts were adopted at the three EPC sessions in March, June and November. By volunteering their time and technical skills, the Ph. Eur.'s worldwide community of experts produce a rich content. The texts – whether revised or new – incorporate recently developed analytical procedures and provide science-based and data-driven quality standards for products of high market relevance and emerging domains, thus contributing to public health protection in the Ph. Eur.'s 39 member states and the 130 countries worldwide in which they are applied. Another 16 texts addressing further topics of interest were added to the Work Programme and the EPC also continued to look to the future by creating five new working parties (WPs).

The EPC: a new Chair and two new Vice-Chairs

At its March and June sessions, respectively, the EPC elected its new Chair, Professor Salvador Cañigueral, replacing Professor Torbjörn Arvidsson, and Vice-Chairs, Dr Eugenia Cogliandro (first Vice-Chair, replacing Professor Cañigueral) and Dr Marija Malešević (second Vice-Chair, replacing Dr G. Benkovic). Professor Cañigueral had been first Vice-Chair since June 2019 and specialises in pharmacology, pharmacognosy and therapeutics (Faculty of Pharmacy and Food Sciences, University of Barcelona). Dr Cogliandro has been a member of the EPC since 2009 and a quality assessor for 20 years (Italian Medicines Agency [AIFA] and Italian Ministry for Health). Dr Malešević joined the EPC in 2011 and specialises in market surveillance quality control and pharmacopoeia affairs (Medicines and Medical Devices Agency of Serbia [ALIMS]).

Our experts: an international and dynamic scientific community

The work of the Ph. Eur. is driven by a dynamic international community of experts, a network comprising professionals from national authorities (e.g. pharmacopoeia authorities, official medicines control laboratories, licensing authorities and inspectorates), the private sector (pharmaceutical or chemical industries), academia, research organisations and other fields. These highly qualified individuals share their expertise and experience in the 61 groups and working parties to which they are appointed by the EPC. They are nominated for three years and their mandate coincides with the publication cycle of each new edition of the Ph. Eur. The 2022 call for experts resulted in the official appointment of 886 experts (a higher figure than in previous years) from all backgrounds and from all around the world, some joining for the first time and others returning for their second or more mandate. Eighty-four applications were received from non-Ph. Eur. member states, attesting to the international scope and outreach of the Ph. Eur. All these experts form the backbone of the Ph. Eur. and provide the essential link between practical experimentation and documentary standards.

The 11th Edition

Every three years, activity at the Ph. Eur. reaches a peak with the publication of a new edition. The 11th Edition of the European Pharmacopoeia was published in June 2022, comprising 2474 monographs, 387 general texts and around 2870 descriptions of reagents, followed by Supplement 11.1 in November, comprising the additional 78 texts adopted at the March 2022 EPC session. The EDQM consistently endeavours to adapt to its stakeholders' needs, and to this end, while the change marks continue to be visible in the online version, a new feature allows them to be switched on and off for ease of reading. The publication was marked by an international conference that both celebrated the 11th Edition and laid the foundations for the 12th, to be launched in three years' time.

The 11th Edition conference, under the banner of "Collaboration, Innovation and Scientific Excellence"

Held in in Strasbourg from 19 to 21 September 2022 (in hybrid format), this truly international event[3] brought together almost 300 participants from all over the world, including representatives of European institutions, the World Health Organization, NCAs, NPAs, industry and academia. Several sister pharmacopoeias were also present, including the Japanese Pharmacopoeia, the United States Pharmacopeia (the two other founding members of the Pharmacopoeial Discussion Group) and the Indian Pharmacopoeia Commission, which joined the PDG expansion pilot phase in October 2022, with the Chinese Pharmacopoeia both present and presenting at the conference.

After the two-year hiatus in such large-scale events imposed by the COVID-19 pandemic, the conference provided a unique opportunity for leading experts in the quality of medicines to meet, share their views and experience, and broaden their network. The exchanges, both formal and informal, will certainly contribute to shaping the future of the Ph. Eur.

The rich content highlighted the achievements of the Ph. Eur. in the years since the publication of the 10th Edition, many of which feature in the recently published 11th Edition, but also looked towards the future and the 12th Edition: the importance of pursuing harmonisation of pharmacopoeial quality standards on a global level, the great potential of nanomedicines (including the mRNA vaccines against COVID-19, developed in record time), the next steps towards further reducing animal testing in the health sector and "big data" were just some of the themes discussed.

The round table sessions – the Ph. Eur.'s first foray into this highly interactive format – on 20 different topics and the four open debates, as well as the various featured sessions, brought the EDQM into grassroots-level contact with many of its major stakeholders (national authorities, international organisations, industry and academia), generating immediate and vital feedback that will help shape the 12th Edition over the next three years. The EPC has already used the outcomes of the conference as the basis for its priorities document that identifies a number of the issues and activities considered worthy of particular attention in the period 2023-2025. The feedback from participants has been overwhelmingly positive, particularly where the interactive format was concerned.

Preparing for the future: five new working parties

Predicting future needs with regard to the application of new analytical technologies is also important, in order to commence, as soon as possible, reflections and discussions on possibilities and potential difficulties. Five new WPs were created for this purpose.

mRNA vaccines WP

The mRNA vaccines (mRNAVAC) WP's first task will be to develop a consolidated strategy for future standards addressing these vaccines and their components. The ideas and proposals put forward on this topic during the EDQM Symposium on Nanomedicines will be taken into account during the process, as will the experience gained with these vaccines during the pandemic. (See "Embracing the future: nanomedicines and the role of the European Pharmacopoeia", below.)

High Throughput Sequencing WP

The High Throughput Sequencing (HTS) WP will focus on elaborating a general chapter on HTS for the detection of viral extraneous agents. The new chapter is intended to facilitate the use of this advanced technology with broad virus detection capability, also known as next-generation sequencing, or NGS, as a new analytical tool to ensure the viral safety of biological medicines.

Aluminium WP

The Aluminium (ALU) WP was created to explore the possibility of setting limits for aluminium in parenteral nutrition solutions, since this metal can accumulate in different vital organs, reaching toxic levels after prolonged administration.

3. Collaboration, Innovation and Scientific Excellence: the European Pharmacopoeia 11th Edition: https://go.edqm.eu/PhEurConf2022.

Excipients Strategy WP

The task of the Excipients Strategy (EXS) WP is to refine the Ph. Eur. approach to the quality and control of excipients, all of which play an essential role in medicinal product formulations.

Analytical Quality by Design WP

The Analytical Quality by Design (aQbD) WP will be entrusted with assessing the feasibility and impact of incorporating analytical procedures developed using aQbD concepts in Ph. Eur. texts and will advise the EPC and its expert groups on the strategies required to achieve this goal.

Other activities in 2022

3Rs

The Council of Europe's European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes was opened for signature in 1986. Since that time, the EPC and its experts have carried out a programme of work committed to replacing, reducing and refining (the 3R principles) the use of animals for test purposes. At EU level, the use of animals to test medicinal products is strongly discouraged under EU Directive 2010/63/EU on the protection of animals used for scientific purposes.

The rabbit pyrogen test (RPT) was first described in the Ph. Eur. in 1986. It involves measuring the rise in body temperature evoked in rabbits by the intravenous injection of a sterile solution of the substance to be examined. At its 170th session in June 2021, the EPC took the decision to engage on a path that should ultimately lead to the complete replacement of the RPT in the Ph. Eur., within a five-year timeframe. This strategy was further refined in 2022, leading to the elaboration of a proposed new general chapter, *5.1.13. Pyrogenicity*, providing guidance to users for the selection and implementation of a suitable test to control pyrogenicity in their products (the test for bacterial endotoxins or the monocyte activation test), and the revision of the texts mentioning the RPT. This 59-text package – covering topics as diverse as vaccines for human use, blood products, antibiotics, radiopharmaceuticals and containers – was published in *Pharmeuropa* 35.1 in January 2023 for public consultation.

A three-day hybrid event focusing on the future of pyrogenicity testing and promoting a global strategy for non-animal-based assays was also organised jointly by the EDQM and the European Partnership for Alternative Approaches to Animal Testing (EPAA). This took place in Brussels in February 2023, at the premises of the European Commission.

Embracing the future: nanomedicines and the role of the European Pharmacopoeia

The COVID-19 pandemic and the emergence of mRNA vaccines have highlighted the importance of nanoparticle formulations – especially lipid-based systems which have been used for nucleic acid-based APIs.

Ushering in the next era in drug innovation and seen as part of a broader trend, modern formulations using nanoparticle systems (e.g. liposomes) have long been the focus of pharmaceutical research, with programmes now starting to bear fruit and the development of new treatment strategies. The public health issues surrounding the creation and implementation of standards for nanomedicines have also garnered increasing attention, prompting the EDQM, for the first time in two years, to organise an in-person symposium (7-8 June 2022), entitled *Quality requirements for nanomedicines: what role should the European Pharmacopoeia play?*[4] Bringing together stakeholders from around the world and organised in record time, this important event identified gaps and opportunities for standards concerning modern nanoparticle-based formulations that can be filled by the Ph. Eur., notably by setting common quality standards that will help ensure the safety of these medicines of the future across Europe and beyond.

Selected achievements

First "horizontal" standard for monoclonal antibodies adopted in March

At its 172nd session in March 2022, the EPC adopted a new general chapter, *Cell-based assay for potency determination of TNF-alpha antagonists (2.7.26),* the first of three planned new horizontal standards for monoclonal antibodies (mAbs).

The adoption of the new chapter marks an important milestone in the EPC's efforts to develop – in response to stakeholder demand – a set of widely applicable recommendations for analytical testing strategies that cover the needs of different classes and sub-classes of mAbs. The resulting "horizontal standards" or "performance-based standards" comprise well-defined analytical procedures and tools to control performance and facilitate analytical assessment of key quality attributes of mAbs.

