EDQM & European Pharmacopoeia: State-of-the-art Science for Tomorrow’s Medicines

International Conference organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM),
Council of Europe
19-20 June 2019, Strasbourg, France
International Developments

Outline

1. Introduction
2. ICMRA and Innovation
3. Evolution of ICH
4. Update on IPRP
5. Summary
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Developments in our environment

- Digitisation
- Evidence generation (RWD/RWE)
- Gene and cell therapy
- Cost of healthcare
- Globalised supply chains
- Personalised/Precision medicine
- Digital products
- Artificial intelligence
- Political developments
- Pharmaceutical crime
- Continuous manufacturing
- … and many more
Outline

1. Introduction
2. ICMRA and Innovation
3. Evolution of ICH
4. Update on IPRP
5. Developments at the WHO
6. Summary

International Coalition of Medicines Regulatory Authorities (ICMRA)

ICMRA provides a global architecture to support enhanced communication, information sharing, crisis response and address regulatory science issues.

- 27 member regulators and the WHO as observer
- Strategic initiatives include: Communication, crisis management, pharmacovigilance, supply chain integrity and innovation

www.icmra.info
Innovation at ICMRA

Innovation was adopted as a strategic priority for ICMRA in 2017.
“The ongoing wave of innovations will continue to challenge regulators.”
Aim: Facilitation of safe and timely access to innovative health products
Three work streams were initiated:
1. Analysis of global best practice in horizon scanning methodologies
2. Leveraging outcomes of horizon scanning
3. Novel approaches for licensing

Initial project phase was concluded earlier this year and outcomes were summarised in a report.

Recommended path forward:
1. Establishment of an informal Innovation network within ICMRA
2. Development of a capacity framework for expertise required for regulation in the future
3. Publication of an Innovation position statement

The report and the statement are published on the ICMRA website: www.icmra.info/drupal/strategicinitiatives/innovation
Successful reform

**Governance:** Focus the role of regulators in ICH and further distinguish decision-making role of regulators vs. regulated industry

**Transparency:** Improve transparency and openness of ICH and its processes – provide more on website about ongoing business and work products

**International outreach:** Increase the involvement of other regulators as well as those global industry sectors that are affected by ICH guidelines

**Legal entity:** Set up ICH as a legal entity as continuing activities in the current informal setting will be difficult in the changed environment e.g. with more members

**Funding:** Identify an alternative funding model that would make ICH less dependent in the future of the current form of industry funding
Assembly members and Observers (June 2019)

Members:
- Founding Regulatory: EC/EMA, MHLW/PMDA, FDA
- Founding Industry: EFPIA, JPMA, PhRMA
- Standing Regulatory: Swissmedic, Health Canada
- Regulatory: ANVISA (Brazil), NMPA (China), TFDA (Chinese Taipei), HSA (Singapore) MFDS (South Korea)
- Industry: BIO, IGBA, WSMI

Standing Observers:
- WHO, IFPMA

Observers:
Regulatory authorities, RHIs, international pharmaceutical industry organisations, international organisations with an interest in pharmaceuticals

Assembly Observers (June 2019)

Legislative or administrative Authorities
- ANMAT, Argentina (new)
- SCDMTE, Armenia
- TGA, Australia
- INVIMA, Colombia
- CECMED, Cuba
- CDSCO, India
- NRA, Iran
- CPED, Israel (new)
- National Center, Kazakhstan
- JFDA, Jordan (new)
- NPRA, Malaysia
- COFEPRIS, Mexico
- MMDA, Moldova
- Roszdravnadzor, Russia
- SFDA, Saudi Arabia (new)
- SAHPRA, South Africa
- TİTCK, Turkey

Regional Harmonization Initiatives (RHIs)
- APEC
- ASEAN
- EAC
- GHC
- PANDRH
- SADC

International organisations with an interest in pharmaceuticals
- BMGF
- CIOMS
- EDQM
- IPEC
- PIC/S
- USP

International pharmaceutical industry organisation
- APIC
Enlarged membership of the ICH Management Committee

