THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

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

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PRÉSIDENCE FRANÇAISE
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2019

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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

10th Edition of the European Pharmacopoeia, EDQM, Strasbourg, 20 June 2019

International Developments

swissmedic

Dr. Petra Doerr, Head of Communication & Networking, Deputy Director, Swissmedic

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Outline

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

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Introduction

Developments in our environment

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

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Outline

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

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ICMRA & Innovation

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

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ICMRA & Innovation

Innovation at ICMRA

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

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Successful reform

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

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

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

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 — OK

Funding: Identify an alternative funding model that would make ICH less dependent in the future of the current form of industry funding — OK

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Evolution of ICH

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

16 members

Standing Observers: WHO, IFPMA

32 observers

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

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Evolution of ICH

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

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Evolution of ICH

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

June 2018

Standing Observers: WHO, IFPMA

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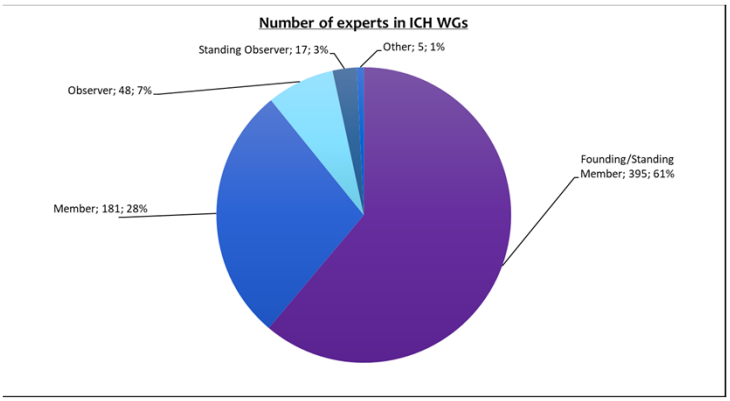
Evolution of ICH

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.

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Evolution of ICH

Implementation of ICH Guidelines

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

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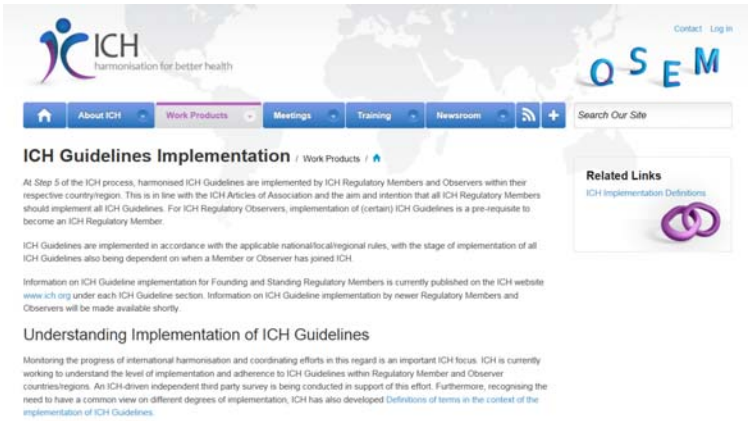
Evolution of ICH

Implementation of ICH Guidelines

https://www.ich.org/products/ich-guidelines-implementation.html



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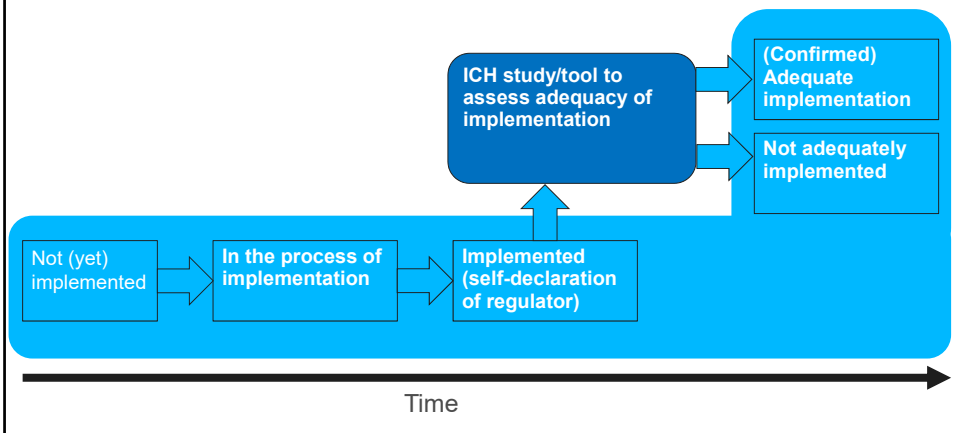
Evolution of ICH