During elaboration, the procedures described in the new general chapter were subjected to extensive and rigorous analytical testing by Ph. Eur. experts from national control laboratories and the EDQM. The

4. Quality requirements for nanomedicines: what role should the European Pharmacopoeia play?: https://go.edqm.eu/Nanomedicines.

scientific evidence gathered during this collaborative process was then used to establish well-defined and globally harmonised methodologies, addressing common expectations widely applicable to tumour necrosis factor alpha (TNF-alpha) antagonist potency determination. The text includes detailed instructions on how to perform four commonly used cell-based assay procedures and universally applicable parameters/criteria to support system and sample suitability testing. It also contains a dedicated section on general recommendations and adjustment of assay conditions that discusses critical aspects contributing to the variability of assay performance. The chapter does not exclude the use of other procedures that are acceptable to the competent authorities.

Cell-based assays are complex procedures that require significant resources to establish and maintain correctly. This new general chapter provides users with analytical tools and practical guidance to further build on and support testing. It will also help establish an accepted and shared analytical language that contributes to standardising the potency determination of TNF-alpha antagonists, both currently available and in the pipeline.

The two existing individual monographs on TNF-alpha antagonists – *Etanercept (2895)* and *Infliximab concentrated solution (2928)* – have been revised to create the link between the respective assay/potency sections and general chapter *2.7.26*. This provides for a diversified choice of *suitable* bioassays for potency determination, while reinforcing and maintaining the *flexibility* already built into the monographs and the use of Ph. Eur. reference standards. Together, the three texts form the Ph. Eur.'s TNF-alpha bioassay package.

These developments are another positive example of the advantages of close collaboration across the scientific community, bringing together Ph. Eur. experts, regulators and manufacturers, and benefiting from continued engagement and enhanced stakeholder support. The Ph. Eur. continues to advance in the field of public standard setting for therapeutic mAbs, exploring flexible concepts of standardisation and pursuing its "bottom-up" approach, by leveraging experience gained from product-specific cases to drive general, transversal matters.

The TNF-alpha bioassay package was published in Ph. Eur. Supplement 11.1, with an implementation date of 1 April 2023.

Essential guidance for users of monographs

One of the new texts included in the 11th Edition of the Ph. Eur. is *Implementation of pharmacopoeial procedures (5.26)* which was adopted by the EPC in November 2021.

Published for information, the new general chapter describes a possible approach to the implementation of analytical procedures, while recognising that other approaches may also be appropriate. It represents a major addition to the Ph. Eur. as it provides more detailed information on one of the key processes underpinning the correct usage of Ph. Eur. monographs.

The General Methods WP that was responsible for elaborating the new chapter also issued a companion text comprising examples of implementation processes applied to various analytical procedures. This example document has been added to the Knowledge database entry for the chapter itself and can be used more widely as a means of better understanding the concepts laid out in the new general text.

The general chapter and its companion document are proving valuable to users developing an approach for the implementation of pharmacopoeial procedures, and during evaluation.

Herbal drugs

Cannabis was added to the work programme of the EPC a number of years ago, in response to the growing interest in the medicinal applications of the plant, the increasing number of people integrating these products into their health regimen and a perceived need for science-based standards governing their quality. Entrusted to Group of Experts 13B, the *Cannabis flos (3028)* monograph was published for public consultation in *Pharmeuropa* 34.4, with a deadline for comments of December 2022.

The monograph covers the herbal drug defined as dried, whole or fragmented, fully developed shoot apices of female cultivars of *Cannabis sativa* L. It is to be read in conjunction with the general monograph *Herbal drugs (1433)*, which includes additional requirements that are applicable unless otherwise stated in the draft monograph.

Cannabis flos takes into account information received from a number of national authorities concerning the use of this herbal drug in their jurisdictions: it can be employed as a raw material for the production of extracts or it can be prescribed as is, to be taken by patients by inhalation or oral administration. An additional requirement has been included in the test for foreign matter if the herbal drug is intended to be prescribed to patients.

The regulatory framework for the approval of medicinal cannabis and its distribution to patients

in Europe has not been harmonised, with highly variable national regulations existing side-by-side. While both the Ph. Eur. and the EMA provide general requirements for herbal medicinal products, this legally binding monograph for cannabis describes standardised quality attributes and testing protocols that will allow manufacturers to verify the quality – particularly the active substance content – of their products and facilitate the free movement of such products between member states.

Updated guides

The Technical Guide

The EPC approved the publication of a new edition of the "Technical Guide for the elaboration of monographs"[5] in June 2022. This guide is an essential aid both to the drafting of monographs and for the transposition of analytical techniques into a pharmacopoeial procedure. It helps ensure a high level of harmonisation throughout the texts of the Ph. Eur., all of which are elaborated by the experts of the different groups and, together with the European Pharmacopoeia Style Guide (also updated in 2022) can also serve more widely as a means of better understanding the requirements, format and set-up of a monograph.

With the previous version of the guide dating back to 2015, it was clear that a substantial overhaul of the text was necessary to incorporate the technical progress and new policies that have been adopted in the intervening years.

The 8th edition of the Technical Guide therefore contains all-new sections in addition to the existing parts, now comprehensively updated, to reflect these changes.

This revised technical guide also applies to medicinal product monographs, where appropriate, and a reference to the complementary "Technical Guide for the elaboration of monographs on medicinal products containing chemically defined active substances" (another guide updated in 2022) has been included as a footnote.

Joint programmes

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Biological Standardisation Programme

The BSP is a joint Council of Europe/EU initiative, partly funded by the EU. Its mission is to establish reference materials for biologicals and to develop and validate new analytical procedures for the quality control of biologicals, including alternative methods for the replacement of animals in laboratory experiments based on the 3R principles (replacement, reduction and refinement).

In 2022, the programme ran 20 projects in different fields, from vaccines for human and veterinary use to plasma-derived and biotechnology products. One project was concluded during the year, leading to the establishment of a replacement reference standard for Hepatitis C Virus RNA for NAT testing BRP.

The EDQM carried forward another 11 projects aimed at establishing replacement batches for existing reference standards and two for a new reference standard for biologicals.

Six ongoing projects focused on the development of new compendial methods. Four of these projects are dedicated to applying the 3R principles to the field of quality control of biologicals.

International co-operation and harmonisation initiatives

The Pharmacopoeial Discussion Group

In September 2022, the PDG which, in its original configuration, brings together the Ph. Eur., the Japanese Pharmacopoeia and the United States Pharmacopeia, with WHO as observer, accepted the Indian Pharmacopoeia Commission into a one-year pilot that is intended to extend its membership beyond the current regions. This was a critical step in the PDG's commitment to expanding recognition of harmonised pharmacopoeial standards with a view to achieving global convergence. The founding members were delighted to welcome the new participant, the first in the 33-year history of the group, at the annual meeting held by videoconference from 18 to 21 October 2022, marking the launch of the one-year pilot. The lessons learned from this pilot will be used to further adjust and refine the group's working methods and will identify any changes necessary to ensure that the PDG continues to perform efficiently with a larger membership when the pilot comes to an end.

One of the primary outcomes of this landmark annual meeting was the consensus reached on the ongoing proof-of-concept study for the maintenance of the ICH Q4B annexes. Following exchanges with the other pharmacopoeias at the PDG interim videoconferences on 15 and 28 March 2022, revised drafts of three selected Q4B annexes (Annex 6: Uniformity of Dosage Units, Annex 7: Dissolution and Annex 8: Sterility) had been prepared. Based on these drafts, the PDG finalised the report and submitted the conclusions of

5. All European Pharmacopoeia technical guides are available for free at https://go.edqm.eu/TechnicalGuides.

the study and recommendations for the next steps and some of the key questions raised to the ICH Assembly in November 2022.

In addition to membership expansion, the PDG is currently investigating and taking part in strategic discussions designed to enhance the global reach and impact of international harmonisation of quality standards, seen as essential for the future of the PDG. Two areas are considered of particular interest: stakeholder engagement and regulator engagement. In 2022, discussions on the first of these led to the proposal of an early engagement model for stakeholders using the excipient "Polysorbate 20" as a pilot; this was submitted in parallel with a revision proposal for the existing PDG monograph, "Polysorbate 80", which has a similar technical content. With regard to the second topic, the PDG is currently investigating ways to improve interaction with regulators by a better anticipation of items critical for regulators and better reactivity where potential issues are identified.

The work programme continued to grow, with the addition of two items, "Purified Water" and "Water for Injections", in response to stakeholder request. Adding these two key excipients, essential for any aqueous liquid preparation, is a further indication of the PDG's commitment to preparing impactful harmonised texts. Two revised and now harmonised monographs, *Paraffin, white soft (1799)*, and *Paraffin, yellow soft (1554),* were also published in the 11th Edition of the Ph. Eur. which also contains the harmonised chapter on chromatography (G-20). Their sign-off and subsequent publication is the successful outcome of several years of discussion between the members of the PDG.

The PDG has now successfully harmonised 30 of the 31 general chapters and 48 of the 63 excipient monographs on the current work programme.

Publications, databases and website

Standard Terms database

Co-funded by the European Union

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Co-funded and implemented by the Council of Europe

Initially drawn up at the request of the European Commission for use in marketing authorisation applications, the Standard Terms database provides users and prescribers with harmonised vocabularies to describe dosage forms, routes of administration, units of presentation, containers, closures and delivery devices for medicinal products. It also includes a mapped terms section, which allows users of external databases across the world to introduce and map their own terms against Standard Terms, and web services (also known as application programming interfaces) which allow registered users to extract data directly from the database for use in their own systems.

Reference standards

The EDQM ensures the supply of Ph. Eur. reference standards (RSs) to help safeguard the availability of quality medicines in Europe and beyond. Official reference standards are an integral part of the Ph. Eur. since they are used in conjunction with Ph. Eur. documentary standards to perform the analytical procedures described in monographs.