Members:
- Founding Regulatory: EC/EMA, MHLW/PMDA, FDA
- Founding Industry: EFPIA, JPMA, PhRMA
- Standing Regulatory: Swissmedic, Health Canada
- Regulatory: NMPA (China), HSA (Singapore), MFDS (South Korea)
- Industry: BIO, IGBA

Standing Observers: WHO, IFPMA

Experts in ICH Working Groups

As of May 2019, 39 % of the 646 experts in ICH Working Groups came from members, observers and standing observers (March 2017: 24 %, November 2018: 34 %).
Implementation of ICH Guidelines

ICH Implementation Subcommittee established in Nov. 2017

Mandate:
• Build an implementation survey to serve ICH objectives:
  • Harmonization of standards to benefit public health;
  • Identification of training opportunities;
  • Transparency
• The long-term objective is to establish a sustainable ICH-driven mechanism to assess implementation of the ICH Guidelines over time.

Definition of terms around implementation
• Not (yet) implemented
• In the process of implementation
• Implemented (self-declaration by regulator; step 5)
• (Not) adequately implemented
• (Lack of) adherence (in practice)
• Confirmed adequate implementation/adherence (by survey)
• Not applicable
Implementation of ICH Guidelines


Definitions: (Initial) Implementation

- Implemented (self-declaration of regulator)
- Not adequately implemented
- Adequate implementation
- Not (yet) implemented
- In the process of implementation
- ICH study/tool to assess adequacy of implementation

Evolution of ICH
Definitions: **Adherence** (in practice)

ICH study/tool to assess adequacy of implementation

- Implemented (self-declaration of regulator)
- Not adequately implemented
- (Confirmed) Adequate implementation
- (Confirmed) Lack of Adherence

ICH study/tool to assess adherence to guideline

Evolution of ICH

**Implementation of ICH Guidelines**

- Participants in the survey
  - ICH member regulatory authorities - mandatory
  - ICH observer regulatory authorities - on a voluntary basis
  - List of companies identified by ICH MC industry associations (BIO, EFPIA, IGBA, JPMA, PhRMA)
- Survey has been conducted in 1st half of 2019.
- Results have been presented to ICH Assembly in June 2019.
- A summary report will be made public before the end of 2019.
- The implementation subcommittee has completed its mandate and has been disbanded.
ICH New topics 2018

• Q2(R2)/Q14 Analytical Procedure Development and Revision of Q2(R1) Analytical Validation
• Q13 Continuous manufacturing
• M11 Clinical electronic Structured Harmonised Protocol (‘CeSHarP’)
• E20 Adaptive Clinical Trials (work will start shortly)
• M12 Drug interaction Studies (work will start shortly)

ICH New topics 2019

• Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin
• E6(R3) Guideline for Good Clinical Practice
• E2D(R1) Post Approval Safety Data Management
• S12 Guideline on Non-clinical Biodistribution Studies for Gene Therapy Products
• Q15 Guideline on Impurity: Assessment and Control of Extractables and Leachables (E&L) for Pharmaceuticals and Biologics (delayed start)
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International Pharmaceutical Regulators Program (IPRP)

IPRP consolidates activities of IPRF and IGDRP

- Eight working groups:
  - Former IPRF
    - Cell therapy
    - Gene therapy
    - Nanomedicines
    - Biosimilars
    - Identification of medicinal products
  - Former IGDRP
    - Information sharing for generics
    - Bioequivalence of generics
    - Quality of generics
International Pharmaceutical Regulators Program (IPRP)

New chair and vice-chair taking over after Amsterdam meeting.

