IPRP Good Reliance Practices Repository - 8 October 2024

Reliance examples	Regulatory function	Technical scope	National, Regional or Global	Principles	Overview of the process	Regions, and/or countries involved	Link to publicly available information
WHO Listed Authorities (WLA)	All	Medicines, vaccines	Global	A framework for evaluating and publicly designating regulatory authorities as WHO Listed Authorities (WLA)	A transparent and evidence-based pathway for regulatory authorities operating at an advanced level of performance to be globally recognized as meeting WHO standards and other internationally recognized standards and practices.	All regions	WHO-Listed Authority (WLA)
AVAREF (African Vaccine Regulatory Forum)	Clinical trials oversight	Medicines, vaccines	Regional	Joint assessment of clinical trial applications between national regulatory authorities and ethic committees	Joint assessment of clinical trial applications for African countries involving national regulatory authorities and ethic committees. The process includes two steps, the joint assessment followed by the individual national decisions.	African countries	https://www.afro.who.int/health-topics/immunization/avaref; https://www.afro.who.int/health-topics/immunization/avaref/joint-review-process
Clinical trial authorisations in the European Union	Clinical trials oversight	Medicines, vaccines	Regional	Joint assessment of clinical trial applications between member states	Sponsors submit one single e-submission to all concerned member states with an harmonized dossier via the single Webportal (Clinical Trial Information System), joint assessment between concerned member states led by the reporting member states, one single decision (including national regulatory authority and ethic committee outcome) per member state.	European Union Member States	https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/data-submission-investigational-medicines-guidance-clinical-trial-sponsors
Fast track for multi-regional clinical trials from TFDA, Chinese Taipei	Clinical trials oversight	Medicines	National	Shortened review timelines of clinical trial applications if already authorised by the ten medical-advanced countries	Review timelines for clinical trial application reduced from 45 to 15 days in case the clinical trials is already approved by one authority from a list of the ten reference countries (Germany, USA, UK, France, Japan, Canada, Australia, Belgium, Switzerland, and Sweden) and domestically conducted in one of medical centers.	Chinese Taipei	http://www.fda.gov.tw/TC/siteListContent.aspx?sid=4254&id=37085
EU-M4All (Article 58)	Scientific Advice, Marketing Authorisation	Medicines, vaccines	Global	Scientific opinion from the European Medicines Agency for medicinal products to be used outside of the European Union	The European Medicines Agency (EMA), in cooperation with the World Health Organization (WHO), can provide scientific opinions on high priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU). Target national regulatory authorities are invited to participate in the EMA evaluation. The EMA scientific opinion is then used to facilitate in-country registration. Target national regulatory authorities are also invited to participate in scientific advice procedure.	All regions	https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/medicines-use-outside-european-union
Swissmedic, Switzerland Marketing Authorisation for Global Health Products	Scientific Advice, Marketing authorisation	Medicines, vaccines	Regional	Involvement of target National Regulatory Agencies (NRAs) and the WHO in the Swissmedic assessment process	The MAGHP is based on the approach of involving target National Regulatory Agencies (NRAs) and the WHO in the Swissmedic assessment process. Scientific advice: to clarify scientific questions in the development phase regarding the planned submission. Marketing authorisation: procedure follows the regular Swissmedic marketing authorisation procedure (same time frame, procedural steps and evaluation criteria) with the difference that concerned NRAs and the WHO are involved.	Sub-saharan region of Africa	https://www.swissmedic.ch/swissmedic/en/home/about-us/development-cooperation/marketing-authorisation-for-global-health-products.html
Access Consortium (Australia, Canada, Singapore, Switzerland and United Kingdom)	Marketing Authorisations, Pharmacovigilance	Medicines, vaccines	Global	Information sharing and work-sharing between NRAs	The Access Consortium explores opportunities to share information and work in areas such as new active substances, generic medicines, biosimilar products, advanced therapy medicinal products, clinical trials and information technology. The Consortium capitalises on each country's strengths, addresses gaps in science, knowledge and expertise and leverages resources to expedite risk assessment, while maintaining or raising quality and safety standards.	Australia, Canada, Singapore, Switzerland and United Kingdom	https://www.tga.gov.au/international-activities/australia-canada-singapore-switzerland-united-kingdom-access-consortium; https://www.canada.ca/en/health-canada/services/drugs-health-products/international-activities/australia-canada-singapore-switzerland-consortium.html; https://www.hsa.gov.sg/international-collaboration/therapeutic-products/access; https://www.swissmedic.ch/swissmedic/en/home/about-us/international-collaboration/multilateral-co-operation-with-international-organisations---ini/multilateral-co-operation-with-international-organisations---ini.html; https://www.gov.uk/government/news/uk-medicines-regulator-joins-up-with-australia-canada-singapore-and-switzerland-regulators