Activities

The Ph. Eur. reference standard portfolio consists of 3 151 RSs. In 2022, the European Pharmacopoeia Commission adopted 335 RSs based on establishment reports submitted by the EDQM Laboratory.

The EDQM distributes its RSs worldwide and its portfolio is constantly evolving: new standards are regularly introduced to be used with new or revised Ph. Eur. texts, or to replace existing RSs when corresponding stocks run out. The overall life-cycle management of the RS portfolio involves a wide variety of tasks, ranging from the procurement of candidate materials, characterisation and establishment, to manufacturing, quality control, quality assurance, release, distribution and monitoring.

The EDQM distributed Ph. Eur. RSs directly to 131 countries in 2022 (132 in 2021).

Joint programmes

The international collaborative studies performed in 2022 as part of the BSP led to the adoption of a replacement biological reference preparation (BRP) (BSP158 - Ph. Eur. Hepatitis C Virus RNA for NAT testing BRP batch 2).

International co-operation

Collaboration with WHO

The EDQM is responsible for establishing, manufacturing, monitoring and distributing WHO ICRSs. Currently, the ICRS catalogue consists of 215 RSs. ICRSs are used worldwide in conjunction with the texts of the International Pharmacopoeia, which is published and maintained by the WHO ECSPP.

In 2022, the WHO ECSPP adopted three new ICRSs and three replacement ICRSs, based on establishment reports submitted by the EDQM Laboratory.

The EDQM is also responsible for establishing, manufacturing, storing and distributing WHO ISAs, which are essential for the standardisation and quality control of antibiotic drug substances and medicinal products. There are currently 24 RSs in the ISA catalogue.

Collaboration with ISO

The EDQM continued its participated as liaison organisation in the activities of ISO TC 334, the ISO Technical Committee on Reference Materials.

Collaboration with national laboratories

The EDQM Laboratory can count on a number of official laboratories for support when collaborative studies are required for the establishment of Ph. Eur. reference standards. In 2022, 35 OMCLs, representing 26 countries, enrolled in such RS establishment studies.

Publications, databases and website

Throughout 2022, the EDQM continued to run and maintain its Reference Standards Online Database (https://crs.edqm.eu), providing access to all standards officially valid for the uses prescribed in Ph. Eur. monographs. RSs can be searched by code, name, monograph number or CAS number. In addition, RS Batch Validity Statements (BVSs) are available to users to document the validity of the particular RS batch supplied at the time of use. Downloadable Safety Data Sheets (SDSs) and Biological Safety Data Statements, as well as leaflets, are also available in the EDQM's online database.

Certification of suitability to the Ph. Eur. monographs

The Certification of suitability procedure was set up to evaluate and validate the capacity of Ph. Eur. standards to control the quality of substances used in the manufacture of medicinal products. It includes a programme for the inspection of manufacturing sites of active substances, and Certificates of suitability (CEPs) granted to manufacturers provide assurance to both industry and national authorities that their products are adequately controlled by the Ph. Eur. quality standards. CEPs are recognised by all EU states, but also in Canada, Australia, New Zealand, Morocco, South Africa, and by WHO, among others.

Significant steps in certification

New and revised Certificates of suitability granted

In 2022, the EDQM received 424 new CEP applications (+3% over 2021) and around 2 190 CEP revision requests (-2.5%). Some 459 new certificates (+71%) and 1 532 revised certificates (+4%) were issued. As of 31 December 2022, there were almost 6 000 valid CEPs covering chemical purity, transmissible spongiform encephalopathy (TSE) and herbal drug preparations.

Processing times for new dossiers were impacted both by the increase in requests and because quality experts from competent authorities were unable to support the EDQM's Certification Department in the assessment of dossiers due to the COVID-19 pandemic. The EDQM was therefore still processing new CEP applications with delays at the end of 2022.

Some 67.8% of revision deadlines were respected in 2022 versus 46.4% in 2021, with no further delays observed at the end of the year thanks to the measures taken.

CEPs suspended and/or withdrawn

In 2022, 13 CEPs were suspended and/or withdrawn, mainly after the respective CEP holders were unable to meet the requirements of the procedure for the maintenance of their dossiers, to address the presence of impurities or due to GMP non-compliance. On the other hand, 11 CEPs were restored after the companies concerned took appropriate action in response to the suspension of their CEP.

Communication with Ph. Eur. groups of experts: requests for revision

In 2022, 16 requests for revision of Ph. Eur. monographs were submitted to the relevant Ph. Eur. groups of experts for consideration, mainly proposing the addition of specified impurities to the monograph's transparency list, together with a suitable test method.

Inspections carried out, including Real-Time Remote Inspections

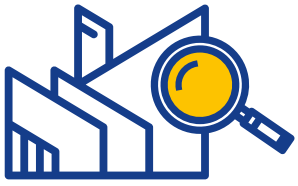
The EDQM GMP inspection programme for active substance manufacturers, like many supervisory programmes worldwide, continued to suffer the consequences of the COVID-19 pandemic in 2022. On-site inspections only recommenced in September, and only in India. On the other hand, the EDQM concluded the pilot phase of the RTEMIS programme and the new tool can now be routinely used for the supervision of the GMP compliance of manufacturing sites for which CEP applications are submitted. Nine such inspections were carried out, in India and China. The results obtained were satisfactory, both from a technical point of view and in terms of expected outcomes. In addition, the EDQM performed desktop assessments for 10 manufacturing sites by exchanging data with inspectorates from international partners.

Certification of suitability

Adherence to deadlines for revisions improved (67.8% in 2022 vs 46.4% in 2021)

Adherence to deadlines (revisions)

67.8%



RTEMIS inspections

92

On-site inspections

1

Potentially mutagenic azido impurities in sartan active substances

In 2022, the EDQM finishing reviewing the corrective action taken by manufacturers to address the potential formation of mutagenic azido impurities in sartan active substances and, when appropriate, introduced limits on the corresponding certificates.

International co-operation

Throughout 2022, the Certification Department continued to work closely with the EMA and NCAs in Europe and beyond. This continued co-operation is crucial to ensuring consistency in the approaches applied for the assessment of quality information on active substances, as well as for GMP implementation.

Communication with applicants, partners and stakeholders

The "CEP of the future" project

The EDQM continued work on the "CEP of the future" project in 2022, to better meet the current needs of stakeholders. Following a survey conducted in 2020, different aspects of the project were presented to stakeholders at three targeted consultation workshops in September 2022. These workshops were organised to gather feedback on a number of proposals and to discuss specific outstanding questions.

The CEP Steering Committee approved changes to the layout and content of CEPs, and the EDQM will roll out the new format in 2023.

Update of application forms and CEP guidelines

In 2022, CEP application forms were updated to facilitate their handling and the transfer of the collected data to the IT tools deployed at the EDQM.

Recent issues (e.g. nitrosamines) have highlighted a lack of knowledge on the part of some CEP holders regarding their obligations towards marketing authorisation holders. In order to enable them to fulfil their respective legal responsibilities, the EDQM published the "CEP holders responsibilities towards their customers" guideline, to help clarify the issue. The guideline is available on the EDQM website.[6]

The EDQM has also updated its policy for the elaboration of documents related to the CEP procedure. A stakeholder consultation phase (public or targeted) for certain documents has been introduced in order to ensure transparency of the process, to inform stakeholders of upcoming proposed changes and to give them the opportunity to provide input and feedback. This will be implemented in 2023.

6. "EDQM reminds CEP holders of their responsibilities towards their customers", https://go.edqm.eu/NewsCEP220203.

The European Network of Official Medicines Control Laboratories

The OMCL Network brings together official laboratories based in 34 European member states and in seven non-European countries. Together, they ensure the quality of medicines on the market and prevent substandard or falsified medicinal products from reaching final users. This safeguards patients' health by ensuring the efficacy of their treatment and averting potential harm.

In 2022, the EDQM successfully continued to co-ordinate the activities and carry out the work programme of the General European OMCL Network, which is co-funded by the EU. The network members demonstrated their flexibility and resilience in reorganising and redeploying resources in order to overcome a wide range of logistical, economic and political difficulties.

Quality management

Co-funded by the European Union

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Work programme

▶ Mutual Joint Audits/Mutual Joint Visits (MJAs/MJVs) and Training Visits (TVs)

Harmonising quality management systems (QMSs) among OMCLs and achieving appropriate quality levels that enable mutual recognition of test results between members (for example, official batch release testing of biologicals, market surveillance of authorised medicines and falsified medicines testing) remain the principal goals of this programme.

In response to the pandemic, the audit programme was pursued remotely via videoconferences for the first half of the year, followed by on-site assessments in the laboratories starting in late June 2022.

Sixteen MJAs – including two follow-up and two surveillance MJAs – and two remote training visits were carried out in 2022. Since the launch of the QM programme for OMCLs in 1997, a total of 223 MJAs, 52 MJVs and 27 TVs/tutorials have been conducted.

▶ Training courses/workshops

The EDQM organised a workshop for both newly qualified and more experienced auditors consisting of a communication session and a technical session to share the experience on difficulties and challenges in implementation of the ISO/IEC 17025:2017 standard.

OMCL Network

The OMCL Network brings together official laboratories based in 34 European member states and in seven non-European countries.

Participating OMCLs **68**

EU member states **34**

Non-EU states **7**

MJAs, MJVs and TVs conducted since 1997

Since the launch of the QM programme for OMCLs in 1997, a total of 223 MJAs, 52 MJVs and 27 TVs/tutorials have been conducted.

MJAs
223

MJVs
52

TVs/tutorials
27

▶ Proficiency Testing Scheme studies

The EDQM PTS provides laboratories with an objective means of assessing and demonstrating the reliability of their data. In 2022, five studies each were organised in the physico-chemical and biological fields.