Chair: Dr. Junko Sato, MHLW/PMDA, Japan
Vice-chair: Dr. Hacer Coşkun Çetintaş, TİTCK, Turkey

Focus areas of Amsterdam meeting:
• Regulatory updates from various members; discussion of best practices and common challenges
• Updates from working-groups
• Big data / RWD in the area of pharmacovigilance
• Outcome of survey on reliance and work-sharing
Reliance is the key to an efficient, risk-based regulatory system

- Global Benchmarking Tool (GBT): audit, define maturity level and identify gaps
- WHO Listed Authorities (WLA): Regulatory Authorities with a maturity level of 3 or 4
- Good Regulatory/Reliance Practices (GRP: Guidance on how to regulate and rely.
- IPRP: best practices, exchange of experiences & lessons learnt

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ICMRA, ICH and IPRP

- ICMRA strategic priority on innovation has concluded initial phase; innovation network established.
- ICH increases its outreach and now involves close to 50 organisations.
- More than a third of experts in ICH working groups come from new members and observers.
- ICH completes first survey on the status of implementation of and adherence to ICH guidelines.
- IPRP completes work on a survey in the area of reliance and recognition approaches of its member regulators.
- This feeds into the development of Good Reliance Practices by the WHO.

List of abbreviations (in alphabetical order)

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ANMAT</td>
<td>National Administration for Drugs, Food and Medical Devices</td>
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<td>ANVISA</td>
<td>Brazilian Health Surveillance Agency</td>
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<tr>
<td>APEC</td>
<td>Asia-Pacific Economic Cooperation</td>
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<td>APIC</td>
<td>Active Pharmaceutical Ingredients Committee</td>
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<td>ASEAN</td>
<td>Association of Southeast Asian Nations</td>
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<tr>
<td>BIO</td>
<td>Biotechnology Innovation Organization</td>
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<td>BMGF</td>
<td>Bill &amp; Melinda Gates Foundation</td>
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<tr>
<td>CDSCO</td>
<td>Central Drugs Standard Control Organization, India</td>
</tr>
<tr>
<td>CECMED</td>
<td>Regulatory Authority for Medicines and Medical Devices, Cuba</td>
</tr>
<tr>
<td>CIOMS</td>
<td>Council for International Organizations of Medical Sciences</td>
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<tr>
<td>COFEPRIS</td>
<td>Federal Commission for the Protection against Sanitary Risks, Mexico</td>
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<tr>
<td>CPED</td>
<td>Center for Pharmaceuticals and Enforcement Divisions, Israel</td>
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<tr>
<td>EAC</td>
<td>East African Community</td>
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<tr>
<td>EC</td>
<td>European Commission</td>
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<tr>
<td>EDQM</td>
<td>European Directorate for the Quality of Medicines and Healthcare</td>
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<tr>
<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries and Associations</td>
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<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
</tr>
<tr>
<td>GBT</td>
<td>Global Benchmarking Tool, WHO</td>
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<tr>
<td>GHC</td>
<td>Gulf Health Council</td>
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<tr>
<td>HSA</td>
<td>Health Sciences Authority, Singapore</td>
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<tr>
<td>ICH</td>
<td>International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use</td>
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<tr>
<td>ICMRA</td>
<td>International Coalition of Medicines Regulatory Authorities</td>
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<td>IFPMA</td>
<td>International Federation of Pharmaceutical Manufacturers &amp; Associations</td>
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<tr>
<td>IGBA</td>
<td>International Generic and Biosimilar Medicines Association</td>
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<tr>
<td>INVIMA</td>
<td>National Institute of Food and Drug Monitoring, Columbia</td>
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<td>IPERG</td>
<td>International Pharmaceutical Excipients Council</td>
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<td>IPRP</td>
<td>International Pharmaceutical Regulators Programme</td>
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<td>JFDA</td>
<td>Jordan Food and Drug Administration</td>
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<tr>
<td>JPMA</td>
<td>Japan Pharmaceutical Manufacturers Association</td>
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<tr>
<td>MedDRA</td>
<td>Medical dictionary for adverse event reporting and coding of clinical trial data</td>
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<tr>
<td>MFDS</td>
<td>Ministry of Food and Drug Safety, Korea</td>
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<tr>
<td>MHLW</td>
<td>Ministry of Health, Labour and Welfare, Japan</td>
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<tr>
<td>MMDA</td>
<td>Medicines and Medical Devices Agency, Moldova</td>
</tr>
<tr>
<td>NMPA</td>
<td>National Medical Products Administration, China</td>
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<tr>
<td>NPRA</td>
<td>National Pharmaceutical Regulatory Agency, Malaysia</td>
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<tr>
<td>PANDRH</td>
<td>Pan-American Network for Regulatory Harmonisation</td>
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### List of abbreviations (in alphabetical order)

