EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Connecting the dots

Towards global knowledge of the international medicine regulatory landscape: mapping of international initiatives

An agency of the European Union

About the ICMRA Mapping Project

In December 2013, the heads of a number of regulatory authorities from across the globe created the International Coalition of Medicines Regulatory Authorities (ICMRA)[1].

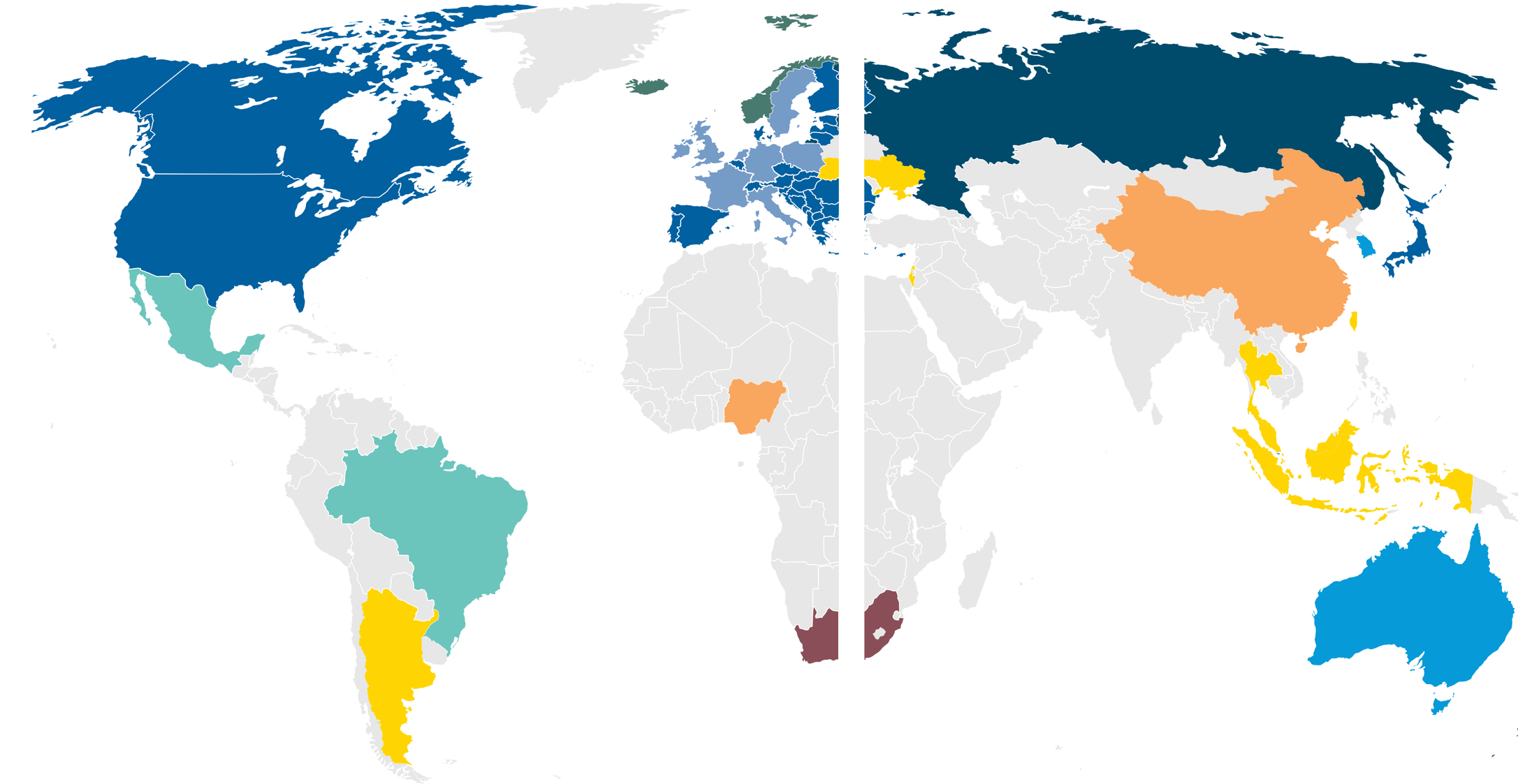
The purpose is to develop strategies to address current and emerging challenges in global human medicine regulation and to provide direction for common activities and areas of work. One of the aims of the coalition is to identify ways to better use existing initiatives and resources to tackle shared problems such as the growing complexity of globalised supply chains.

An early task of the coalition was therefore to identify the variety of international initiatives currently underway so that ICMRA members could have a global overview in order to consider those that would benefit from strategic coordination. This task was assigned to the European Medicines Agency (EMA), who set up a working group with other ICMRA members, to map existing international initiatives. In addition to identifying multinational multi-project initiatives, work areas for a first mapping exercise included generic medicines, good manufacturing practice (GMP) inspections and arrangements for exchanging of confidential information. The work then progressed with the mapping of other working areas of common interest such as supply-chain integrity, crisis management and pharmacovigilance, and with the development of analysis papers based on these mappings, designed to inform the future work of ICMRA.

This report describes the mapping activities performed from February 2014 to December 2015, the results of the analyses and how this work will steer ICMRA efforts in the future. The mapping also aims at raising awareness of ongoing international activities in the area of medicines regulation and is the first clear and comprehensive overview of international projects in which international medicines regulators are involved.

1. ICMRA participation includes regulatory authorities from the following countries/regions: Australia, Brazil, Canada, China, European Union, France, Germany, Ireland, Italy, Japan, Korea, Mexico, the Netherlands, New Zealand, Nigeria, Singapore, South Africa, Switzerland, United Kingdom and United States. The specific regulatory authority(ies) for any of the countries/regions can be found in the annex Mapping of multinational multi-project initiatives. The World Health Organization (WHO) participates as observer.

Figure 1. ICH, PIC/S, IPRF, and ICMRA members (valid as of September 2016)



Notes

1. The map includes only members of forums, not observers
2. It does not include regional membership of ICH
3. Not all EU Member States are members of all forums, but are counted as being members if European Commission's DG SANTE or EMA is a member. Where EU Member States are individual members of ICMRA this is indicated by a lighter colour
4. The 3 EEA-EFTA countries Iceland, Liechtenstein and Norway are members of PIC/S and are treated as included in ICH because EU guidelines apply to them

Introduction

Ever more sophisticated techniques such as biotechnology, gene editing or cell therapies are the basis for increasingly complex medicines that enter the market. Manufacturing phases of a medicine may now be carried out in different countries or even different continents, and a medicine may often be distributed in multiple regions.

In this globalised context, international cooperation among medicine regulators has become key to supervising complex supply chains and avoiding duplication of work to make best use of precious human and financial resources. The fundamental question is not if medicine regulators worldwide need to cooperate, but how they can best cooperate in order to achieve the desired results.

The need for international cooperation has been widely recognised by medicine regulators and many international initiatives have emerged to boost cooperation and convergence at all levels (national, regional and global), covering areas of interest such as inspections, pharmacovigilance and generic medicines. In addition to the work coordinated by the World Health Organization (WHO), the International Council for Harmonisation (ICH), the Pharmaceutical Inspection Co-operation Scheme (PIC/S), the International Pharmaceutical Regulators Forum (IPRF) and the International Coalition of Medicines Regulatory Authorities (ICMRA) are examples of this growing number of international regulatory initiatives.

However, there is a lack of integration and strategic direction for these initiatives, often leading to overlap or duplication of activities, but equally allowing gaps into which important topics can fall. Additionally, the focus of and participation in existing initiatives is variable (figure 1). International cooperation of medicine regulators would greatly benefit from increased coordination among the existing initiatives and from agreed global strategic directions in areas of mutual interest. The ICMRA mapping project was developed to give heads of agencies involved in ICMRA a comprehensive overview of the number and scope of global collaborative initiatives and thus allow them to make informed decisions on the need for involvement or coordination.

Mapping of international initiatives

Phase I

To raise awareness of existing and emerging activities, EMA led the mapping project and developed a project plan for agreement by the ICMRA Management Committee in February 2014. At the time, EMA proposed that the mapping project should firstly, provide a general overview of multi-project initiatives in which multiple regulators were involved and secondly, look at thematic areas on which the ICMRA Management Committee was already focusing (i.e. generic medicines, GMP inspections). In addition, an overview of the status of confidentiality arrangements, memoranda of understanding or other bilateral arrangements on or including pharmaceuticals between ICMRA members was prepared.