International co-operation

The EDQM is a recognised stakeholder of the European Co-operation for Accreditation association (EA) and regularly attends the EA/Laboratory Committee (EA/LC) meetings in order to strengthen collaboration with EA/LC members, clarify technical questions of interest to the OMCL Network related to the interpretation of ISO/IEC 17025 requirements, and share experience in the field of auditing. The EDQM attended the two EA/LC meetings held in 2022.

Publications, databases and website

Common QM guidelines supporting laboratories in the implementation of ISO/IEC 17025 requirements are drafted by experts belonging to the network and are updated on a regular basis under the co-ordination of the EDQM Secretariat.

In 2022, four guidelines or recommendation documents were adopted; a further six documents are under revision.

Quality management documents elaborated in 2022

Topic	Status	*Guideline*/ Recommendation document
Management of Volumetric Glassware	Adopted	Guideline
Evaluation of Measurement Uncertainty ▶ Annex 2: Estimation of measurement uncertainty using top-down approach ▶ Annex 2.5: Use of Data from Proficiency Testing Studies for the Estimation of Measurement Uncertainty	Adopted	Guideline
Evaluation and Reporting of Results and related annexes	Adopted	Guideline
General requirements for infrequently performed techniques	Adopted	Guideline
Preface and Notes for Use of QM Documents	Under revision	Explanatory Notes
Interpretation of Screening Results for Peptides and Proteins by Mass Spectrometry based Methods	Under revision	Recommendation document
Qualification of Equipment – Core Document	Under revision	Guideline
Annex I to Qualification of Equipment – Qualification of HPLC Equipment	Under revision	Guideline
Annex VI to Qualification of Equipment – Qualification of Piston Pipettes	Under revision	Guideline
Annex VIII to Qualification of Equipment – Qualification of Balances	Under revision	Guideline

GEON activities

Work programme

▶ GEON Annual General Meeting

The GEON Annual General Meeting was held in-person from 13 to 17 June 2022 in Strasbourg, bringing together over 230 participants attending a number different sessions. The four strategic goals of the network were addressed through specific examples over the course of the meeting week.

Specific topics were addressed, including the use of mass spectrometry in OMCLs for different analytical purposes. Another highlight was the presentation by representatives from the Malta Medicines Authority on Malta's current project to set up an OMCL on their territory. A part of the session was also dedicated to the experience of network members of moving and refurbishing laboratory facilities.

▶ General market surveillance studies

During 2022, participants analysed samples for the two market surveillance studies (MSS), "Tadalafil drug substance and tablets" (MSS059) and "Breaking of glass ampoules" (MSS061), initiated in 2021. A new MSS on Olazapine API and tablets (MSS060) was also launched.

▶ Active Pharmaceutical Ingredients Working Group

The MSSFP005 study on Tadalafil was finalised in October 2022.

▶ OMCL Falsified Medicines Working Group

The sixth market surveillance study on suspected illegal products (MSSIP) study on "Selective Androgen Receptor Modulators (SARMs), Metabolic Modulators and Small Molecule Growth Hormone Secretagogues used as Sport Performance Enhancers" was launched in 2022.

As part of the Suspicious Unknown Products (SUP) programme, a new study (SUP011) confirmed that 26 participating OMCLs correctly identified the substance present in a "blind" sample.

▶ OMCL Gene Therapy Products Working Group (GTWG)

Currently composed of 11 OMCLs, the GTWG's 12th annual meeting was hosted by Swissmedic. Despite resource reallocation due to the COVID-19 pandemic, progress was made in validating standard methods for quality control of adeno-associated virus (AAV) based vector products.

International co-operation

The 4th Falsified Medicines Symposium for OMCLs was held at the Istituto Superiore di Sanità (ISS) in Rome, under the motto "New Trends, New Frontiers". It brought together more than 100 participants from OMCLs, health authorities, police, forensic laboratories, customs authorities, customs laboratories and the European Commission.

The CAP Advisory Group observed a network-wide need to increase capacity in cell-based potency assay testing of biotherapeutics (e.g. monoclonal antibody preparations). In May 2022, the EDQM organised a first workshop for GEON members covering case studies of all relevant analytical and statistical aspects including cell culturing for these assays.

The OMCL Falsified Medicines Working Group continued its collaboration with the Customs Laboratories European Network (CLEN). The second joint meeting took place in November on the premises of the Dutch OMCL in Bilthoven, during which participants agreed to take concrete action aimed at fostering exchanges between the two networks and joining efforts in the fight against falsified medicines.

In December 2022, the OMCL Network suspended the memberships of two Russian and one Belarusian OMCL, following the exclusion of representatives from both countries from EPC activities.

Publications, databases and website

In 2022, the revision of 11 general OMCL Network documents was finalised.

CombiStats™ is a recognised reference tool for the statistical analysis of bioassay results which contributes to the mutual recognition of data and results by all interested parties. In 2022, its widespread use continued to increase, with 964 CombiStats™ licences issued and the tool used in 34 European countries and 35 others around the world.

EU/EEA-specific activities

Work programme

▶ Market surveillance for products with a centralised marketing authorisation

The CAP regular programme covers an annual list of products drawn up by the EMA Secretariat together with the EMA Scientific Committees, and with final input from the OMCL CAP Advisory Group. In 2022, 33 medicinal products for human use, seven for veterinary use and four API or medicinal product intermediates were scheduled for testing.

The 2022 CAP Generics programme included imatinib, memantine and pregabalin products.

The CAP Biosimilar programme comprises three projects to be conducted over a five-year period (2019-2023), covering filgrastim, etanercept and rituximab products. In 2022, the filgrastim project was finalised.

An additional CAP market surveillance programme focuses on authenticity checks on parallel-distributed products, and testing of two products was concluded in 2022.

Furthermore, the absence of nitrosamines was tested and confirmed for three centrally authorised medicinal products.

The results showed that the vast majority of the products tested were of the expected quality and complied with authorised specifications. By 31 December 2022, no confirmed out-of-specification results were found, although a few regulatory or technical findings were reported to and followed up by the EMA.

▶ Mutual Recognition Procedure/ Decentralised Procedure post-marketing surveillance scheme

The 18th regular programme was carried out in 2022, covering roughly 1 500 product testing projects. Testing reports for 2022 were issued by 28 different OMCLs and 15% of the tested products were for veterinary use. Regulatory issues were identified in 1.8% of projects. In 1.6% of cases, one or more out-of-specification results were reported.

The OMCLs involved in this activity met twice in 2022 (June and November) to evaluate the programme and discuss ways of optimising collaboration.

In September 2022, the HMA Post-Marketing Risk Assessment (PM RA) Tool Working Group chaired a stakeholders meeting bringing together GMP inspectors, quality assessors, quality defect managers and OMCLs. Discussions focussed on the adequacy of the current Pre-Authorisation RA tool for Mutual Recognition Procedure/Decentralised Procedure (MRP/DCP) products, as well the most appropriate design of a future PM RA tool.

▶ OCABR of biologicals for human use

The activities of the network activity foster the mandatory mutual recognition of batch release for human vaccines and medicinal products derived from human blood and plasma. OMCLs perform a quality review of every batch through testing and protocol review.

The human OCABR annual meeting focused on blood products, vaccines and common issues, and provided an opportunity to exchange expertise and optimise resources to solve recurrent problems. The year 2022 provided an opportunity to reflect on the best use of network resources, with lessons learned from the COVID-19 pandemic taken into consideration.

Priority activities in 2022 included maintaining regular batch release to ensure a steady supply of essential medicines – such as childhood vaccines and human clotting factors – to the public, together with facing the continued high demand for batch release of approved COVID-19 vaccines and preparations for new COVID-19 vaccines in development. Thanks to co-ordination within the network, levels of "regular" batch release carried out in 2022 were unaffected by the large demand for COVID-19 vaccines. OMCLs evaluated more than 12 430 final batches of vaccines for human use and human blood derived medicinal products and screened more than 10 790 plasma pools for safety. This included the release of more than 1 740 lots of COVID-19 vaccines. This activity provides independent confirmation that the quality of these products meet the established requirements before they reach patients. Further activities linked to COVID-19 vaccines are highlighted in "EDQM initiatives in the context of COVID-19", above.

▶ Batch release of immunological veterinary medicinal products

The Veterinary Batch Release Network (VBRN) Advisory Group met twice in 2022 to move forward on important issues and prepare for the annual meeting in June. The regular Official Batch Protocol Review (OBPR) and OCABR activities for immunological veterinary medicinal products (IVMPs) were largely

Control of biologicals for human use

OMCLs evaluated more than 12 430 final batches of vaccines for human use and human blood derived medicinal products and screened more than 10 790 plasma pools for safety. This included the release of more than 1 740 lots of COVID-19 vaccines

Final batches of vaccines for human use and human blood derived medicinal products

12 430

Plasma pools screened for safety

10 790

Lots of COVID-19 vaccines

1 740

unaffected by the COVID-19 pandemic conditions thanks to careful planning by the OMCLs.

The use of common templates to better co-ordinate activities for post-marketing surveillance was continued with four OMCLs contributing data in 2022.

The Advisory Group continued to update guidelines and network documents to be in line with the implementation of the new EU veterinary legislation that entered into force in January 2022. In addition, a major restructuring of the EU Administrative Procedures for OCABR and OBPR was undertaken to combine both procedures in one document for ease of use and in line with the new structure of the legislation. The combined EU Administrative Procedure for Official Batch Release of Immunological Veterinary Medicinal Products in Application of Article 128 of Regulation (EU) 2019/6 was adopted in April 2022 and entered into force on 1 July 2022.

International co-operation

The Human OCABR Network continued co-operation in the global arena via its Memoranda of Understanding with authorities from Canada, the UK, the USA, Israel and the Taiwan Food and Drug Administration (TFDA).

Publications, databases and website

By end of 2022, the MRP/DCP Product Testing Database – set up in 2007 to improve co-operation on planning, sampling and reporting of testing activities carried out on MRP and DCP products within the OMCL Network – held more than 15 800 records, with contributions from 37 different OMCLs. Database access is restricted to OMCLs and health authorities.