WHO Certificate of a Pharmaceutical Product (CPP)	Marketing authorisation, post-authorisation changes	Medicines, vaccines	Global	The WHO Certification Scheme for a Certificate of Pharmaceutical Product (CPP) allows to confirm the quality of pharmaceutical products moving in international commerce	The WHO Certification Scheme for a Certificate of Pharmaceutical Product (CPP) is an international voluntary agreement to provide assurance to countries participating in the Scheme, about the quality of pharmaceutical products moving in international commerce. NRAs are encouraged to consider use of electronic CPP. These certificates are being used in lieu of a full or partial review, accelerating assessment in many countries	All regions	https://www.who.int/teams/regulation-prequalification/pharmacovigilance/certification-scheme/eligibility-for-participation

WHO Collaborative Registration Procedure	Marketing Authorisation	Medicines, vaccines, in-vitro diagnostics	Global	Facilitation of in-country registration by sharing assessment and inspection reports from WHO PQ or stringent regulatory authorities	Facilitate in-country registration of medical products that have already been prequalified or authorised by the stringent regulatory authorities by providing assessment and inspection reports.	All regions	https://extranet.who.int/prequal/medicines/collaborative-procedure-accelerated-registration; https://extranet.who.int/pqweb/vitro-diagnostics/collaborative-procedure-accelerated-registration#:~:text=%20Collaborative%20Procedure%20for%20Accelerated%20Registration%20%201,A%20one-year%20pilot%20project%20aiming%20at...%20More%20
WHO Prequalification of active pharmaceutical ingredients	Marketing Authorisation	Medicines	Global	Validation of the quality of active pharmaceutical ingredients	Prequalification of active pharmaceutical ingredients (APIs) is an independent procedure that identifies APIs that are of good quality and manufactured in compliance with WHO Good Manufacturing Practices (GMP). Some countries recognize confirmation of API prequalification document facilitating the review process for marketing authorisation applications.	All regions	https://extranet.who.int/prequal/medicines/active-pharmaceutical-ingredients
WHO Prequalification of Finished Pharmaceutical products and biotherapeutics	Marketing Authorisation	Medicines	Global	Assessment of quality of finished pharmaceutical products and biotherapeutics	WHO's prequalification assessment and listing procedure convenes national assessors in assessing the quality of FPPs and BTPs. The listing helps international procurers and countries to undertake reliance based procurement decisions and national registrations respectively. Prequalification includes an abridged assessment pathway for products that have already undergone stringent assessment, in addition to the full assessment procedure applicable for products that have not undergone stringent assessment.	All regions	https://extranet.who.int/prequal/medicines
Post-approval changes management, WHO CRP	Marketing authorisation, post-authorisation changes	Medicines	Global	Sharing post-approval changes assessments	For CRP of prequalified products, WHO informs the participating NRAs proactively about any variations approved by the WHO Prequalification team.	All regions	https://extranet.who.int/prequal/medicines/collaborative-procedure-accelerated-registration
Nitrosamine assessment	Marketing authorisation, Scientific advice, Market Surveillance and Control, Post-authorisation changes	Medicines	Global	International collaboration between regulatory agencies, including calculation of AIs by one region and reliance by others	EMA and national competent authorities are monitoring the presence of nitrosamine impurities in medicines, in co-operation with regulators from outside the European Union (EU) and find a common acceptable intake (AI) for substances concerned, agreeing on scientific sound approaches harmonised at international (NSIG and technical subgroups) level such as the Carcinogenic Potency Categorization Approach (CPCA) and Enhanced Ames Test (EAT) discussing potential and identification of potential nitrosamine-related topics for ICH development	Global (i.e. EU/EEA, Australia, Brazil, Canada, Japan, Singapore, Switzerland, the United States of America, the EDQM, the WHO)	https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/referral-procedures-human-medicines/nitrosamine-impurities
Project Orbis	Marketing Authorisation	Medicines	Global	Concurrent submission and review of oncology products (new medicines and new indications)	Framework for concurrent submission to, and collaborative review by, the US FDA and Project Orbis Partners (POPs) of applications for new oncology treatments. Such collaboration aims to give patients around the world faster access to promising treatments. An application is proposed for review through Orbis by the US FDA (or by a pharmaceutical sponsor), generally based on a combination of breakthrough designation, impressive results and unmet need. Assuming the global/affiliate sponsors wish to participate, the relevant POPs determine how they will collaborate (ie. the "type" of Orbis). The FDA and participating POPs work closely during the review, sharing information (information requests, assessment reports, etc) and attending teleconferences.	USA (lead), Australia, Brazil, Canada, Israel, Singapore, Switzerland, UK	https://www.fda.gov/about-fda/oncology-center-excellence/project-orbis