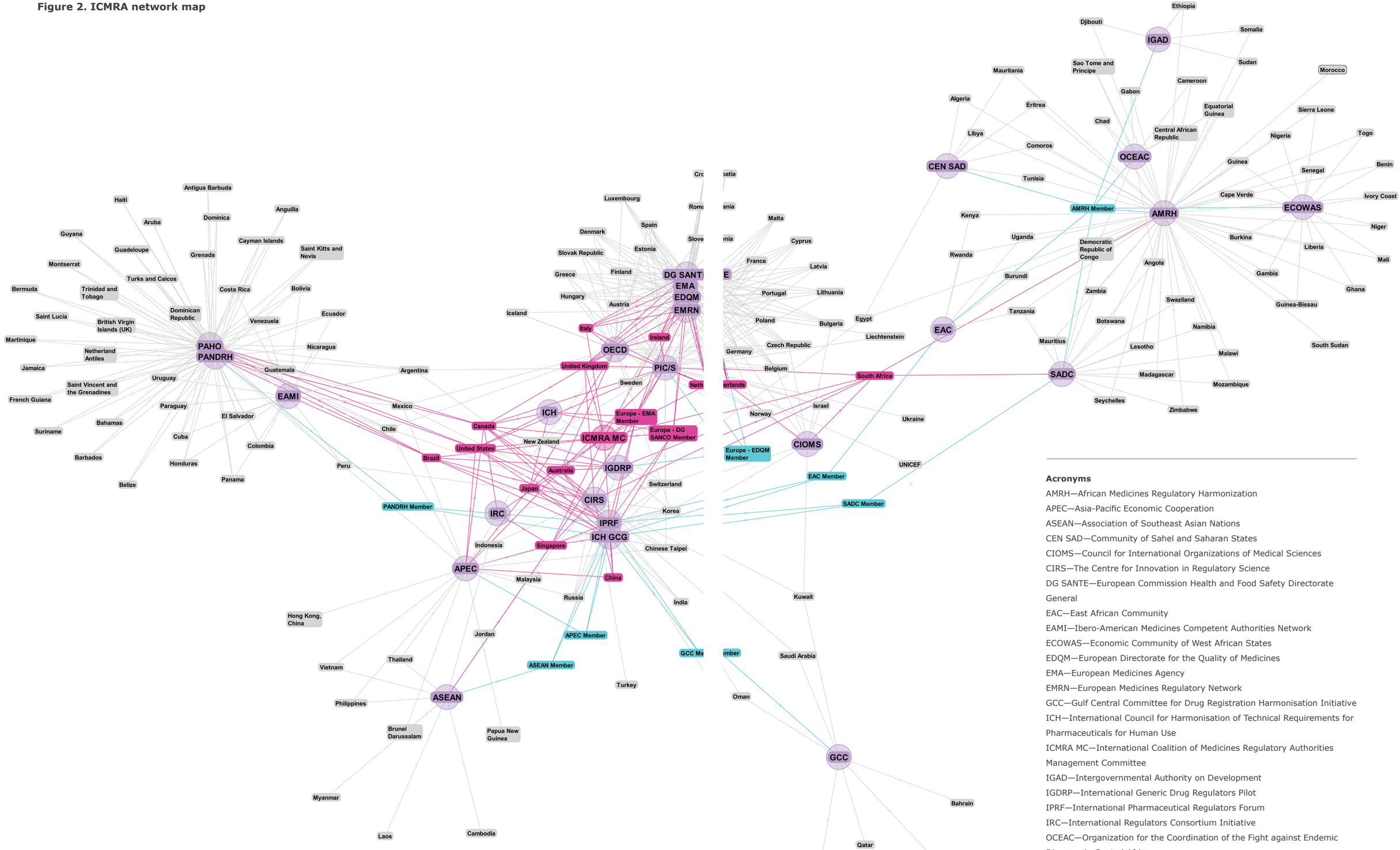
The mapping included the initiative's name, objective, scope, membership, and work products. Where possible, a contact point/email address was made available. Registering different initiatives under common headings facilitated comparison and helped to identify overlaps and gaps. Two examples of the initial mappings (the mapping of multinational multi-project initiatives and of the bilateral arrangements on or including pharmaceuticals between ICMRA members) are provided in the annex. The complete set of mapping documents will be made available on EMA's website.

The mappings produced were compiled based on publicly available information, EMA's existing knowledge and input from other ICMRA members. The initial ICMRA mapping group consisted of representatives from EMA, the United States Food and Drug Administration (FDA), the Health Science Authority (HSA) of Singapore, the National Health Surveillance Agency of Brazil (ANVISA), the Health Products and Food Branch of Health Canada (HPFB-HC), and the Ministry of Food and Drug Safety of South Korea (MFDS). However all ICMRA members were invited to review and contribute. The mapping of generic medicines activities was prepared by the Therapeutic Goods Administration of Australia (TGA) in the context of the ICMRA generic medicines project.

The mappings need to be considered as 'living documents' based on information available at the time of production. They might be amended in the future as new initiatives emerge or existing ones are modified.

Suggestions on the published mappings can be submitted electronically via EMAinternational@ema.europa.eu and will be taken into consideration for future revision.

Figure 2. ICMRA network map



Key

Initiatives*—indicated by purple nodes and matching halos

Organisational members*—indicated by blue nodes

Country members*—indicated by light grey nodes

*ICMRA members are indicated by pink nodes and halos

Acronyms

AMRH—African Medicines Regulatory Harmonization

APEC—Asia-Pacific Economic Cooperation

ASEAN—Association of Southeast Asian Nations

CEN SAD—Community of Sahel and Saharan States

CIOMS—Council for International Organizations of Medical Sciences

CIRS—The Centre for Innovation in Regulatory Science

DG SANTE—European Commission Health and Food Safety Directorate General

EAC—East African Community

EAMI—Ibero-American Medicines Competent Authorities Network

ECOWAS—Economic Community of West African States

EDQM—European Directorate for the Quality of Medicines

EMA—European Medicines Agency

EMRN—European Medicines Regulatory Network

GCC—Gulf Central Committee for Drug Registration Harmonisation Initiative

ICH—International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

ICMRA MC—International Coalition of Medicines Regulatory Authorities Management Committee

IGAD—Intergovernmental Authority on Development

IGDRP—International Generic Drug Regulators Pilot

IPRF—International Pharmaceutical Regulators Forum

IRC—International Regulators Consortium Initiative

OCEAC—Organization for the Coordination of the Fight against Endemic Diseases in Central Africa

OECD—Organization for Economic Co-operation and Development

PAHO—Pan American Health Organization

PANDRH—Pan-American Network for Drug Regulatory Harmonization

PIC/S—Pharmaceutical Inspection Co-operation Scheme

SADC—Southern African Development Community

Initial results and analysis

International (multi-country, multi-regional, multi-project) initiatives in the area of human medicines collaboration were the first to be analysed, in August 2014. This mapping provides a general overview of the existing initiatives, showing the presence of multiple initiatives, some with similar or linked objectives. Figure 2[1] highlights the links between countries or regions and different activities. The mapping table (see annex) gives a factual and illustrative overview of a large range of international projects involving ICMRA members. These could be classified into regionally-focused and cross-regional initiatives.

Regionally-focused initiatives involve countries in a similar geographical area and tend to have objectives such as harmonisation and information and work-sharing, sometimes including elements of mutual recognition. Examples include the Pan American Health Organization (PAHO), the East African Community (EAC), the Southern African Development Community (SADC), the Association of Southeast Asian Nations (ASEAN), the Asia-Pacific Economic Cooperation (APEC), Ibero-American Medicines Competent Authorities Network (EAMI).

EMA identified opportunities to improve management by increasing ICMRA member agencies' awareness of participation in multilateral efforts. Better knowledge management and reduction in redundancy and overlaps could be achieved by identifying best practices and applying them to different regional initiatives. Other opportunities for improvement include:

- Use of common elements for information sharing;
- Defining how regional databases can be adapted for use by other regions;
- Focusing activity on one initiative only when countries are active in multiple regional initiatives with similar objectives.