Definitions: (Initial) Implementation



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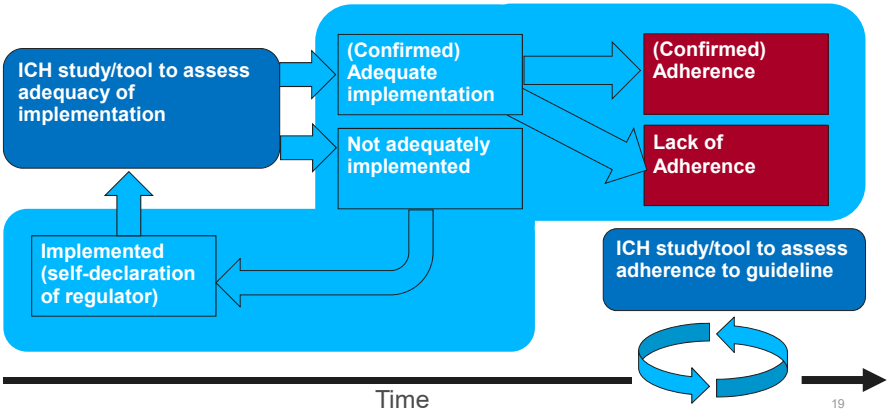
Evolution of ICH

Definitions: Adherence (in practice)



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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 be 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.

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Evolution of ICH

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)

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Evolution of ICH

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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Update on IPRP

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

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Update on IPRP

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

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Update on IPRP

International Pharmaceutical Regulators Program (IPRP)

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

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Update on IPRP

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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Summary

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.

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List of abbreviations (in alphabetical order)

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

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List of abbreviations (in alphabetical order)

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

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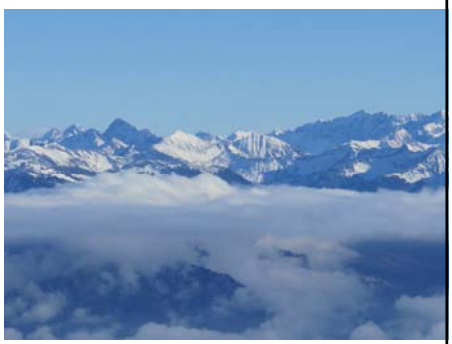

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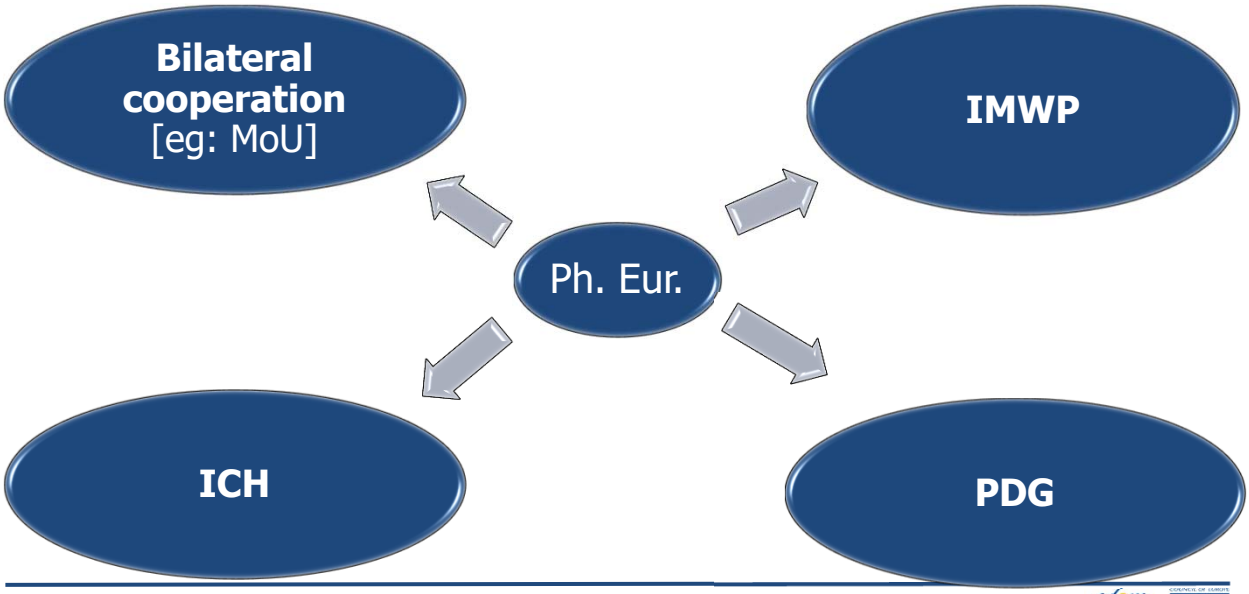
EDQM in International Harmonisation Initiatives