<table>
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<th>Abbreviation</th>
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<tbody>
<tr>
<td>PhRMA</td>
<td>Pharmaceutical Research and Manufacturers of America</td>
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<td>PIC/S</td>
<td>Pharmaceutical Inspections Cooperation Scheme</td>
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<td>PMDA</td>
<td>Pharmaceuticals and Medical Devices Agency, Japan</td>
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<td>RHI</td>
<td>Regional Harmonisation Initiative</td>
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<td>Roszdravnadzor</td>
<td>Federal Service on Surveillance in Healthcare, Russia</td>
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<tr>
<td>RWD/RWE</td>
<td>Real-world data/real-world evidence</td>
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<tr>
<td>SADC</td>
<td>Southern African Development Community</td>
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<tr>
<td>SAHPRA</td>
<td>South African Health Products Regulatory Authority</td>
</tr>
<tr>
<td>SCDMTE</td>
<td>Scientific Center of Drug and Medical Technologies Expertise, Armenia</td>
</tr>
<tr>
<td>SFDA</td>
<td>Saudi Food and Drug Authority, Saudi Arabia</td>
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<tr>
<td>TFDA</td>
<td>Taiwan Food and Drug Administration</td>
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<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration, Australia</td>
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<tr>
<td>TITCK</td>
<td>Turkish Medicines and Medical Devices Agency</td>
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<tr>
<td>US-FDA</td>
<td>United States Food and Drug Administration</td>
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<td>USP</td>
<td>United States Pharmacopeia</td>
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<td>WG</td>
<td>Working Group</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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<td>WLA</td>
<td>WHO Listed Authority</td>
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<td>WSMI</td>
<td>World Self-Medication Industry</td>
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### Contact Information

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EDQM in International Harmonisation Initiatives

Cathie Vielle
Head of the Ph. Eur. Department – Secretary to the Ph. Eur. Commission
EDQM, Council of Europe
As far as the Ph. Eur. ("documentary standards") is concerned...

Bilateral cooperation [eg: MoU]

ICH

IMWP

PDG
Bilateral cooperation (1/2)

Informal prospective harmonisation:

- Ph. Eur. & USP: 19 monographs harmonised:
  - 13 monographs on API
  - 6 monographs on finished products
  - Further 15 monographs on the work program

<table>
<thead>
<tr>
<th>Monograph</th>
<th>Date</th>
<th>Adopted</th>
<th>Version</th>
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<tbody>
<tr>
<td>Carboclit</td>
<td>2013</td>
<td></td>
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<tr>
<td>Dexamethasone hexahydrate</td>
<td>2013</td>
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<tr>
<td>Cyclodextrin</td>
<td>2013</td>
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<td>Furosemide hydrochloride</td>
<td>2013</td>
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<td>Lamotrigine</td>
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<tr>
<td>Metabolites</td>
<td>2013</td>
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<td>Neuramidase activity</td>
<td>2013</td>
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<td>Penicillin sulphate</td>
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<td>Saccharose diastase</td>
<td>2013</td>
<td></td>
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<td>Saline solution</td>
<td>2013</td>
<td></td>
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<tr>
<td>Thrombin</td>
<td>2013</td>
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Bilateral cooperation (2/2)

MoU on collaboration and exchanges e.g. EDQM – ChP; EDQM – MHLW/JP; EDQM – ANVISA;

- involvement of observers in the elaboration/revision of texts.
- Information sharing (of data, know-how...) ; co-organisation of events
International Meetings of World Pharmacopoeias

- Recent initiative for harmonisation/convergence at a global scale following a meeting of world pharmacopoeias.
- Outcome to date: “Good Pharmacopoeial Practices”, a document describing policies and approaches to monograph development, publicly available on WHO website as well as two annexes on herbal medicines and compounded preparations.
- Intended to serve as basis for exchanges and networking between different pharmacopoeias to identify opportunities for collaboration and, where relevant, work sharing and recognition.
- WHO as a “neutral platform”.
- Ongoing: elaboration of a *white paper on added value of pharmacopoeia standards for public health*.