Cross-regional initiatives involve multiple countries and regions and may have different primary objectives to those described above, although some of the activities may overlap. Apart from activities carried out by WHO, the main cross-regional initiatives are the International Council for Harmonisation (ICH), the Pharmaceutical Inspection Co-operation Scheme (PIC/S), the International Pharmaceutical Regulators Forum (IPRF) and ICMRA itself.

EMA identified similar opportunities to improve management and increase ICMRA members' awareness as regards participation in multilateral efforts. Defining common areas of interest and linkages across initiatives that enable knowledge-sharing could streamline the process.

In February 2015, EMA presented the ICMRA Management Committee with a full summary of the entire project (Figure 3) and the lessons learnt, identifying the difficulties encountered in drawing conclusions. While multiple international initiatives have been identified, the focus and participation in these initiatives was extremely variable, which prevented relevant comparisons (Figure 4).

1. The network map in figure 2 is based on one previously prepared by the US FDA Office of International Programs (OIP).

Figure 3. Mapping project: Status as of February 2015

21.02.2014	Comparison between GMP inspection initiatives
24.03.2014	Comparison between generic medicines initiatives
25.03.2014	Mapping of multinational multi-project initiatives
21.08.2014	Preliminary analysis of mapping multinational multi-project initiatives (medicinal products)
07.11.2014	Comparison of confidentiality arrangements and memoranda of understanding
07.11.2014	Project update

Figure 4. Comparison of main objectives (ICMRA, ICH, IPRF, PIC/S, IGDRP)

ICH, PIC/S	Harmonised technical guidelines
ICH, ICMRA, IGDRP, IPRF, PIC/S	Sharing of regulatory information
ICMRA, IGDRP, IPRF, PIC/S	Regulatory cooperation
ICH, ICMRA, IPRF, PIC/S	Training activities
IGDRP, IPRF, PIC/S	Worksharing
ICMRA	Concerted strategic leadership
ICH	Facilitate international electronic communication Interpretation and implementation of ICH guidelines

The diversity of the parties involved in these initiatives leads to significant differences in defined objectives, which represents a major challenge for cross-project awareness (Figure 5). However, EMA identified a number of common objectives such as "information sharing" and "harmonisation" that were applied in different thematic areas such as generic medicines or GMP inspections.

Based on the review of these initial results, the heads of the regulatory agencies involved in ICMRA were faced with the question of whether to continue to use the mapping activities to better inform the work on current priorities or to start carrying out preliminary mappings of other areas of potential interest for ICMRA, in order to gather better information on potential ICMRA future priorities. This question stimulated a new approach which is described under Phase II below.

Figure 5. Mapping project preliminary conclusions (February 2015)

Multiple international initiatives—focus and participation are both variable	Focus can be multi-regional, regional and thematic Participation can include different ICMRA members and non-members
Comparing 'apples and oranges'	All objectives worded differently, however some are broadly overlapping There are some common objectives (e.g. information sharing, harmonisation) But may be applied to different areas (e.g. GMP, generic medicines)
Which came first—the chicken or the egg?	Should mapping identify priorities or be used to better inform on potential priorities?

Phase II

In June 2015, the ICMRA Management Committee identified four potential strategic priorities: supply-chain integrity, crisis management, pharmacovigilance and IT systems. EMA was asked to use the mapping process to identify existing international initiatives in these areas and to inform the decision makers on which aspects of these new potential priorities ICMRA should focus on.

Between June and December 2015, EMA produced new mappings and strategic analyses based on these mappings for all four areas of work.

Based on the results it was agreed that ICMRA would focus on supply-chain integrity, crisis management and pharmacovigilance as potential priority areas in which ICMRA could add most value.

The strategic analysis prepared by EMA outlined a problem statement, explained the rationale behind the definition of an area as a potential ICMRA priority and specified the initiatives taken into account. The mapping results highlighted gaps and overlaps for each concerned area, as well as opportunities and potential threats for ICMRA.

The following additional aspects were reviewed:

- How can success be defined for an ICMRA project in a specific area?
- How would a possible ICMRA project be taken forward and by whom?
- What are tangible outcomes and deliverables?
- What approach should ICMRA take to maximise its added value (e.g. create a new ICMRA group or leverage other existing initiatives)?
- What are the key steps and the timeframe for an ICMRA project?
- How can the success of a project and its impact be evaluated?

Figure 6. Overview of all mappings prepared

Comparison between generic medicines initiatives

Comparison of confidentiality arrangements and memoranda of understanding

Mapping of multinational multi-project initiatives

Comparison between GMP inspections initiatives

Mapping of supply-chain and anti-counterfeiting initiatives

Mapping of pharmacovigilance initiatives

Mapping of crisis management initiatives

Mapping of IT initiatives in support of global medicines regulation

Analysis of findings

The main findings of the analyses carried out by EMA for the new ICMRA priority areas are showcased below.

Supply-chain integrity

Manufacture and distribution of medicines has become increasingly globalised, and supply chain integrity is one of the main challenges this poses to the quality and safety of medicines. A consistent global approach to monitoring and managing global supply chains requires collaboration between regulators worldwide. The mapping focused on international initiatives designed to strengthen the legitimate supply chain and prevent illegal entry into this supply chain. The mapping covered alert systems, points of contact, databases, IT systems, track and trace projects and focused on projects in which a medicine regulatory authority was already involved, including anti-counterfeiting initiatives related to medicines. While recognising the role of GMP oversight, GMP measures impacting the supply chain were not included. A total of 14 different initiatives were mapped and classified by global coverage, regional coverage and some European-focused projects (figure 7).

The mapping revealed that participation in these initiatives varied significantly and that only a few linkages exist between the different projects.

A number of overlaps were identified, e.g. multiple databases, track and trace initiatives, alert systems and systems to ensure 'single points of contact'. The identified gaps included lack of mutual awareness, inability to link systems and to leverage different projects. Raising mutual awareness, promoting synergies and avoiding duplication were identified as opportunities for regulators (figure 8).

Figure 7. Supply-chain/anti-counterfeiting initiatives for medicines

Global initiatives	● ● ● ● ● ●
European initiatives	● ● ● ● ●
Regional initiatives	● ● ●

Figure 8. Main overlaps, gaps, and opportunities regarding supply chain integrity

Overlaps	Multiple databases, track and trace initiatives, alert systems, etc.
Gaps	Lack of mutual awareness Inability to link systems and to leverage different projects
Opportunities	Raise mutual awareness Promote synergies Avoid duplication

Despite multiple track and trace initiatives on a national or regional basis that share a common aim, none of them seem to have looked beyond their borders and identified compatibilities with other approaches. Leadership at the highest level would be needed to try to ensure greater international connectivity of track and trace systems.

In order to be able to link databases and alert systems, regulators need to be sure they are referring to the same product. Although the international standard on the identification of medicinal products has been agreed internationally, it is still a long way from being integrated into national or regional databases, and maintenance issues are still being dealt with. This impacts not only on the supply-chain integrity but also on pharmacovigilance collaboration between medicine regulators.

Pharmacovigilance

A total of eighteen pharmacovigilance initiatives were mapped and reviewed. The mapping encompassed:

- The main multinational pharmacovigilance databases and IT tools for reporting, collection, management and analysis of ADRs;
- International initiatives to develop pharmacovigilance guidelines and policies on harmonisation and convergence;
- Platforms for networking, discussions and sharing of knowledge on pharmacovigilance topics.

Given the high profile of pharmacovigilance activities in regulators' agendas worldwide, there are many initiatives at national, regional (multinational) and global level aimed at improving adverse reaction reporting, collection, management and analysis. Again, however, there is a lack of mutual awareness among various initiatives and an inability to link and leverage different projects.

A specific gap in the pharmacovigilance area relates to harnessing the potential of emerging approaches and technologies, such as the use of 'big data' or real world evidence for pharmacovigilance purposes.

It is generally accepted that only a fraction of the adverse reactions occurring in real life are reported, and safety and efficacy of medicines are largely established based on clinical trial results. The use of big data technologies may allow the production of a huge amount of post-marketing data and the development of better predictive models. The analysis found that no international initiative explicitly addressed the use of big data technologies in pharmacovigilance as one of its objectives.