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 (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

Monograph	Mono. No.	Adopted	API/FP
Aprepitant	2757	COM 153, November 2015	API
Celecoxib	2591	COM 140, June 2011	API
Dronedarone hydrochloride	3039	COM, 163 Nov 2018	API
Everolimus	2918	COM 160, March 2018	API
Fingolimod hydrochloride	2988	COM 160, March 2018	API
Lacosamide	2992	COM 158, June 2017	API
Lacosamide infusion	2991	COM 160, March 2018	FP
Lacosamide oral solution	2990	COM 160, March 2018	FP
Lacosamide tablets	2989	COM 161, June 2018	FP
Montelukast sodium	2583	COM 138, November 2010	API
Prasugrel hydrochloride	3040	COM, 163 Nov 2018	API
Raltegravir chewable tablets	2939	COM 158, June 2017	FP
Raltegravir potassium	2887	COM 157, March 2017	API
Raltegravir tablets	2938	COM 158, June 2017	FP
Regorafenib monohydrate	3012	COM 161, June 2018	API
Rizatriptan benzoate	2585	COM 138, November 2010	API
Sildenafil citrate	2270	COM 141, November 2011	API
Sitagliptin phosphate monohydrate	2778	COM 151, March 2015	API
Sitagliptin tablets	2927	COM 151, March 2015	FP

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


Chinese and European Pharmacopoeia Joint Workshop
What's New in the field of excipients in China
19 September 2018
Location: EDQM premises, Strasbourg, France
Working languages: English
FINAL PROGRAMME


IPC-EDQM Symposium on
Drug Standards and Regulatory Updates
26-27 April 2018
Location: Hotel Courtyard Marriott, Mumbai, India
DRAFT PROGRAMME
26 April 2018
WELCOME ADDRESSES
OPENING SESSION


第二届中欧药典专题研讨会（草案）
ChP-EDQM Joint Workshop on International Standards (draft agenda)
2019年7月3日 山东济南
5 July, 2019, Jinan, Shandong, China