Risk-assessment templates, which also include test recommendations for MRP and DCP products, have been regularly transferred to this database since March 2020. The database now holds about 1 300 templates.

Five new and 16 revised guidelines for vaccines for human use and one revised guideline for human blood and plasma-derived medicinal products came into force.

Twenty-four revised VBRN guidelines also came into force in 2022. All of the OCABR and VBRN guidelines were published on the EDQM website.

Response to nitrosamine contamination

Certain types of nitrosamines (*N*-nitrosodiethylamine [NDEA] and *N*-nitrosodimethylamine [NDMA]) were detected in a number of active substances used in the treatment of hypertension and in related medicines in 2018. Nitrosamines are known as possible carcinogens for humans and, according to current regulatory requirements, only very low amounts are acceptable.

In line with its mandate to promote and protect public health in Europe by ensuring access to good quality medicines and healthcare, the EDQM has been working actively at various levels to address this problem, co-operating continually with regulatory authorities at international and EU level. Full information on this matter can be found on the EDQM's dedicated web page.

Ph. Eur. strategy

Rapid implementation of revised sartan monographs

The EPC continued to roll out its comprehensive nitrosamines action plan in 2022 by adopting revised versions of two central and legally binding general monographs, *Substances for pharmaceutical use (2034)* and *Pharmaceutical preparations (2619),* which now include a paragraph explaining the Ph. Eur. approach to *N*-nitrosamine impurities. This approach was defined based on the comments received on these texts during the last round of public consultation in *Pharmeuropa* together with recent feedback from HMA and EMA groups and from the NCAs of non-EU Ph. Eur. member states.

Added to the "Production" section of each of these major texts, the new paragraph states that manufacturers are now expected to evaluate the potential risk of *N*-nitrosamine formation and contamination occurring throughout their manufacturing process and during storage (2034) and shelf life (2619). If confirmed, manufacturers should mitigate as far as possible the risk of *N*-nitrosamines being present – for example by modifying their manufacturing process – and implement a control strategy to detect and control them.

The revised monographs will be published in Ph. Eur. Supplement 11.3 (July 2023) and implemented as from 1 January 2024. The next step in the action plan will be defining how to address the issue of nitrosamine control in individual monographs.

Action on CEPs

The EDQM Certification Department has reviewed most of the applications for which a nitrosamine risk was identified. Some of the CEP dossiers for substances that were found to present a nitrosamine risk are now in the third step of the call for review, i.e. companies submitting requests for revision to amend the manufacturing process and/or introduce controls (e.g. limits in specifications), as necessary. The deadline for this step has been extended to 1 October 2023 in line with EU policy.

An evaluation of the potential presence of nitrosamines is conducted routinely for all new CEP applications and at the time of renewal, as well as for revisions that are likely to impact the level of risk, based on data to be submitted by applicants.

Collaboration with European and international partners

The EDQM maintains ongoing co-operation with regulatory authorities at national, EU and global level on this issue – for example via the Nitrosamines International Strategic Group (NISG) and its technical working group (NITWG) – and will continue to do so to ensure a co-ordinated, harmonised approach to making and implementing decisions.

Sampling strategies and testing methods with OMCLs

Members of the GEON have been involved in various activities related to the detection of nitrosamines in APIs and medicinal products since mid-2018. A dedicated OMCL working group has met 15 times since then and has extended its scope beyond the nitrosamine group to the determination of mutagenic impurities at trace levels (e.g. azido impurities reported in tetrazole sartans).

The OMCL Mutagenic Contaminants Testing Group met once in March 2022 to discuss ongoing and planned testing activities on national level and future testing strategies, and to exchange information on international initiatives ongoing in this area. A rifampicin testing campaign involving four network members, launched jointly with the EMA/CMDh in February 2021, was closed in 2022. Several OMCLs participated in an international regulatory collaboration on the analysis of nitrosamines in metformin-containing medicines. Another common project with the United States Food and Drug Administration (FDA), an inter-laboratory study of nitrosamine testing in losartan and valsartan, was finalised in 2022. Five members of the OMCL Network and the FDA laboratory (the lead on this project) were involved in the study, which aimed to assess the performance characteristics of the participants' different in-house methods. In addition, some OMCLs have commenced targeted testing of selected nitrosamine active substance-related impurities (e.g. in angiotensin-converting enzyme inhibitors). Finally, the EDQM, with the help of the OMCL Network, continued implementing recommendations for sampling and testing based on the outcome of the EMA lessons learned exercise in response to the sartan incident.

Anti-falsification activities

Falsified medical products (medicines and medical devices) represent a serious threat to public health. The EDQM's anti-falsification activities aim to foster international dialogue and co-operation, encourage expertise and information sharing, and develop tools, frameworks and strategies for risk prevention and harm mitigation. They are conducted mainly through the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), its subordinate Committee of Experts on Minimising the Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED), and the OMCL Falsified Medicines Working Group. The EDQM also provides support to the Council of Europe MEDICRIME Convention and its Committee of the Parties (CoP).

Work programme

A Council of Europe draft recommendation on reporting of unaccounted disappearances of medicines was prepared in 2022, for adoption in 2023. A survey was conducted in 2021 in all member states. More information on the topic and the survey results is available on the EDQM web site (*Medicines > Anti-falsification activities > Work programme CD-P-PH/CMED*).

CD-P-PH/CMED's work also focused on medical devices. A survey was conducted in the second half of 2022 regarding different aspects of falsified medical devices and related fraudulent behaviour.

Borderline products (i.e. cases in which it is not clear from the outset whether a given product is a medicine or another health product) represent a specific challenge. The Network on Borderline Products, whose Terms of Reference were adopted at the end of 2021, supported work on issues touching on the enforcement or supervision of legislation for borderline products.

Communication with partners and stakeholders

Throughout 2022, representatives of the EDQM took part in the meetings of the EU HMA-WGEO to strengthen co-operation.

Co-operation between OMCLs and health and law-enforcement authorities was strengthened thanks to the OMCL Symposium in Rome on Combating Falsified and Other Illegal Medicines, in which the CMED committee was deeply involved (see "OMCL Network", above, for more details).

The Network on Borderline Products welcomed the European Food Safety Authority (EFSA) to its annual meeting at the end of 2022 to discuss the challenges posed by cannabidiol (CBD) in novel foods and other products.

An online meeting with stakeholders active in the field of falsified medical products and pharmaceutical care was organised jointly with the Committee of Experts

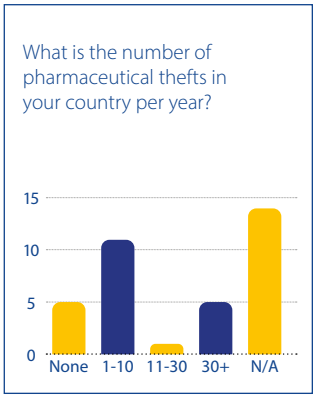
Thefts, losses & diversions of medicines

The CD-P-PH/CMED drafted a recommendation on reporting of unaccounted disappearances of medicinal products for human and veterinary use from the legal supply chain. The results of a survey targeting health regulatory authorities, carried out in 2021, were compiled and analysed in 2022.

Participation

- 24 out of 27 EU countries
- 13 out of 20 non-EU countries

Full details available at https://www.edqm.eu/en/web/edqm/work-programme-cd-p-ph-cmed



on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC).

Publications, databases and website

The EDQM's Know-X database stores comprehensive information on individual cases of falsified medical products (medicines and medical devices). The database enables health and law-enforcement authorities across Europe to share information and to act more rapidly in cases of suspect medical products (for instance via its "Rapid Alert" function that allows users to alert others to new cases in real time). The CD-P-PH/CMED and the OMCL Falsified Medicines Working Group work together to maintain the database, and continue to work on improvements. They also co-operate in promoting the database and offer training to users.

The outcome of the survey on the issue of unaccounted disappearances of medicines from the legal supply chain was published in 2022.

More information is available on the EDQM web site (*Medicines > Anti-falsification activities*).

Pharmaceuticals and pharmaceutical care

The European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) contributes to the optimal use of medicines and to improving patient quality of life, public health and access to good quality medicines and healthcare, with the support of three subordinate bodies – the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC), the Committee of Experts on the Classification of Medicines as Regards their Supply (CD-P-PH/PHO) and the Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED).

Activities

The year 2022 saw a gradual return to normal: face-to-face meetings resumed and significant progress was made on ongoing projects and activities.

A stakeholder consultation on the draft guidelines on medication review was conducted. It targeted international organisations active in public health and social matters, NCAs in member states, healthcare professionals, patients and academia, and provided a valuable opportunity for stakeholders to share their feedback. The guidelines based on this input will be published in 2023.

Another survey was conducted among associations representing patients, consumers and healthcare professionals on the use of herbal food supplements and the need to better inform consumers of the benefits and potential risks associated with their use. The survey results will be used to develop consultation and information materials to support the safe and correct use of herbal food supplements.

Significant progress was also made on the drafting of a best practice document for the traceability of medicines in hospital settings to minimise the occurrence of medication administration errors and ensure patient safety.

The CD-P-PH adopted a proposal to develop a methodological guide for selecting medicines at risk of shortage during public health emergencies. This is part of a joint initiative with the EPC working in parallel on a pan-European formulary. It aims to minimise the impact of shortages of medicines during public health emergencies via the optional and temporary use of standardised pharmacy preparations in hospital and community pharmacy settings. The approach is based on the lessons learned from the issues with the supply of essential medicines experienced at the start of the COVID-19 pandemic in 2020.

The CD-P-PH/PHO held two virtual meetings, at which it issued 37 recommendations on the classification of medicines and their supply conditions (prescription and non-prescription status).