Pharmacopoeial Discussion Group (PDG)

PDG reforms approved in 2017:
- Restructuring meeting format to engage more at the technical level and introduce more direct exchange between the experts in the regions
- Streamlining of working procedure, reducing complexity => elimination of two stages to increase efficiency and improve focus.
- Strategic review of harmonization areas and individual work items currently in progress and for future consideration still ongoing.
- Cleaning of the work programme => identification of items to be considered outside of PDG (e.g. bilateral discussion)

Prioritisation scheme for excipient monographs and general chapter:
- Strategic review conducted of 10 excipient monographs and 5 general chapters
- Extension to remaining general chapters
- Need for further discussion for excipient monographs
Transparency => another PDG priority

• Towards other Pharmacopoeias:
  • Discussion on how information on progress made by the PDG should be shared amongst the PDG member pharmacopoeias and other pharmacopoeias participating in the International Meeting of World Pharmacopoeias (IMWP) => to be continued at the next face-to-face meeting which will be hosted by the JP on 1-2 October 2019 in Tokyo (Japan)

• Towards other harmonisation initiatives:
  • New Maintenance Procedure on the ICH Q4B Annexes Adopted by the ICH Assembly

• Towards users:
  • PDG harmonisation policy to be further updated to provide additional clarity to users.

Chapter 5.8 : will change in 10th Edition

10th Edition:

NOTE ON THE GENERAL CHAPTER
With a view to increasing transparency on the texts harmonised by the PDG, it is proposed to stop mentioning the harmonised and non-harmonised items, as well as the local requirements, in this chapter; conversely sign-off coversheets signed off by the PDG will be made available on the EDQM website. This chapter has been revised accordingly.

• Chapter 5.8 will no longer give details on harmonisation of individual monographs, PDG process explained in general

• List of harmonised monographs will be published separately

• It remains the ultimate responsibility of the user to verify the current content of the texts in force in the respective pharmacopoeias
Why a new maintenance procedure? Some history

1989
- PDG formed (EP, JP, USP)

1990
- WHO observer to PDG

1999
- establishment of ICH

2001
- approval of ICH Q6A “Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances” by ICH SC

2003
- evaluation of all texts on the work program was concluded and 14 ICH Q4B annexes had been adopted

2010
- They are published on the website of ICH and of individual regulatory authorities, e.g. the EMA.

2018
- PDG new maintenance procedure of ICH Q4B annexes approved by the ICH Assembly (14-15 Nov. 2018, Charlotte, NC, USA)

ICH SC decided not to further expand the ICH Q4B work programme and to disband the ICH Q4B EWG.

establishment by ICH of the Q4B EWG to evaluate selected PDG harmonised chapters to facilitate their recognition by regulatory authorities for use as interchangeable in the ICH regions.

=> harmonisation of several compendial test chapters (“general chapters”) considered as critical by the ICH SC => PDG requested to include these general chapters in its work program.
As with the former ICH Q4B process, the need to revise a Q4B annex would be triggered by PDG’s sign-off of a revised text subject to Q4B. Potentially non-harmonised and/or local requirements are highlighted in the sign-off coversheet.

Step 1:
- PDG compares the corresponding current ICH Q4B Annex, the PDG sign-off text as well as the corresponding Ph. Eur., JP and USP chapters as published in the respective Pharmacopoeias. All other pharmacopoeias are informed of the ongoing review via the contact list of the International meeting of World Pharmacopoeias (IMWP).
- Based on this review, the PDG prepares a revised Q4B annex, which is submitted to the ICH Secretariat for proceeding to Step 2. Depending on the case, revision could be limited to an update on the pharmacopoeial reference texts (i.e. updated versions of the pharmacopoeia).
Future Maintenance process of the ICH Q4B Annexes

Step 2 (former ICH Q4B Step 3):
The draft Q4B annex is submitted to the ICH Secretariat to initiate regulatory consultation (generally for 3 months). The regulatory consultation and discussion should focus on the Q4B Outcome in the annex, i.e. regulatory interchangeability; comments on the harmonised pharmacopeial text itself are not expected. Comments will be evaluated by PDG and the annex revised by PDG, where necessary.