Another challenge is the lack of coordination between most pharmacovigilance systems and healthcare systems, which means that feedback on experience with new medicines is often not shared with regulatory authorities. Similarly, there was often a lack of connection between health care programmes and medicines regulators in resource-constrained countries. Therefore it is crucial to establish links between medicine regulators and pharmacovigilance systems.

Issues with the sharing of confidential data between regulators can be an obstacle as these can limit an accelerated sharing of safety information. Data protection legislation may also need to be taken into account.

The analysis found that in order to reach a more globally connected pharmacovigilance system, increased transparency and increased efficiency in the exchange of information (e.g. through rapid alert systems and database linkages) is necessary.

Crisis Management

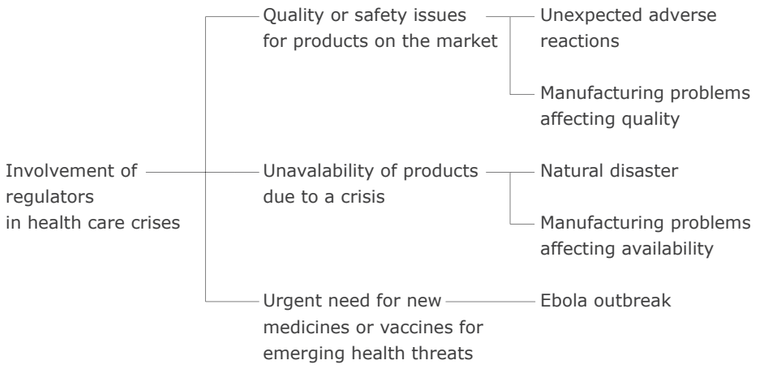
The analysis of the international health crisis management system revealed a lack of common understanding among regulators of what a health crisis means. Therefore it was necessary to agree on a definition. EMA proposed a definition of a health crisis as a situation where, after the assessment of an incident's associated risks, routine measures are not considered sufficient, and therefore urgent and coordinated actions are required to manage and control the situation.

- Quality or safety issues for products on the market (e.g. due to manufacturing problems or unexpected adverse reactions);

- Unavailability of products due to a crisis (e.g. natural disasters such as earthquakes, tsunami, etc., problems with radionuclide generators leading to possible long-term shortages of otherwise available products and need for a replacement strategy, sudden lack of availability of intermediates for the manufacture of e.g. antibiotics);

- Urgent need for new medical treatments or vaccines in the face of an emerging health threat e.g. Ebola outbreak.

Figure 9. Schematic of involvement of regulators in health care crises



For the first category above, regulators have national or regional mechanisms in place that enable quick reactions and rapid exchange of information. Therefore an incident is normally tackled proactively by routine measures, before it escalates to a crisis.

As regards the second category, there have been some concerted bilateral and multilateral regulatory actions on a case by case basis (e.g heparin, radionuclide generators), seeking to avoid global shortages in a coordinated way; yet there is no systematic international mechanism to address them.

For the third category, regulators' involvement usually starts when a crisis is declared at international level (usually by WHO, e.g. Ebola outbreak declaration in August 2014, H1N1 influenza pandemic declaration in June 2009). As with the second category, concerted bilateral and multilateral regulatory actions have been carried out in such situations, but no coordinated international approach to manage the crisis at the level of medicines regulators has yet been put in place. Although a number of coordinated international mechanisms do exist, the involvement of medicines regulators in those is not systematic.

In conclusion, the lack of an international mechanism for health crisis management focused on medicines regulation is a gap in the international regulatory framework.

Full analyses were subsequently reviewed by all participants at the ICMRA meeting in Mexico in December 2015 and used to inform ICMRA decision makers on the projects to be taken forward in 2016.

Conclusion

The mapping activities led by EMA are a first attempt to produce a global overview of current international initiatives in key areas for medicines regulators, which is a pre-requisite for achieving more effective coordination of regulators worldwide.

The analyses of key initiatives (multiregional, regional or thematic) showed that there is a myriad of initiatives but no strategic coordination. The focus and membership of the various initiatives are highly variable. Similar initiatives often have differently-worded objectives which frequently overlap. There are some recurrent objectives e.g. information sharing and harmonisation, but they usually apply to different regions or thematic areas.

The above-mentioned issues hinder the provision of a comprehensive overview and comparison of various initiatives. Clear overlaps can be identified within multiple initiatives addressing the same or similar issues. At the same time, there are still gaps and critical areas that are not yet addressed by any international initiative.

Mappings and analyses strongly support the need for a global strategy to support cooperation between international medicines regulators, to help avoid an overlap of activities and make resources available for areas where gaps still exist.

Not only did the exercise help to inform the future work of ICMRA, it also provided a comprehensive overview and may be a valuable resource that can be used by others.

Annex 1. Bilateral arrangements between ICMRA members (pharmaceuticals)

Australia AU Therapeutic Goods Administration (TGA)	**BR CA CH CN EU[1] IE JP SG UK US / CA EU[1] SG / NZ[8] SG[9] US[10]**
Brazil BR Brazilian Health Surveillance Agency (ANVISA)	**AU CA CH CN IE IT JP KR[3] UK US ZA[4] / US[12]**
Canada CA Health Products and Food Branch, Health Canada (HPFB-HC)	**AU BR CH EU[1] IE JP NL SG UK US / AU EU[1] / CN[12]**
China CN China Food and Drug Administration (CFDA)	**AU BR DE[4] EU[1] IE JP KR NL SG UK US ZA[6] / EU[13] SG[14] CH[15]**
European Union EU European Commission (EC) DG SANTE and European Medicines Agency (EMA)	**AU CA CH JP US / AU CH CA JP NZ / CN[13]**
France FR National Agency of Medicines and Health Products Safety of the French Republic (ANSM)	**EU Arrangements[1]**
Germany DE Paul-Ehrlich-Institute of the Federal Republic of Germany (PEI)	**EU Arrangements[1] CH CN[4] SG / KR[16]**
Ireland IE Health Products Regulatory Authority (HPRA)	**EU Arrangements[1] BR CH KR[5] SG**
Italy IT Italian Medicines Agency (AIFA)	**EU Arrangements[1] BR KR[2]**
Japan JP Ministry of Health, Labour and Welfare (MHLW), Pharmaceuticals and Medical Devices Agency (PMDA)	**AU BR CA CH CN EU[1] KR[2] MX SG US / EU[1]**
Mexico MX Ministry of Health of the United Mexican states through the federal commission for the protection against sanitary risks (COFEPRIS)	**JP KR US**
Netherlands NL Medicines Evaluation Board (MEB) and The Health Care Inspectorate (IGZ)	**EU Arrangements[1] SG**
New Zealand NZ New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE)	**UK US / EU[1] / AU[8]**
Nigeria NI National Agency for Food and Drug Administration and Control (NAFDAC)	**N/A**
Singapore SG Health Sciences Authority (HSA)	**AU CA CH CN DE IE JP KR NL UK US / AU / AU[9] CN[14] EU[1, 17]**
Republic of Korea KR Ministry of Food and Drug Safety (MFDS)	**BR[2] CH CN IE[5] IT[2] JP[2] MX SG UK / DE[16]**
South Africa ZA Medicines Control Council (MCC), Department of Health	**BR[3] CH CN[5] UK[2] US / EU[1, 18]**
Switzerland CH the Federal Department of Home Affairs of the Swiss Confederation (Swissmedic)	**AU BR CA DE EU[1] IE JP KR SG ZA US / EU[1] / CN[15]**
United Kingdom UK Medicines and Healthcare Products Regulatory Agency (MHRA)	**EU Arrangements[1] BR CN KR NZ SG ZA[2]**
United States US Food and Drug Administration (FDA)	**AU BR CA CH CN[7] EU[1] JP MX NZ SG ZA / AU[10] BR[11]**