Communication with partners and stakeholders

Exchanges took place with international organisations and professional bodies, such as the Organisation for Economic Co-operation and Development (OECD) and the European Association of Hospital Pharmacists (EAHP), to harmonise efforts related to the promotion of patient-centred care and safe and effective use of medications in Europe.

A joint EDQM–South-eastern Europe Health Network survey was carried out among the eight member states of the SEEHN to map the implementation of pharmaceutical care and related services in daily practice. The survey report will be published in 2023.

Resolution CM/Res(2020)3 on the implementation of pharmaceutical care for the benefit of patients and health services and the ongoing project on medication review were presented at the 80th World Congress of Pharmacy and Pharmaceutical Sciences of the International Pharmaceutical Federation (FIP) and annual symposium of the European Society of Clinical Pharmacy (ESCP).

Publications, databases and website

Evidence-based reviews of the classification of medicines

Evidence-based reviews of the classification of medicines were completed for sympathomimetics used as decongestants (Anatomical Therapeutic Chemical [ATC] group: S01GA) and Other antiallergics (ATC group: S01GX). These will be published on the EDQM website in 2023.

Melclass

The Melclass database (melclass.edqm.eu) was regularly updated with relevant recommendations from the CD-P-PH/PHO to national health authorities on the classification of medicines and their supply conditions, and with national related information.

European Paediatric Formulary

The European Paediatric Formulary (PaedForm) is a freely available, pan-European collection of formulations for unlicensed pharmaceutical preparations currently described in national formularies and formulations that are already well established in European countries. Its aim is to give clinicians, pharmacists and healthcare providers access to formulations of appropriate quality, allowing the preparation of medicinal products for children when no licensed alternative is available on the market.

Work programme

The revised monograph *Phosphate 60 mg/mL Oral Solution (F0011)*, used in the treatment of hypophosphataemia, was published in *Pharmeuropa PaedForm* for public consultation at the end of 2021, approved by the EPC and then adopted by the CD-P-PH in 2022. *Simple syrup (preservative-free) (F0008)*, which provides a standardised formulation and target strength for a widely used vehicle, was approved by the EPC and is pending adoption of the CD-P-PH before being published in PaedForm. One more monograph, *Chloral hydrate 100 mg/mL oral solution (F0010)* was published in *Pharmeuropa PaedForm* for public consultation in December.

Two new formulations, *Amiodarone hydrochloride capsules* – the first PaedForm monograph on a solid oral dosage form – and *Valaciclovir hydrochloride oral solution*, were added to the work programme; 12 monographs are now in development. In keeping with the founding principle of PaedForm, these products are medicines intended to satisfy unmet paediatric needs as identified by the experts following a review of scientific data published by the EMA, for example. Further candidate formulations are currently in the assessment pipeline.

The PaedF WP has 17 members from all over Europe, attesting to the lively interest in its work, including an observer from the EMA (Paediatric Committee, or PDCO). The WP met six times in 2022 (one in-person meeting and the rest by videoconference), both to discuss and progress the items on the work programme and to reflect upon its working methods going forward.

Communication with partners and stakeholders

The EDQM maintained its vital link with professional associations such as the EAHP and the industry-oriented European Paediatric Formulation Initiative (EuPFI). Continued communication with these associations ensures that the PaedF WP's priorities reflect actual needs in the field.

The EDQM looks forward to continued partnerships with national formularies, hospital pharmacies and universities, and to developing connections with other stakeholders.

European Paediatric Formulary

Activities

Addition of an annex to monographs comprising a list of known licensed options that prescribers or pharmacists should consider when treating individual patients.

Two monographs experimentally evaluated and published for public consultation.

Two monographs added to the work programme.

Work programme (2022)

- Amiodarone hydrochloride capsules
- Baclofen oral suspension
- Chloral hydrate oral solution
- Chloral hydrate rectal solution
- Clonidine hydrochloride oral solution
- Ethambutol hydrochloride oral solution
- Flecainide acetate oral solution
- Furosemide oral solution
- Isoniazid oral solution
- Lorazepam oral solution
- Pyrazinamide oral suspension
- Valaciclovir hydrochloride oral solution
- Vehicle for oral solution or suspension - Simple syrup (preservative-free)

Quality and safety
of substances of human origin

Blood transfusion

The EDQM's transfusion activities, overseen by the European Committee on Blood Transfusion (CD-P-TS), include the collection of international data and monitoring of practices in Europe, knowledge sharing between organisations and experts through training and networking, and the elaboration of reports and guidance documents. Promoting voluntary and non-remunerated donation, mutual assistance, optimal use of blood and blood components and the protection of donors and recipients are the major guiding principles of these activities. They address ethical, legal and organisational aspects of blood transfusion to ensure the safety, quality and optimal use of blood supplies, increasing their availability and avoiding wastage.

Work programme

Blood Guide

In accordance with Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components,[7] the CD-P-TS is responsible for the regular review and update of common technical standards for blood and blood components in its *Guide to the preparation, use and quality assurance of blood components* (the "Blood Guide") and Good Practice Guidelines for blood establishments.

In 2021, the dedicated working group entrusted by the CD-P-TS with updating the Blood Guide and ensuring it keeps abreast of scientific developments and regulatory changes (the GTS), finalised the drafting of the 21st edition after an extensive stakeholder consultation. The 21st edition of the Blood Guide was adopted by the CD-P-TS at its 19th plenary meeting in November 2022, and it was published in April 2023.

Data collection and monitoring of practices

The CD-P-TS publishes annual activity reports on the donation, collection, testing, use and quality aspects of blood and blood components. Each report provides comprehensive activity data from the CD-P-TS member states and highlights new or changed practices, addressing trends in the blood sector in Europe. The 2017-2019 report was published in 2022; the 2020 and 2021 data will be published in 2023.

Risk behaviours with an impact on blood donor management and transfusion safety

As required by Resolution CM/Res(2013)3 on sexual behaviours of blood donors that have an impact on transfusion safety, a dedicated working group of the CD-P-TS is responsible for the continuous collection of data on the incidence and prevalence of sexually transmitted infections that might impact the safety of transfusions. In 2022, this working group compiled a compendium of deferral policies applied by member states to donors displaying behaviour that creates risks for the safety of transfusion. A report detailing the outcome of this compilation will be published in 2023.

European database of frozen blood units of rare blood groups

The CD-P-TS maintains the European database of frozen blood units of rare blood groups. The database is a tool for blood establishments to facilitate searches for frozen blood units of rare blood groups. Individual blood establishments voluntarily contribute their data on stored frozen blood units to this database.

Optimal use of blood components and plasma-derived medicinal products

The EDQM has worked on the optimal use of blood components and plasma-derived medicinal products (PDMPs) since the 1990s. It organises regular symposia – known as the Kreuth Initiatives – which provide a unique platform for exchanging and discussing current clinical practices and projections of future developments across European member states. From these symposia, recommendations and/or legal instruments are developed, which aim at providing a course of action to stakeholders and decision makers in the field to contribute to optimal use and to achieving a higher degree of self-sufficiency. In 2022, the proceedings from Kreuth Initiative V on the optimal treatment of haemophilia were published. The resulting recommendations are to be included in an updated technical annex of CM/Res(2017)43 on principles concerning haemophilia therapies (expected publication 2023).

7. All Council of Europe Committee of Ministers recommendations and resolutions related to blood transfusion are available at https://go.edqm.eu/BloodTexts.

Blood Supply Contingency and Emergency Plan

As part of its co-operation with the European Commission, the EDQM co-ordinates the Blood Supply Contingency and Emergency Plan (B-SCEP) Project. It aims to strengthen national plans to ensure continuity of the blood supply in emergency situations, developing strategies to support European countries in this regard. In 2022, recommendations and a model preparedness plan were published, from which action and mitigation plans based on the overall impact on the blood supply can be tailored accordingly, to accommodate individual blood systems.

Blood Proficiency Testing Scheme and Blood Quality Management Programmes

The EDQM continued to run the Blood Proficiency Testing Scheme (B-PTS) and the Blood Quality Management (B-QM) Programmes to support BEs in implementing the EU blood legislation, as well as the standards laid out in the Blood Guide and the GPGs. Both programmes have been co-funded by the European Commission and the EDQM since 2010.

The external assessment of the testing capability of European BEs also continued in 2022. Seven B-PTS studies were organised, with an average of 55 laboratories[8] participating in each.

In 2022, the B-QM Programme was run both remotely and on-site. The EDQM continued to perform remote educational training sessions and auditing schemes as initiated in 2021 and was able to resume on-site visits of experts to BEs in September 2022. Following the successful pilot scheme organised in October 2021, three new virtual auditing schemes were organised in February, June and November 2022.

A new type of scheme, Blood Tailored Expert Support (B-TES), was launched in 2022, to be offered in addition to the already existing schemes to further support BEs in the development and implementation of their QMS. The first B-TES was organised virtually in June 2022.

The first Blood Mutual Joint Audit (pilot B-MJA) of the B-QM Programme took place successfully on-site in September 2022.

A virtual training programme on Audit Practices in BEs was organised in October 2022 ; it ran over a period of five weeks. The number of participants was limited to 40 to facilitate discussions with the trainers. Weekly supporting materials and exercises were distributed to participants. The programme concluded with a five-day live session during which practical examples and case studies were discussed in an interactive format.

Romanian Blood System reorganisation project

In 2020, the European Commission's DG REFORM entrusted the EDQM with co-ordinating the reorganisation of the Romanian Blood System (RBS), including both the blood transfusion service and its regulatory oversight.

In 2022, the outcomes of the EDQM study on the RBS were used to devise, in close co-operation with Romanian blood transfusion experts, well-designed and fit-for-purpose restructuration proposals to enable the RBS to meet the EU blood legislation requirements and EDQM/Council of Europe standards. The EDQM also provided the Romanian Ministry of Health with guidance on how to implement the reorganisation in practice, to improve the availability of safe blood components of high quality for all Romanian patients as soon as possible.