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

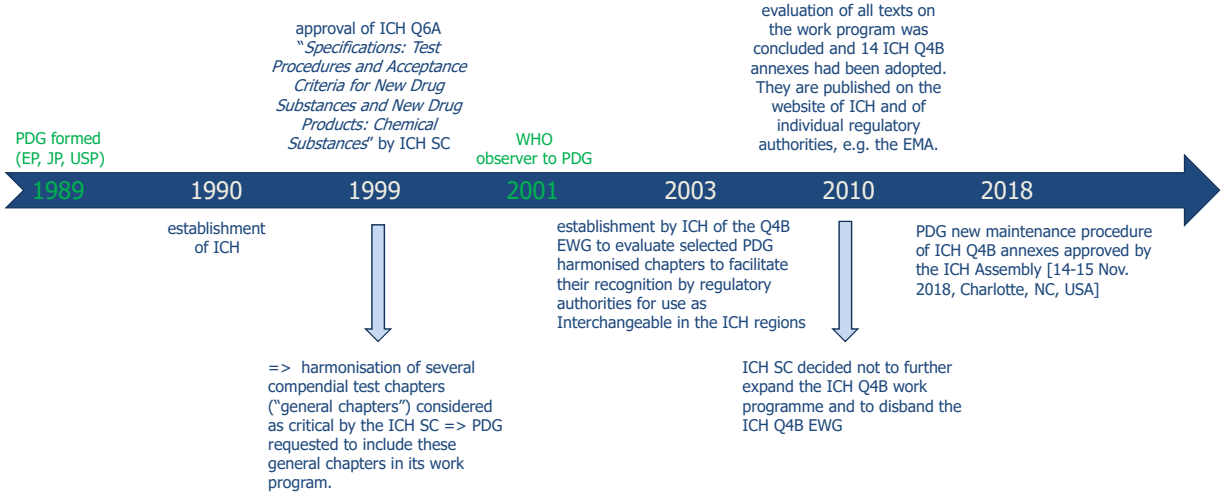
With a view to increasing transparency on the texts harmonised by the PDG, it is proposed to stop mentioning the harmonised and non-harmonised items, as well as the local requirements, in this chapter; conversely sign-off coversheets signed off by the PDG will be made available on the EDQM website. This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

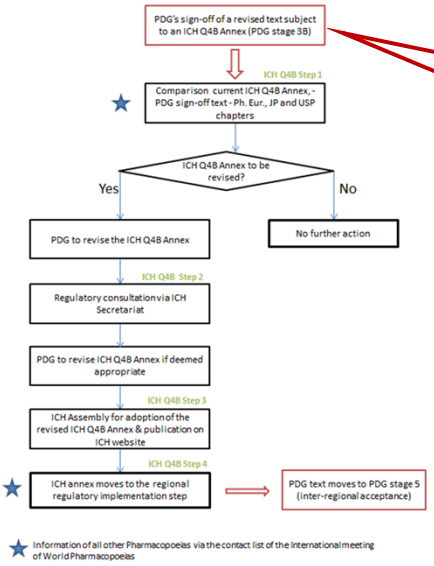
PDG Chapter ⇔ ICH Q4B Annex

CP	PDG Number	PDG Name	Q4B Annex
JP	Q-10	Residue on Ignition	Q4B Annex 1R1 Residue on Ignition/Sulphated Ash
EP	Q-08	Extractable Volume	Q4B Annex 2R1 Test for Extractable Volume of Parenteral Preparations
EP	Q-09	Particulate Contamination	Q4B Annex 3R1 Test for Particulate Contamination: Sub-Visible Particles
EP	Q-05a	Test for Specified Microorganism	Q4B Annex 4AR1 Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests
EP	Q-05b	Microbial Enumeration	Q4B Annex 4BR1 Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-Organisms
EP	Q-05c	Limits for Non-sterile Products	Q4B Annex 4CR1 Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use
USP	Q-02	Disintegration	Q4B Annex 5R1 Disintegration Test
USP	Q-03/04	Uniformity of Content/Mass	Q4B Annex 6 Uniformity of Dosage Units
USP	Q-01	Dissolution	Q4B Annex 7R2 Dissolution Test
EP	Q-11	Sterility Test	Q4B Annex 8R1 Sterility Test
USP	G-06	Tablet Friability	Q4B Annex 9R1 Tablet Friability
EP	B-06	Polyacrylamide Gel Electrophoresis	Q4B Annex 10R1 Polyacrylamide Gel Electrophoresis
EP	B-02	Capillary Electrophoresis	Q4B Annex 11 Capillary Electrophoresis
USP	G-01	Analytical Sieving	Q4B Annex 12 Analytical Sieving
EP	G-02	Bulk Density and Tapped Density	Q4B Annex 13 Bulk Density and Tapped Density of Powders
JP	Q-06	Bacterial Endotoxins	Q4B Annex 14 Bacterial Endotoxins Test