1. The European Union (EU) is formed by 28 Member States including six ICMRA members: France, Germany, Ireland, Italy, the Netherlands and the United Kingdom. EU bilateral arrangements are valid for all the 28 EU Member States. As all the EU Member States are part of a single EU system for pharmaceuticals, confidential information is exchanged between the EU Member States and results of inspections carried out by any of the EU Member States are automatically recognised by all the others. EU Member States can sign individual bilateral arrangements.
2. In progress
3. General Memorandum of Understanding (MoU) of BRICS
4. Memorandum of Understanding with the Chinese National Institute for Food and Drug Control, NIFDC
5. To strengthen political and economic relations
6. On information exchange on biological products, medical devices, drug use, cosmetics
7. On safety of drugs and medical devices
8. Trans-Tasman early warning system
9. Memorandum of Intention of Cooperation (MoI)
10. Cooperative arrangements on GMP and orphan drugs
11. Statement of cooperation regarding cooperation to enhance activities of mutual interest
12. Plan of action on cooperation
13. Consultation and cooperation mechanism
14. China Singapore Free Trade Agreement (CSFTA), ASEAN-China (ACFTA)
15. Agreement on cooperation in the areas of foodstuffs, medicinal products, medical devices and cosmetics
16. Joint declaration on vaccines and biomedicines
17. Implementation Plan on the Sharing of Confidential information between the EC's Health and Food Safety Directorate General and the FDA
18. Free Trade Agreement

Disclaimer

The table above provides a general overview of the existing bilateral arrangements on pharmaceuticals worldwide and reflects the information available to EMA after consultation with all the authorities involved, at the time of preparation of the document (February 2015). As the information in this table may be in certain cases not completely accurate and/or incomplete, due to continuous changes, EMA strongly advises that the information in the table is confirmed with the authorities involved.

- Agreements on exchange of confidential information
- Mutual recognition agreements on GMP
- Other agreements

Annex 2. Mapping of multinational multi-project initiatives[1]

ICH

The **International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use** makes recommendations towards achieving greater harmonisation in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration, thereby reducing or obviating duplication of testing carried out during the research and development of new human medicines.

Scope

Medicinal products for human use[2]

Work products

- Harmonised guidelines
- Process of harmonisation
- Medical Dictionary for Regulatory Activities terminology (MedDRA)
- Common technical document (CTD) to assemble all the quality, safety and efficacy information in a common format
- Electronic standards

Members[3]

Founding regulatory members

European Commission (EC)
United States Food and Drug Administration (FDA)
Ministry of Health, Labour and Welfare (MHLW) of Japan also represented by the Pharmaceuticals and Medical Devices Agency (PMDA)

Founding industry members

European Federation of Pharmaceutical Industries and Associations (EFPIA)
Japan Pharmaceutical Manufacturers Association (JPMA)
Pharmaceutical Research and Manufacturers of America (PhRMA)

Standing observers

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
World Health Organization (WHO)

Observers

Legislative or administrative authorities

Brazilian Health Surveillance Agency (ANVISA, Brazil)
Central Drugs Standard Control Organization (CDSCO, India)
Ministry of Health of the United Mexican states through the federal commission for the protection against sanitary risks (COFEPRIS, Mexico)
Health Sciences Authority (HSA, Singapore)
Ministry of Food and Drug Safety (MFDS, South Korea)
Federal Service for Surveillance in Healthcare (Roszdravnadzor, Russia)
Food and Drug Administration (TFDA, Chinese Taipei)
Therapeutic Goods Administration (TGA, Australia)

Regional harmonisation initiatives (RHIs)

Asia-Pacific Economic Cooperation (APEC)
Association of Southeast Asian Nations (ASEAN)
East African Community (EAC)
Gulf Cooperation Council (GCC)
Pan American Network for Drug Regulatory Harmonization (PANDRH)
Southern African Development Community (SADC)

Standing regulatory members

Health Canada (Canada)
Swissmedic (Switzerland)

Industry members

International Generic and Biosimilar Medicines Association (IGBA)
World Self-Medication Industry (WSMI)

International pharmaceutical industry organisations

Biotechnology Innovation Organisation (BIO)

International organisations with an interest in pharmaceuticals

Council for International Organizations of Medical Sciences (CIOMS)
European Directorate for the Quality of Medicines & HealthCare (EDQM)
International Pharmaceutical Excipient Council (IPEC)
United States Pharmacopeia (USP)

1. The information in this table may be in certain cases not completely accurate and/or incomplete, due to continuous changes. EMA strongly advises that the information in the table is confirmed with the respective initiatives.
2. Unless otherwise specified, medicinal products for human use include: drugs, vaccines, biologicals, prescription drugs, non-prescription drugs, generics, traditional medicines, herbal medicines, etc.
3. Membership as recognised by the individual initiatives (updated as of August 2016)

IPRF

The **International Pharmaceutical Regulators Forum** aims to enable exchange of information between members on issues of mutual concern and regulatory cooperation. In particular, to enable all members to identify new approaches and specific best practices, and develop smart strategies for dealing with the challenges.

The forum provides a global overview of the different regulatory developments at national and international level, supports international regulatory cooperation in areas which are not covered by existing initiatives, and aims to identify the need for regulatory harmonisation or convergence, as well as for regulatory cooperation, including worksharing, in specific areas.

Scope

Medicinal products for human use

Work products

Current working groups:

- Gene Therapy
- Cell Therapy
- Biosimilars
- Nanomedicines

Completed work of good clinical practice (GCP) group:

"General Principles for Training and Education of GCP inspectors"

Various publications

Members

Regulatory Authorities

TGA (Australia)
ANVISA (Brazil)
Health Canada (Canada)
EMA and DG-SANTE (European Union)
MHLW and PMDA (Japan)
MFDS (Korea)
COFEPRIS (Mexico)
Roszdravnadzor (Russia)
HSA (Singapore)
Swissmedic (Switzerland)
FDA (United States)

Regional Harmonisation Initiatives (RHIs)

Asia-Pacific Economic Cooperation (APEC)
Association of Southeast Asian Nations (ASEAN)
East African Community (EAC)
Cooperation Council for the Arab States of the Gulf (GCC)
Pan American Network for Drug Regulatory Harmonization (PANDRH)
Southern African Development Community (SADC)
World Health Organization (WHO)

ICMRA

The **International Coalition of Medicines Regulatory Authorities** provides high level of leadership to address current and emerging human medicine regulatory and safety challenges. In particular, it aims to develop and establish an international executive coalition of heads of medicines regulatory authorities, allowing heads of authorities to exercise collective and concerted strategic leadership over existing and new international initiatives and enablers, as well as over shared regulatory issues and challenges.

Scope

Medicinal products for human use

Work products

- Generic medicine project
- Good manufacturing practice (GMP) project
- Rapid sharing of information and confidentiality commitment within the ICMRA project
- Capacity building project
- Mapping existing international projects
- Supply-chain project
- Pharmacovigilance project
- Crisis management project

Members

Heads of regulatory authorities

TGA (Australia)
ANVISA (Brazil)
Health Canada/HPFB (Canada)
CFDA (China)
EMA and EC (European Union)
ANSM (France)
PEI (Germany)
HPRA (Ireland)
AIFA (Italy)
PMDA and MHLW (Japan)
MFDS (South Korea)
COFEPRIS (Mexico)
MEB (Netherlands)
Medsafe (New Zealand)
NAFDAC (Nigeria)
HSA (Singapore)
MCC (South Africa)
Medical Products Agency (Sweden)
Swissmedic (Switzerland)
MHRA (United Kingdom)
FDA (United States)

Observers

World Health Organization (WHO)

PIC/S

The **Pharmaceutical Inspection Co-operation Scheme** leads the international development, implementation and maintenance of harmonised good manufacturing practice (GMP) standards and quality systems of inspectorates in the field of medicinal products. Generally, it leads international cooperation in the field of GMP.