Publications

- "Report on the collection, testing and use of blood and blood components in Europe for 2017-2019". All reports are available at https://www.edqm.eu/en/reports-blood.
- B-SCEP Recommendations and Model Preparedness Plan, available at https://go.edqm.eu/BSCEP.
- "Optimal treatment of haemophilia", Wildbad Kreuth Initiative V – European symposium proceedings and recommendations, available at https://freepub.edqm.eu/publications/PUBSD-133/detail.

8. The calculation of the average number of participants does not take into account the B-PTS044 HEV NAT study, which is not a routine study.

Organs, tissues and cells

The EDQM's transplantation activities, overseen by the European Committee on Organ Transplantation (CD-P-TO), include the collection of international data and monitoring of practices in Europe, knowledge sharing between organisations and experts through training and networking, and the elaboration of reports and guidance documents.

Work programme

Risk of commodification of substances of human origin

The human body and its parts must not, as such, give rise to financial gain. However, it is conceivable that "reasonable fees" may be charged for legitimate medical or related technical services rather than the direct purchase of SoHO. In this scenario, the use of SoHO for the treatment of patients, including through the production of innovative treatments, has created a situation where procurement organisations, commercial tissue and blood banks, pharmaceutical companies and numerous brokers and distributors can charge fees for their services, with far-reaching consequences.

A number of Council of Europe bodies have taken up this issue. In its recently published position statement,[9] the CD-P-TO evaluated the risks of commodification of SoHO and put forward several proposals aimed at ensuring three essential points:

- the ethical principles of voluntary and unpaid donation and the non-commercialisation of the human body must be respected;
- the sustainability of healthcare systems must be protected;
- patients must have access to SoHO when necessary, even in the context of innovative therapies that may, on occasion, need to be regulated under different regulatory frameworks.

Likewise, the Committee on Social Affairs, Health and Sustainable Development of the Parliamentary Assembly of the Council of Europe and the Committee of Ministers both referred to the CD-P-TO paper in recent documents on this topic.[10]

Fight against unethical transplantation practices

The EDQM Network of National Focal Points on Travel for Transplantation (NETTA) was established in line with Resolutions CM/Res(2013)55[11] and CM/Res(2017)2.[12] To date, 35 countries have designated national focal points (NFPs), which provide information to the Registry of International Travel for Transplantation Activity (RITTA) on an annual basis. The international exchange of information about patients who travelled abroad to receive an organ transplant serves to shed light on this phenomenon, identify possible transplant tourism hotspots and profile donors and recipients. It also provides insight into the quality of transfer of care and its impact on post-transplant outcomes. By the end of 2022, RITTA contained information on almost 800 patients.

Expanding the organ donor pool

The Committee of Ministers adopted Recommendation CM/Rec(2022)3.[13] This legal instrument, elaborated by the CD-P-TO, recommends that states develop and optimise programmes for the donation of organs after the circulatory determination of death, due to their potential to increase significantly the donor pool and thus the number of available organs.

Supporting self-sufficiency in tissues and cells

In 2022, the Committee of Ministers adopted Recommendation CM/Rec(2022)19,[14] elaborated by the CD-P-TO, encouraging member states to harmonise the collection of data on the availability and use of tissues and cells according to a predefined set of parameters and definitions. This text aims to support self-sufficiency and to facilitate data sharing across borders with the ultimate goal of ensuring rational, fair, timely and equitable access to safe tissues and cells for human application.

9. Available at https://go.edqm.eu/CommodificationSoHO.
10. "Combating the commodification of and trafficking in tissues of human origin", AS/Soc (2023) 10 / Declaration, available at https://pace.coe.int/en/pages/assoc-docdecs; Committee of Ministers, CM/Inf(2023)2, available at https://go.edqm.eu/CMInf20232.
11. Available at https://go.edqm.eu/CMRes201355.
12. Available at https://go.edqm.eu/CMRes20172.
13. Available at https://go.edqm.eu/CMRec20223.
14. Available at https://go.edqm.eu/CMRec202219.

Joint programmes

In the framework of its co-operation with the European Commission, the EDQM led a project to benchmark screening practices in Europe for blood samples obtained post-mortem from potential tissue donors and to develop recommendations in the field. The ultimate goal of the project was to support future policy decisions that would increase the number of tissue donors while maintaining safety standards for the detection of infectious diseases. A report based this project was subsequently published (see "Publications", below).

The EDQM also organised the "2nd European training course on Quality Management for Tissue Establishments",[15] with 150 participants from 29 countries in attendance. This training event provided tools for the successful implementation of a quality management system, from identification of a potential donor through processing and storage of the tissues or cells, to the final preparation for application in the patient.

European Day for Organ Donation and Transplantation

The 2022 European Day for Organ Donation and Transplantation (EODD) was hosted by Poland on 8 October, and featured a conference for healthcare professionals on hot topics in transplantation, such as the impact of the COVID-19 pandemic on transplantation services, donation after circulatory determination of death and transplant registries.[16]

EODD was supported by a social media campaign aimed at raising awareness of organ, tissue and cell donation. This year's campaign sought to recruit "influencers for life" who would take the time to consider organ, tissue and cell donation.[17]

Publications

Guide to the quality and safety of organs for transplantation

The EDQM published the 8th edition of the Organ Guide. The updated guide provides guidance to all professionals in the field to improve access to safe transplantation therapy.

Guide to the quality and safety of tissues and cells for human application

The EDQM also published the 5th edition of the Tissues and Cells Guide, intended for healthcare professionals involved in all stages of the handling of tissues and cells, from identifying potential donors to clinical application in patients. It is complemented by the EDQM Microbiological Risk of Contamination Assessment (MiRCA) online tool, which helps users assess such risks during the procurement and processing of tissues and cells.

"Tissue donation. Everything you need to know"

The CD-P-TO also published a booklet on tissue donation[18] drafted in collaboration with the European Association of Tissue Banks (EATCB) and the European Eye Bank Association (EEBA), which provides clear, accurate and balanced information to help readers make informed, responsible decisions on tissue donation.

Organs, tissues and cells

Guide to the quality and safety of organs for transplantation

8th Edition

Guide to the quality and safety of tissues and cells for human application

5th Edition

Newsletter Transplant

2022 Edition

15. See https://go.edqm.eu/TrainingQMTE.
16. See https://www.eodd2022.eu/index-en.html.
17. More information available at https://www.edqm.eu/en/eodd.
18. All booklets for the general public on tissues and cells are available for download at https://go.edqm.eu/OTCbooklets.

Newsletter Transplant

In addition, the *Newsletter Transplant* was published. This annual publication, co-ordinated by the Spanish National Transplant Organisation (ONT), provides comprehensive information and data from 79 countries worldwide on donation and transplantation, management of waiting lists, organ donation refusals and authorised centres for transplantation activities.

"Understanding post-mortem blood testing practices for tissue donation"

Screening donors for infectious diseases is a critical step in tissue donation. The report based on the project carried out on this topic in co-operation with the European Commission was published along with a companion volume presenting complementary information.[19]

Other publications included:

- "An Analysis by the European Committee on Organ Transplantation of the Council of Europe Outlining the International Landscape of Donors and Recipients Sex in Solid Organ Transplantation", published in *Transplant International* (19 July 2022);[20]
- "The Reality of Inadequate Patient Care and the Need for a Global Action Framework in Organ Donation and Transplantation", published in *Transplantation* (November 2022);[21]
- "International Travel for Transplantation: Time for Transparency", published in *Transplantation* (February 2022).[22]

19. https://freepub.edqm.eu/publications/PUBSD-173/detail.
20. https://doi.org/10.3389/ti.2022.10322.
21. https://doi.org/10.1097/tp.0000000000004186.
22. https://doi.org/10.1097/tp.0000000000003971.

Consumer health

Cosmetics

The cosmetics work programme of the EDQM is aimed at protecting human health across Europe through common product quality and safety requirements, as well as through the co-ordination of official controls, the development of common analytical procedures and the verification of proficiency testing.

Activities

In 2022, the European Committee for Cosmetics and Consumer Health (CD-P-COS) held its annual plenary meeting by videoconference with all its members and observers and took part in a joint meeting with the Network of Official Cosmetics Control Laboratories (OCCL Network) to co-ordinate efforts in market surveillance of cosmetic products.

"Safe cosmetics for young children"

The first edition of this guidance document that provides safety recommendations for the risk assessment of cosmetic products for young children was released in 2012.[23] A complete update was undertaken in 2022 to address the issues of endocrine disruptors and nanomaterials. The new edition (in English and French) will be released in 2023.

Essential oils as ingredients

The CD-P-COS initiated the review of the guidance published in 2016 on the use of essential oils in cosmetic products. Quality requirements and recommendations for risk assessment will be updated. The revised edition should be available in 2023.

The OCCL Network

Quality control of cosmetics: market surveillance studies

The OCCL Network launched an MSS to analyse skin-whitening products for the presence of hydroquinone, mercury and corticosteroids (all of which are prohibited substances) and collect data on their content in arbutin and kojic acid.

An MSS on nail varnishes was initiated to determine their nitrosamine content. Nitrosamines are classified as probable human carcinogens.

It was decided to pursue the MSS on cosmetics for children, started in 2011, to monitor the compliance of "kids' cosmetics" (i.e. cosmetics designed to appeal to children and often perceived as toys) with European regulations.

Nitrosamines

Several OCCLs worked on the validation of an analytical procedure for the determination of non-polar *N*-nitrosamines in cosmetics by LC-MS/MS.

Proficiency Testing Scheme studies

In 2022, two PTS studies were finalised, giving the participants the opportunity to assess their ability to determine four skin-whitening substances in body lotion and chlorhexidine in mouthwash and shampoo. In addition, a PTS study on camphor, menthol, safrole, methyl eugenol and ethanol in cream and mouthwash was run with 18 laboratories registered.