Step 3 (former ICH Q4B Step 4):
PDG submits the revised annex to the ICH Assembly for adoption and publication on the ICH website.
Future Maintenance process of the ICH Q4B Annexes

The annex moves to the regional regulatory implementation step. The corresponding PDG chapter moves to PDG stage 5 (inter-regional acceptance). All other pharmacopoeias are informed via the contact list of the International meeting of World Pharmacopoeias (IMWP).

Other Int’l activities with EDQM involvement

ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use):

The EDQM is an observer to:
  • ICH Assembly
  • important ICH working groups (e.g. Q2/Q14, Q3C, Q3D, Q13, IQDG, IGDG)

=> alignment of Ph. Eur. standards to ICH guidelines but also supporting the implementation of ICH standards in Europe.
But also:

IPRP (International Pharmaceutical Regulators Programme):
www.iprp.global

The EDQM is:

• an observer to the Management Committee
• co-chair of the IPRP Quality Working Group for Generics:
  ➢ Information sharing and work sharing of Quality information for ASMF/DMF
    and applications for generic products
  ➢ For greater collaboration and potentially regulatory convergence in
    assessment of generic products

Some further examples ...

in the field of RS
Biological Standardisation Program

For the BSP in the context of globalisation of medicines, international awareness and co-operation is essential to:

- Avoid duplication
- Have commonly recognised and comparable units
- Foster method adoption, particularly in the 3R field

Examples

- Establishing common reference materials with WHO and other regions
- Encouraging multi-regional participation in collaborative trials and method development
- Exchanging views in common fora for strategy development

Some BSP International Partners

- **International Organisations**
  - WHO, OIE

- **EU Organisations**
  - VAC2VAC, EPAA

- **EU Authorities**
  - EMA, EU Commission

- **International Authorities**
  - Canada, USA (FDA, USDA), Mexico, Brazil, Australia, Japan, South Korea, Taiwan FDA, China, India and others
EDQM activities for the WHO – ECSPP & ECBS

The EDQM is an observer to the WHO Expert Committee on:
• Specifications for Pharmaceutical Preparations (ECSPP) which aims at the development of standards and guidelines to promote the quality assurance and quality control of medicinal products around the world.
• Biological Standardization (ECBS) which provides detailed recommendations and guidelines for the manufacturing, licensing and control of blood products and related in vitro diagnostic tests, biotechnology products and vaccines along with the establishment of WHO Biological Reference Materials.

EDQM activities for the WHO - ICRS

The EDQM is responsible for the establishment and distribution of the
WHO International Chemical Reference Substances

These reference substances are used in conjunction with the monographs and texts of the International Pharmacopoeia, which is published and maintained by the WHO.
EDQM activities for the WHO - Int’l standards

In 2018, the EDQM Laboratory participated in two international collaborative studies organised by the WHO for the establishment of two new International Standards:

• D-Antigen content of sIPV preparations and
• Adalimumab.

EDQM activities for the WHO - ISA

The EDQM is responsible for the establishment and distribution of the WHO International Standards for Antibiotics

which are essential for the standardisation and quality control of antibiotic drug substances and medicinal products.

These standards are supplied across the world for microbiological assays performed in the context of the quality control of antibiotics.
Call for experts 2019-2022

Provide a **vital and invaluable contribution** to the elaboration and maintenance of Ph. Eur. texts **by taking part** in the work of the Ph. Eur.

- **Expand** your knowledge of the Ph. Eur. and the European regulatory system
- **Network** with peers and other professionals with various backgrounds and from all over Europe and beyond
- **Help shape** Ph. Eur. texts, internationally-recognised quality standards for medicines
- **Share** information and experience

Nomination process **now open** to all experts!

- Ph. Eur. member states: via your respective National Pharmacopoeia Authorities.
- Non Ph. Eur. member states: via EDQM [Helpdesk](#) service.

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Thank you for your attention
Thank you for your attention

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