Scope

Medicinal products for human use
Medicinal products for veterinary use

Work products

- Harmonised GMP standards and guidance documents
- Training activities and seminars
- Harmonised inspections procedure
- Audits of inspectorates

Members

Participating authorities

INAME (Argentina)
TGA (Australia)
AGES (Austria)
AFMPS (Belgium)
HPFB/Health Canada (Canada)
TFDA (Chinese Taipei)
HALMED (Croatia)
CyPHS (Cyprus)
SUKL and ISCVBM (Czech Republic)
DHMA (Denmark)
SAM (Estonia)
FIMEA (Finland)
ANSM and ANSES (France)
BMG and ZLG (Germany)
EOF (Greece)
PPBHK (Hong Kong)
GYEMSZI (Hungary)
IMA (Iceland)
NADFC (Indonesia)
IMB (Ireland)
ISCP (Israel)
AIFA (Italy)
MHLW and PMDA (Japan)
MFDS (South Korea)
ZVA (Latvia)
AG (Liechtenstein)
SMCA (Lithuania)
NPCB (Malaysia)
MAM (Malta)
IGZ (Netherlands)
Medsafe (New Zealand)
NOMA (Norway)
MPI (Poland)
INFARMED IP (Portugal)
NAMMD (Romania)
HSA (Singapore)
SIDC (Slovakia)
JAZMP (Slovenia)
MCC (South Africa)
AEMPS (Spain)
MPA (Sweden)
Swissmedic (Switzerland)
SAUMP (Ukraine)
FDA (Thailand)
MHRA and VMD (United Kingdom)
FDA (United States)

Partners

European Directorate for the Quality of Medicines & HealthCare (EDQM)
European Medicines Agency (EMA)
United Nations International Children's Emergency Fund (UNICEF)
World Health Organization (WHO)

IGDRP

The **International Generic Drug Regulator's Programme** aims to promote collaboration and regulatory harmonisation in the area of generic medicines, in order to strengthen the ability of health authorities to meet their respective mandates. The project aims to reach a greater availability of generic medicines, mutual reliance and worksharing, international regulatory oversight, and exchange of safety and quality information on marketed products.

Scope

Medicinal products for human use (generic medicines only)

Work products

Current Working Group:

- Active substance master files/ drug master file (ASMF/DMF): establishing a framework for information-sharing and potential mutual reliance in the assessment of ASMFs/DMFs)
- Biowaivers: establishing a common set of conditions for granting biowaivers as well as the possible expanded application of waivers
- IT Business needs: an IT platform for information sharing

Worksharing models:

Piloting the EU's decentralised and centralised procedures as policy models for worksharing

Members

ANVISA (Brazil)
CFDA (China)
EMA, CMDh and EC (European Union)
COFEPRIS (Mexico)
Roszdravnadzor (Russia)
Health Canada (Canada)
HSA (Singapore)
MFDS (South Korea)
MHLW (Japan)
MCC (South Africa)
Medsafe (New Zealand)
Swissmedic (Switzerland)
TFDA (Taiwan)
TGA (Australia)
FDA (United States)

Observers

European Directorate for the Quality of Medicines & HealthCare (EDQM)
World Health Organization (WHO)

WHO/EMP

The **World Health Organization/ Essential Medicines and Pharmaceutical Policies** aims to support the achievement of the health-related Millennium Devolopment Goals (MDGs) by assisting governments and organisations to ensure equitable access to efective medicines of assured quality, and their rational use by prescribers and consumers.

Scope

Medicinal products for human use
Medical devices

Work products

Medicines policy:

- Governance and country collaboration
- medicines policy
- Essential medicines and human rights
- Monitoring and evaluation
- Technical briefing seminars
- Country and regional medicines projects
- Good governance in the pharmaceutical sector
- Pharmaceutical country profile Information and publications

Quality assurance and safety:

- Medicines international nonproprietary names
- Quality assurance
- Blood products and related biologicals
- Substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medicines
- Regulatory support
- Safety and efficacy
- The International Pharmacopoeia Prequalification of medicines
- Regulation

Medicine Access and Rational Use:

- Access to non communicable diseases medicines
- Antimicrobial resistance
- Better medicines for children
- Controlled substances
- Medicine pricing and financing
- Medicines supply
- Rational use
- Selection

Quality, safety and standards

Members

WHO Member States

Afghanistan
Albania
Algeria
Andorra
Angola
Antigua and Barbuda
Argentina
Armenia
Australia
Azerbaijan
Bahamas
Bahrain
Bangladesh
Barbados
Belarus
Belgium
Belize
Benin
Bhutan
Bolivia
Bosnia and Herzegovina
Botswana
Brazil
Brunei Darussalam
Bulgaria
Burkina Faso
Burundi
Cape Verde
Cambodia
Cameroon
Canada
Central African Republic
Chad
Chile
China
Colombia
Comoros
Congo
Cook Islands
Costa Rica
Côte d'Ivoire
Croatia
Cuba
Cyprus
Czech Republic
Democratic Republic of the Congo
Denmark
Djibouti
Dominica
Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Estonia
Ethiopia
Fiji
Finland
France
Gabon
Gambia
Georgia
Germany
Ghana
Greece
Grenada
Guatemala
Guinea
Guinea-Bissau
Guyana
Haiti
Honduras
Hungary
Iceland
India
Indonesia
Iran
Iraq
Ireland
Israel
Italy
Jamaica
Japan
Jordan
Kazakhstan
Kenya
Kiribati
Kuwait
Kyrgyzstan
Laos
Latvia
Lebanon
Lesotho
Liberia
Libya
Lithuania
Luxembourg
Madagascar
Malawi
Malaysia
Maldives
Mali
Malta
Marshall Islands
Mauritania
Mauritius
Mexico
Micronesia
Monaco
Mongolia
Montenegro
Morocco
Mozambique
Myanmar
Namibia
Nauru
Nepal
Netherlands
New Zealand
Nicaragua
Niger
Nigeria
Niue
North Korea
Norway
Oman
Pakistan
Palau
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Poland
Portugal
Qatar
Moldova
Romania
Russia
Rwanda
Saint Kitts and Nevis
Saint Lucia
Saint Vincent and the Grenadines
Samoa
San Marino
Sao Tome and Principe
Saudi Arabia
Senegal
Serbia
Seychelles
Sierra Leone
Singapore
Slovakia
Slovenia
Solomon Islands
Somalia
South Africa
South Korea
South Sudan
Spain
Sri Lanka
Sudan
Suriname
Swaziland
Sweden
Switzerland
Syria
Tajikistan
Tanzania
Thailand
The former Yugoslav Republic of Macedonia
Timor-Leste
Togo
Tonga
Trinidad and Tobago
Tunisia
Turkey
Turkmenistan
Tuvalu
Uganda
Ukraine
United Arab Emirates
United Kingdom
United States
Uruguay
Uzbekistan
Vanuatu
Venezuela
Vietnam
Yemen
Zambia
Zimbabwe

CIOMS

The **Council for International Organizations of Medical Sciences** aims to facilitate and promote international activities in the field of biomedical sciences, to maintain collaborative relations with the United Nations and its specialised agencies, in particular with WHO and UNESCO, and to serve the scientific interests of the international biomedical community in general.

Scope

Medicinal products for human use

Work products

Long-term programmes on drug development and use:

- Safety requirements for the use of drugs
- Assessment and monitoring of adverse drug reactions (pharmacovigilance) and pharmacogenetics, with recommendations on:
  — International reporting of adverse drug reactions
  — Introduction of the standardized "CIOMS I reporting form", international reporting of periodic drug safety updates (PSUR), core clinical safety information on drugs, evaluation of benefit/ risk balance, current challenges of pharmacovigilance, management of safety information from clinical trials and development safety update report (DSUR) and signal detection in pharmacovigilance

- Working groups dedicated to pharmacogenetics, standardised MedDRA Queries (SMQs), reporting and terminology of adverse drug reactions, vaccine pharmacovigilance, drug development research and pharmacovigilance in resource-poor countries

- International workshops

Members

International Members

World Allergy Organization
International College of Angiology
International Society of Audiology
International Union of Basic and Clinical Pharmacology (IUPHAR)
International Society of Internal Medicine
International Federation of Otorhinolaryngological Societies
World Association of Societies of Pathology and Laboratory Medicine (WASPaLM)
International Society for Pharmacoepidemiology (ISPE)
International Society of Pharmacovigilance (ISOP)
World Psychiatric Association
International Rhinologic Society
Medical Women's International Association
World Medical Association

National Members

Comité des Académies Royales de Médecine (Belgium)
Union of the Scientific Medical Societies of Bulgaria (Bulgaria)
Czech Medical Association (Czech Republic)
Association of the Scientific Medical Societies in Germany (Germany)
The Israel Academy of Sciences and Humanities (Israel)
Korean Academy of Medical Sciences (South Korea)
Islamic Organization for Medical Sciences (Kuwait)
Royal Netherlands Academy of Arts and Sciences (Netherlands)
The Research Council for Norway/ The National Committee for Medical Research Ethics (Norway)
South African Medical Research Council (South Africa)
Swiss Academy of Medical Sciences (Switzerland)