Communication with partners and stakeholders

The EDQM shared information on market surveillance activities with the Platform of European Market Surveillance Authorities for Cosmetics of the European Union (EU PEMSAC). A dialogue was established with the European Commission's DG GROW with a view to co-ordinating and regularly exchanging information on the work of both organisations in the field of cosmetics market surveillance.

23. See www.edqm.eu: *Consumer health > Cosmetics & tattoos > Publications on cosmetic products and tattoo inks.*

Food contact materials and articles

The food contact materials and articles work programme of the EDQM is aimed at protecting human health across Europe through common quality and safety requirements for food contact materials and articles.

Council of Europe Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food[24] includes guiding principles for the implementation of suitable policies and serves as a framework for all technical guidance published by the EDQM on specific food contact materials. Technical guidance documents, test protocols and common analytical procedures help to ensure that these materials and articles comply with the regulations.

Communication with partners and stakeholders

To protect consumers from contaminants in food that originate from packaging materials or containers, NCAs contribute to the elaboration of guidelines, provide expertise and carry out experimental testing.

The EDQM collaborates with the European Commission, its Joint Research Centre and the EFSA to ensure consistency and complementarity of Council of Europe resolutions and technical guidelines with relevant regulations and guidelines in the EU.

The EDQM includes business operators and associations in discussions on how to ensure the safety and quality of materials intended for food contact.

Publications

Experts from competent authorities, official control laboratories and industry were invited to comment on the updated chapters of the practical guide for manufacturers and regulators "Metals and alloys used in food contact materials and articles – A practical guide for manufacturers and regulators" (1st edition 2013).[25] The second edition of this technical guide should be published in 2023, once the comments received have been reviewed.

Best practices on how to prepare, update and check the Declaration of Compliance of food contact materials and articles were discussed among regulators, control laboratories and stakeholders. The outcome of these discussions was a technical guidance document, also to be released in 2023.

To protect consumers from ingesting potentially harmful substances in food that originate from packaging materials or containers, the substances used in the production of materials must be safe, especially when their migration to food cannot be ruled out completely. The safety of many substances has been established by NCAs and the EFSA and this information should be made publicly available. To address this task, the European Committee for Food Contact Materials and Articles (CD-P-MCA) defined the procedures for the compilation of data on substances that were officially evaluated. The data compilation templates will be defined in 2023 and calls for data issued.

A survey report entitled "Metal release from enamelware", based on data collection from official controls in Europe between 2015 and 2018, was released for download on FreePub.[26] NCAs have planned further MSSs and one expert meeting was organised in 2022 to review the different testing conditions and release limits applied in Europe.

24. See https://go.edqm.eu/CMRes20209.
25. See www.edqm.eu: *Consumer health > Food contact materials and articles > Publications on food contact materials and articles.*
26. See https://freepub.edqm.eu/publications/PUBSD-159/detail.

Appendix

Table of abbreviations

3R principles	replacement, reduction and refinement (animal testing)
AAV	adeno-associated virus
AIFA	Italian Medicines Agency
ALIMS	Medicines and Medical Devices Agency of Serbia
API	active pharmaceutical ingredient
aQbD	analytical quality by design
ATC	anatomical therapeutic chemical
BE	blood establishment
B-MJA	Blood Mutual Joint Audit
B-PTS	Blood Proficiency Testing Scheme
B-QM	Blood Quality Management
BRP	biological reference preparation
B-SCEP	Blood Supply Contingency and Emergency Plan
BSP	Biological Standardisation Programme
B-TES	Blood Tailored Expert Support
BWP	Biologics Working Party (EMA)
CAP	Centrally Authorised Product
CAS number	Chemical Abstracts Service Registry number
CAT	Committee for Advanced Therapies
CBD	cannabidiol
CD-P-COS	European Committee for Cosmetics and Consumer Health
CD-P-MCA	European Committee for Food Contact Materials and Articles
CD-P-PH	European Committee on Pharmaceuticals and Pharmaceutical Care
CD-P-PH/CMED	Committee of Experts on Minimising the Public Health Risks Posed by Falsification of Medical Products and Similar Crimes
CD-P-PH/PC	Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care
CD-P-PH/PHO	Committee of Experts on the Classification of Medicines as Regards their Supply
CD-P-TO	European Committee on Organ Transplantation
CD-P-TS	European Committee on Blood Transfusion
CEP	Certificate of Suitability to the European Pharmacopoeia monographs
CEPI	Coalition for Epidemic Preparedness Innovations
CHMP	Committee for Medicinal Products for Human Use
CLEN	Customs Laboratories European Network
CMDh	Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human
CoP	Committee of the Parties
COVAX	COVID-19 Vaccines Global Access initiative
COVID-19	coronavirus disease
CVMP	Committee for Veterinary Medicinal Products (EMA)

DCP	decentralised procedure
DG GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (European Commission)
DG REFORM	Directorate-General for Structural Reform Support (European Commission)
EA	European Co-operation for Accreditation
EA/LC	European Co-operation for Accreditation/Laboratory Committee
EAHP	European Association of Hospital Pharmacists
EATCB	European Association of Tissue and Cell Banks
ECBS	Expert Committee on Biological Standardization
ECDC	European Centre for Disease Prevention and Control
ECSPP	Expert Committee on Specifications for Pharmaceutical Preparations (WHO)
EDQM	European Directorate for the Quality of Medicines & HealthCare
EEA	European Economic Area
EEBA	European Eye Bank Association
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EODD	European Day for Organ Donation and Transplantation
EPAA	European Partnership for Alternative Approaches to Animal Testing
EPC	European Pharmacopoeia Commission
ESCP	European Society of Clinical Pharmacy
EU	European Union
EUNDB	European Union Network Data Board
EuPFI	European Paediatric Formulation Initiative
FDA	Food and Drug Administration (USA)
FIP	International Pharmaceutical Federation
GDG	Generics Discussion Group
GDP	good distribution practice
GEON	General European OMCL Network
GMDP IWG	GMP/GDP Inspectors Working Group (EMA)
GMP	good manufacturing practice
GPGs	Good Practice Guidelines
GTS	CD-P-TS working group entrusted with updating the *Guide to the preparation, use and quality assurance of blood components*
GTWG	Gene Therapy Products Working Group
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HPLC	high performance liquid chromatography
HTS	high throughput sequencing
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICRS	International Chemical Reference Substance
IDMP	identification of medicinal products (ISO)
IEC	International Electrotechnical Commission
IMI	Innovative Medicine Initiative (EU)
IMWP	International Meeting of World Pharmacopoeias

INN	International Nonproprietary Names
IPRP	International Pharmaceutical Regulators Program
ISA	International Standards for Antibiotics
ISO	International Organization for Standardization
ISO TC	ISO technical committee
ISS	Istituto Superiore di Sanità (Italian National Health Institution)
IT	information technology
IVMP	immunological veterinary medicinal product
IWP	Immunologicals Working Party
JP	Japanese Pharmacopoeia
LC-MS/MS	liquid chromatography with tandem mass spectrometry
mAb	monoclonal antibody
MiRCA	Microbiological Risk of Contamination Assessment
MJA	Mutual Joint Audit
MJV	Mutual Joint Visit
mRNA	messenger ribonucleic acid
mRNAVAC	mRNA vaccine working party (EPC)
MRP	Mutual Recognition Procedure
MSS	market surveillance study
MSSIP	market surveillance study on suspected illegal products
NAT	nucleic amplification technique
NC3Rs	National Centre for the Replacement, Refinement & Reduction of Animals in Research (United Kingdom)
NCA	national competent authority
NDEA	*N*-nitrosodiethylamine
NDMA	*N*-nitrosodimethylamine
NETTA	Network of National Focal Points on Travel for Transplantation
NFP	national focal point
NGS	next-generation sequencing
NISG	Nitrosamines International Strategic Group
NITWG	Nitrosamines International Technical Working Group
NMR	nuclear magnetic resonance
NPA	national pharmacopoeia authority
OBPR	Official Batch Protocol Review
OCABR	Official Control Authority Batch Release
OCCL	official cosmetics control laboratory
OECD	Organisation for Economic Co-operation and Development
OMCL	official medicines control laboratory
ONT	Organización Nacional de Trasplantes (Spanish National Transplant Organisation)
OPV	oral poliovirus vaccine
PDCO	Paediatric Committee (EMA)
PDG	Pharmacopoeial Discussion Group
PDMP	plasma-derived medicinal product
PEMSAC	Platform of European market surveillance authorities for cosmetics

Ph. Eur.	European Pharmacopoeia
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PM RA	post-marketing risk assessment
PTS	Proficiency Testing Scheme
QDG	Quality Discussion Group
QM	quality management
QMS	quality management system
qRMN	quantitative nuclear magnetic resonance
QWP	Quality Working Party
RA	risk assessment
RBS	Romanian Blood System
RITTA	Registry of International Travel for Transplantation Activity
RNA	ribonucleic acid
RPT	rabbit pyrogen test
RS	reference standard
RTEMIS	Real-Time Remote Inspection System
SARE	serious adverse reactions and events
SARM	selective androgen receptor modulator
SDS	safety data sheet
SEEHN	South-eastern European Health Network
SoHO	substance of human origin
SUP	suspicious unknown product
TFDA	Taiwan Food and Drug Administration
TNF-alpha	tumour necrosis factor alpha
TV	training visit
Unicef	United Nations International Children's Fund
UNODC	United Nations Office on Drugs and Crime
USP	United States Pharmacopeia
VAC2VAC	vaccine batch to vaccine batch comparison by consistency testing
VBRN	Veterinary Batch Release Network
VICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Veterinary Use
WG	working group
WGEO	Working Group of Enforcement Officers (HMA)
WGQM	Working Group of Quality Managers
WHO	World Health Organization
WP	working party

This report presents the work carried out in 2022 by the European Directorate for the Quality of Medicines & HealthCare, highlighting its particular achievements.

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