Why a new maintenance procedure? Some history

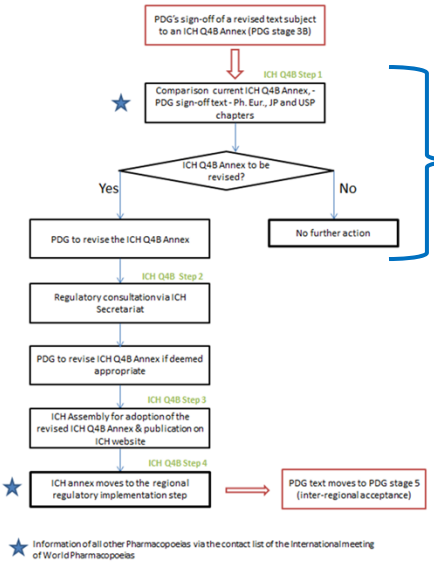


Future Maintenance process of the ICH Q4B Annexes



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.

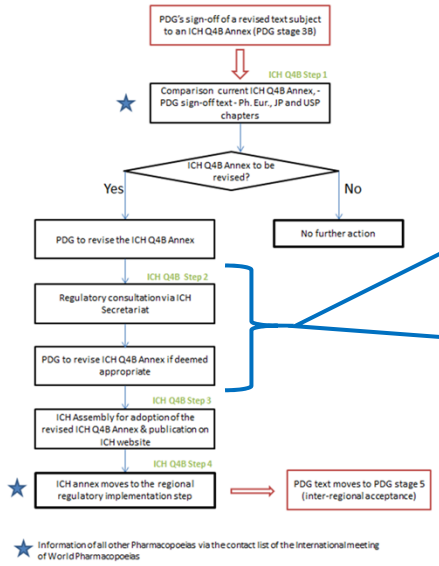
Future Maintenance process of the ICH Q4B Annexes



Step 1:

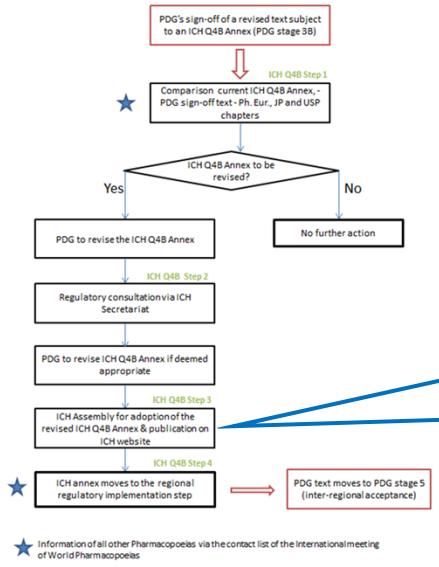
- PDG compares the corresponding current ICH Q4B Annex, the PDG sign-off text as well as the corresponding Ph. Eur., JP and USP chapters as published in the respective Pharmacopoeias. All other pharmacopoeias are informed of the ongoing review via the contact list of the International meeting of World 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



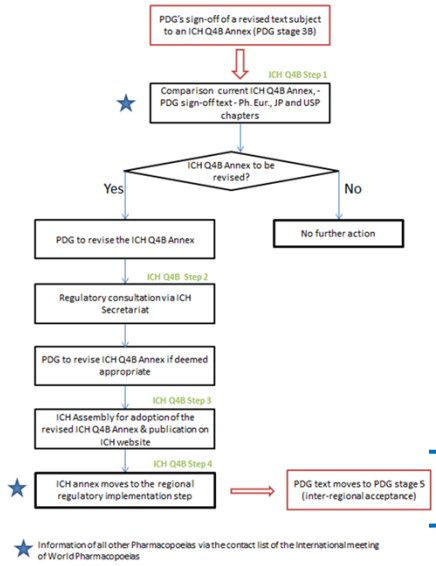
Step 2 (*former ICH Q4B Step 3*):
The draft Q4B annex is submitted to the ICH Secretariat to initiate regulatory consultation (generally for 3 months). The regulatory consultation and discussion should focus on the Q4B Outcome in the annex, i.e. regulatory interchangeability; comments on the harmonised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

Future Maintenance process of the ICH Q4B Annexes



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



Step 4 (*former ICH Q4B Step 5*):
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

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

https://www.edqm.eu/en/WHO-ICRS-Reference-Substances-1393.html

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
https://www.edqm.eu/en/who-international-standards-antibiotics-isa-purpose-use

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.

Thank you for your attention

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