Associate Members

Medical Sciences Society (MSS-UQ) of Queensland University, Haiti
American Society for Bioethics and Humanities
Consulta di Bioetics
World Federation of Chiropractic
International Federation of Clinical Chemistry and Laboratory Medicine
World Organization of Family Doctors (WONCA)
Good Clinical Practice - Alliance
International Council for Laboratory Animal Science (ICLAS)
International Society of Hepatic Encephalopathies & Nitrogen Metabolisim (ISHEN)
The World Association for Medical Law
International Union of Microbiological Societies
Asia Pacific Academy of Ophthalmology
International Union of Physiological Sciences
Federation of Polish Medical Organizations Abroad
Federation of Polish Medical Societies
International Medical Sciences Academy
National Fund for Scientific Research (NSFR)
International Federation of Medical Student Associations
Saudi Neonatology Society

OECD/Health Division

The **Organisation for Economic Co-operation and Development** aims to achieve high-performing health systems and policies by measuring health outcomes and health system resource use and by analysing policies that improve access, efficiency and quality of health care. Additionally, OECD is looking into how to encourage and foster innovation which addresses health needs and priorities, maximises access to the benefits, and manages the challenges and risks in a way that is beneficial for both innovators and health systems.

Scope

Medicinal products for human use
Health policies

Work products

Policy analysis and statistical information on health policies:

- Improving comparative data on health policies and outcomes
- Enhancing the quality of health care
- Getting better value for money in health spending
- The economics of disease prevention and the health workforce

Biotechnology:

- Task force on biomedicine and health innovation
- Biomarkers and targeted therapies
- High-level forum on medicines for infectious diseases
- Regulatory frameworks for nanotechnology pharmacogenetics

Pharmaceuticals:

- Requirements on the guidelines and principles of good laboratory practice (GLP)
- Recommendations on the regulatory harmonisation of clinical trials, publications on opportunities and challenges for health innovation and care, and pharmaceutical pricing policies

Members

Australia
Austria
Belgium
Canada
Chile
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Iceland
Ireland
Israel
Italy
Japan
Latvia
South Korea
Luxembourg
Mexico
Netherlands
New Zealand
Norway
Poland
Portugal
Slovakia
Slovenia
Spain
Sweden
Switzerland
Turkey
United Kingdom
United States

International Regulators Consortium Initiative

The **International Regulators Consortium Initiative** aims to promote greater regulatory harmonisation and collaboration, focused on the alignment of regulatory requirements. Its goal is to maximise international cooperation, reduce duplication, and increase each agency's capacity to ensure consumers have timely access to high quality, safe and effective therapeutic goods.

Scope

Medicinal products for human use
Medical devices

Work products

Regulatory worksharing initiatives including:

- Good manufacturing practices (GMPs)
- Good review practices (GRPs)
- Post-market medicines safety and surveillance
- Assessment reports for pharmaceuticals including generic drugs and new chemical entities
- Coordination of involvement of technical experts in the International Council for Harmonisation (ICH) working groups (regulatory and guidelines harmonisation), and the collaboration on the information technology (IT) architecture
- Pilot generic medicines worksharing program

Members

Participating regulatory authorities

TGA (Australia)
HPFB/Health Canada (Canada)
HSA (Singapore)
Swissmedic (Switzerland)

EMRN

The **European medicines regulatory network** aims to protect and promote public and animal health in Europe, working to foster an effective and efficient European medicines regulatory system.

Scope

Medicinal products for human use
Medicinal products for veterinary use

Work products

Initiatives including:

- Single assessment and inspection
- Common assessments
- Harmonised scientific and regulatory guidelines
- Benchmarking
- Mutual audits
- Trainings
- Information sharing
- Common communication
- Policies
- Common standards and procedures
- Scientific networks

Members

Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Luxembourg
Malta
Netherlands
Poland
Portugal
Romania
Slovakia
Slovenia
Spain
Sweden
United Kingdom
Norway
Iceland
Liechtenstein
European Medicines Agency (EMA)
European Commission (DG-SANTE)

EDQM

The **European Directorate for the Quality of Medicines & HealthCare** of the Council of Europe aims to contribute to the basic human right of access to good quality medicines and healthcare, achieving harmonisation of the quality of medicines throughout the European continent and beyond, and to promote and protect human and animal health.

Scope

Medicinal products for human use
Medicinal products for veterinary use
Healthcare products: blood transfusion; transplantation of organs, tissues and cells; cosmetics and food packaging; pharmaceutical care

Work products

- Establishment and provision of official standards which apply to the manufacture and quality control of medicines in all signatory States of the Convention on the Elaboration of a European Pharmacopoeia and beyond
- Ensuring the application of these official standards to substances used in the production of medicines through the certification of suitability to the monographs of the European Pharmacopoeia Scheme
- Co-ordination of a network of Official Medicines Control Laboratories (OMCL) to collaborate and share expertise among Member States and to effectively use limited resources (surveillance of marketed medicines)
- Proposing ethical, safety and quality standards:
  — For the collection, preparation, storage, distribution and appropriate use of blood components in blood transfusion;
  — For the transplantation of organs, tissues and cells.
- Collaboration of national, European and international organisations in efforts to combat counterfeiting of medical products and similar crimes
- Provision of policies and model approaches for the safe use of medicines in Europe, including guidelines on pharmaceutical care
- Establishment of standards and co-ordination of controls for cosmetics and food packaging

Members

Austria
Belgium
Bosnia and Herzegovina
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Iceland
Ireland
Italy
Latvia
Lithuania
Luxembourg
Malta
Montenegro
Netherlands
Norway
Poland
Portugal
Romania
Serbia
Slovakia
Slovenia
Spain
Sweden
Switzerland
The former Yugoslav Republic of Macedonia
Turkey
Ukraine
United Kingdom
European Union

Observers

Albania
Algeria
Argentina
Armenia
Australia
Azerbaijan
Belarus
Brazil
Canada
China
Georgia
Israel
Kazakhstan
South Korea
Madagascar
Malaysia
Moldova
Morocco
Guinea
Russia
Senegal
Singapore
South Africa
Syria
Tunisia
United States
World Health Organization

AMRH

The **African Medicines Regulatory Harmonisation** programme is an initiative of the African Union's NEPAD (New Partnership for Africa's Development) agency. Its objective is to establish and improve standards and requirements related to the regulation of and access to safe, high-quality medicines for the African population.

Its overall aim is to establish - in partnership with the African Union Commission and the World Health Organization - the African Medicines Agency, which will operate under the authority of AMRH. The agency will oversee the registration of a selected list of medicines and coordinate regional harmonisation systems on the continent.

Scope

Medicinal products for human use
Medicinal products for veterinary use

Work products

Harmonisation

Establishing and harmonising standards and requirements

Model Law

Drafted under the authority of the African Union, the Model Law requires national implementation to ensure all African countries have legal framework in place for medicines regulation. The Model Law foresees the creation of regional or sub-regional agencies

African Medicines Agency

Once operational, the Agency is intended to have a role in marketing authorisations, inspections, market surveillance, safety monitoring, oversight of clinical trials and product quality control

Regulatory science and regional centres of excellence

Members

The AMA will be established by the African Union Summit of Heads of State and Government. It will be governed in accordance with the rules and procedures of the African Union. The resources of the AMA will be provided by the African Union in accordance with its relevant practices and procedures.

African Union members

Algeria
Angola
Benin
Botswana
Burkina Faso
Burundi
Cape Verde
Cameroon
Central African Republic
Chad
Comoros
Congo
Cote d'Ivoire
Democratic Republic of the Congo
Djibouti
Egypt
Equatorial Guinea
Eritrea
Ethiopia
Gabon
Gambia
Ghana
Guinea
Guinea-Bissau
Kenya
Lesotho
Liberia
Libya
Madagascar
Malawi
Mali
Mauritania
Mauritius
Mozambique
Namibia
Niger
Nigeria
Rwanda
Sahrawi Arab Democratic Republic
São Tomé and Príncipe
Senegal
Seychelles
Sierra Leone
Somalia
South Africa
South Sudan
Sudan
Swaziland
Tanzania
Togo
Tunisia
Uganda
Zambia
Zimbabwe

EAC/MRH

The **East African Community Medicines Registration Harmonization Project** aims to achieve medicines regulatory harmonisation and to improve public health by increasing rapid access to good quality, safe and effective medicines by harmonising regulation systems and procedures in accordance with national and international policies and standards, and consequently by reducing the time taken to register essential medicines for the treatment of priority diseases. This project is part of the African Medicines Registration Harmonisation (AMRH) programme created to assist African countries and regions to respond to the challenges posed by medicines registration.

Scope

Medicinal products for human use
Medicinal products for veterinary use

Work products

- Common technical document for registration of medicines
- Common information management system (IMS) for medicines registration
- Quality management system in EAC Partner States' national medicines regulatory authorities
- Platform for information sharing on the harmonised registration system to key stakeholders
- Framework for mutual recognition of regulatory decisions

Members

Burundi
Kenya
Rwanda
Tanzania
Uganda

SADC

The **Southern African Development Community/Pharmaceutical Harmonisation Initiative** aims to improve the quality, safety and efficacy of medicines circulating within the region, and to establish and maintain a regional shared network system for regulatory authorities.

Scope

Medicinal products for human use

Work products

- Development of technical guidelines and policies, relating to the registration and control of medicines across the SADC Member States
- Application form for registration of medicinal products
- Registration of medicinal products
- Stability study
- Good manufacturing practices
- Bioequivalence/bioavailability
- HIV vaccine clinical trials
- Registration of nutritional supplements
- Validation, advertising and licensing
- Post-marketing surveillance
- Registration of vaccines
- Regulation of traditional medicines to support their implementation, regional training programmes will be developed

Members

Angola
Botswana
Democratic Republic of the Congo
Lesotho
Madagascar
Malawi
Mauritius
Mozambique
Namibia
Seychelles
South Africa
Swaziland
Tanzania
Zambia
Zimbabwe

ZaZiBoNa

Scope

Medicinal products for human use
Medicinal products for veterinary use

Work products

- Collaboration among regulators
- Innovative pathway to expedited regulatory approval
- Worksharing

Members

Botswana
Namibia
Zambia
Zimbabwe

The **Zambia, Zimbabwe, Botswana, Namibia Transmission project** interconnects the four countries, creates an alternative wheeling path between north and south, and decongests the central transmission corridor.

EAMI Network

Scope

Medicinal products for human use

Work products

- Fight against fraudulent and falsified medicines in Ibero-American countries—ONLINE rapid alert and exchange of information system of falsified and fraudulent medicines in Ibero-American countries (FALFRA System)
- Reinforcing pharmacovigilance in Ibero-American countries: Regional Pharmacovigilance System for Central America and Dominican Republic; Training courses
- Reinforcing bioequivalence in Ibero-American countries
- Ibero-American formulary for medicinal products prepared in pharmacies
- Protection of subjects involved in clinical research
- Drug safety

Members

National Competent Authorities

Argentina
Bolivia
Brazil
Chile
Colombia
Costa Rica
Cuba
Dominican Republic
Ecuador
El Salvador
Guatemala
Honduras
Mexico
Nicaragua
Panama
Paraguay
Peru
Uruguay
Venezuela

Andorra
Portugal
Spain

The Ibero-American Medicines Authorities Network is a forum to discuss and exchange technical information, organisational information, experiences and best regulatory practices between the member countries' competent authorities, in order to ensure the quality, safety and efficacy of medicinal products.

PANDRH

The **Pan-American Network for Drug Regulatory Harmonization** aims to promote drug regulatory harmonisation for all aspects of quality, safety, and efficacy of pharmaceutical products as a contribution to the quality of life and health care of the citizens of the member countries of the Americas.

Scope

Medicinal products for human use

Work products

Endorsing standards, guidelines and other recommendations, including norms and procedures in areas such as GMPs, bioequivalence, good clinical practice (GCP), medical plants, pharmacopeia, drug counterfeiting, drug registration and classification, pharmacovigilance, good laboratory practices (GLPs)

Training courses on GMP inspection, GCP, GLP, bioequivalence and the basic functions of a regulatory authority

Members

PAHO member states

Antigua and Barbuda
Argentina
Bahamas
Barbados
Belize
Bolivia
Brazil
Canada
Chile
Colombia
Costa Rica
Cuba
Dominica
Dominican Republic
Ecuador
El Salvador
Grenada
Guatemala
Guyana
Haiti
Honduras
Jamaica
Mexico
Nicaragua
Panama
Paraguay
Peru
Saint Lucia
Saint Vincent and the Grenadines
Saint Kitts and Nevis
Suriname
Trinidad and Tobago
United States
Uruguay
Venezuela

Representatives of the regional pharmaceutical industry associations (ALIFAR, FIFARMA), academia, consumer groups, professional associations and representatives from the five sub-regional trade integration groups within the Americas such as the Andean Community, the Caribbean Community (CARICOM), the Central American Integration System (SICA), MERCOSUR and the North American Free Trade Agreement (NAFTA).

ASEAN PPWG

The **Association of Southeast Asian Nations Pharmaceutical Product Working Group** aims to develop pharmaceutical regulatory harmonisation schemes of the ASEAN Member countries in order to complement and facilitate the objective of AFTA (ASEAN Free Trade Area), particularly, the elimination of technical barriers to trade posed by regulations, without compromising on drug quality, efficacy, and safety. The scope of its work integrates the discussion of existing technical guidelines and regulatory requirements; the study of harmonised procedures and regulatory systems currently implemented; and the development of CTDs with a view to arriving at mutual recognition arrangement (MRAs).

Scope

Medicinal products for human use

Work products

- ASEAN common technical requirement (ACTR), guidelines, seminars, tranings
- ASEAN common technical dossier (ACTD), seminars, trainings
- ASEAN glossary of terms
- Process and analytical validation, and bioavailability/bioequivalence, stability, safety and efficacy studies
- Harmonising regulation of traditional medicines and health supplements ahead of ASEAN integration
- ASEAN good manufacturing practice (GMP) guidelines
- Post-market alert system
- Establish working groups, and product working groups
- ASEAN-MRA (mutual recognition arrangement) for GMP inspections

Members

Brunei Darussalam
Cambodia
Indonesia
Laos
Malaysia
Myanmar
Phillipines
Singapore
Thailand
Vietnam

APEC LSIF RHSC

The **Asia-Pacific Economic Cooperation/Life Sciences Innovation Forum/Regulatory Harmonization Steering Committee** aims to achieve regulatory harmonisation for medical products, promoting a more strategic, effective and sustainable approach of harmonisation within the APEC region.

Scope

Medicinal products for human use
Medical devices

Work products

Adoption and implementation of harmonised international guidances and regulatory best practices (regulatory harmonisation initiatives, trainings, actions plans and roadmaps)

Member economies

Regulatory bodies

Health Canada (Canada)
CFDA (China)
TFDA (Chinese Taipei)
PMDA and MHLW (Japan)
Digemid (Peru)
HSA (Singapore)
MFDS (South Korea)
FDA (Thailand)
FDA (United States)

Industry members from the APEC member economies
Director of the APEC Harmonization Center (AHC)

GCC-DR

The **Gulf Central Committee for Drug Registration/Harmonisation Initiative** aims to promote regulatory harmonisation, developing harmonised technical guidelines and regulatory processes in order to provide to Gulf States a safe and effective medication with reasonable price.

Scope

Medicinal products for human use

Work products

- Development of technical guidelines and regulatory processes, which include the registration of pharmaceutical companies and products, as well GMP inspection
- Training in the areas of GMP and post-market surveillance, and other areas where training for Member States is required

Members

Bahrain
Kuwait
Oman
Qatar
Saudi Arabia
United Arab Emirates

Yemen is a member in the Health Council

Notes

European Medicines Agency

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Canary Wharf
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Send a question www.ema.europa.eu/contact

www.ema.europa.eu

Connecting the dots
Towards global knowledge of the international medicine regulatory landscape: mapping of international initiatives
EMA/546107/2016