Certificates of suitability for monographs in The European Pharmacopoeia	Marketing authorisation, post-authorisation changes	Medicines, vaccines	Regional	Validation of the quality of active pharmeceutical ingredients	The procedure certifies the suitability of any substance covered by a European Pharmacopoeia monograph to the monographs to control the chemical purity, microbiological quality and Transmissible Spongiform Encephalopathy risk (if relevant) and to check compliance at the manufacturing and/or distribution site(s) covered by Certificates of Suitability to the monographs of the European Pharmacopoeia (CEPs) with both Good Manufacturing Practice (GMP) for medicinal products for human or veterinary use. This procedure facilitates and simplifies exchanges between regulators and industry to ensure that the quality of substances used in the production of pharmaceutical products is guaranteed and facilitates the management of marketing authorisation applications for medicinal products.	The list of countries using/relying upon CEPs includes: 1. Close to 40 countries in Europe, which are members of the European Pharmacopoeia Convention, including all EU countries. 2. Additional 30 countries outside Europe, including Australia, Canada, Singapore, and more recently Brazil.	https://www.edqm.eu/en/background-legal-framework; https://faq.edqm.eu/display/FAQS/CERTIFICATION+OF+SUBSTANCES+FOR+PHARMACEUTICAL+USE
ASEAN Joint assessment	Marketing authorisation	Medicines	Regional	Joint assessment	This is a formal procedure in which the same marketing authorisation application is simultaneously submitted to all participating NRAs. Assessment work is then carried out together by all participating NRAs and a joint assessment report is prepared. At the end of the process, the final decision on the application is taken by each individual NRA through their normal decision-making process based on the joint report and, where applicable, nationally-relevant considerations.	Association of Southeast Asian Nations	https://www.hsa.gov.sg/therapeutic-products/international-collaboration/ASEAN-JA

Zazibona joint assessment	Marketing Authorisation	Medicines	Regional	Joint assessment	National regulatory authorities from the Southern African Development Community jointly assess medicinal product dossiers. Applicant must compile an application to CTD format and submit the application in at least two active country members of ZAZIBONA. The objectives of ZAZIBONA are to reduce timelines for registration of medicines, to efficiently utilize available regional resources and to ensure the availability of good quality medicines within the region.	Botswana, Democratic Republic of the Congo, Malawi, Mozambique, Namibia, South Africa, United Republic of Tanzania, Zambia, Zimbabwe	https://www.tmda.go.tz/pages/the-zazibona-collaorative-medicines-registration-procedure
East African Community joint assessment	Marketing Authorisation	Medicines, vaccines, medical devices	Regional	Joint assessment	The East African Community (EAC) Medicines Regulatory Harmonization is a regional programme and is part of the continental initiative, the “African Medicine Regulatory Harmonization (AMRH)” whose aim is to address the concerns of lack of standardized approaches in regulation of medicine, vaccines and medical devices. Joint assessments are beneficial to NRAs by spreading the workload, building capacity through broader experience and expertise and helping to build trust in each other’s assessments and decision making processes.	East African Community	https://www.eac.int/mrh
Mutual recognition of marketing authorisation, European Union	Marketing Authorisation	Medicines, vaccines	Regional	Mutual recognition	The European Union is an example of highly integrated regulatory cooperation, and its many regulatory pathways depend heavily on work-sharing, recognition and other forms of reliance. The approval of medicines is based on a single assessment system, so that an assessment report from any agency in the European Union network can be used as a basis for reliance by other regulators.	European Union	https://ec.europa.eu/health/documents/eudralex/
Worksharing procedure for the assessment of active substance master files	Marketing Authorisation	Medicines	Regional	Reliance on the assessment of an ASMF done by one Member State	In order to harmonise assessment of ASMFs, reduce the frequent updates of ASMFs, and reduce the resource and regulatory burden on Competent Authorities, ASMF and MA holders, the Working Group on Active Substance Master File Procedures has established a worksharing procedure for the assessment of ASMFs, including a centralised EU numbering system for ASMFs and a centralised repository for the ASMF assessment reports.	European Union	https://www.hma.eu/human-medicines/cmdh/cmd-working-parties-/-working-groups/working-group-on-active-substance-master-file-procedures.html
Economic Community of West African States/West African Health Organization joint assessment	Marketing authorisation, Regulatory Inspections	Medicines, vaccines	Regional	Joint assessment	This is a procedure for joint assessment by several West African States on medical products dossier assessment of the selected medicinal products, inspection of their respective manufacturing site(s) followed by Steering Committee approval of jointly accepted medicinal products. If the assessment of medicinal products dossier is successfully completed and jointly accepted, the ECOWAS Member Sates NMRAs will grant marketing authorisation within maximum of three (3) months from the date of joint acceptance.	West African States	https://www.wahooas.org/web-ooas/sites/default/files/publications/1993/wa-mrh-regional-joint-medicines-assessment-procedure.pdf
Comparable Overseas Regulator (COR) report-based process	Marketing Authorisation	Medicines, Vaccines	National	Abridged evaluation pathway for prescription medicine applications that have received approval from a comparable overseas regulator	The TGA's reliance framework for prescription medicine applications that have received full approval by a comparable overseas regulator (COR). Sponsor must submit the complete unredacted assessment reports from the COR's approval. Two pathways: • COR-A: Application is all but identical to the application approved by the COR and is submitted to the TGA <1 year after the COR's approval. Legislated decision timeframe of 120 working days • COR-B: Application contains additional/updated data or the application is submitted to the TGA >1 year after the COR's approval. Legislated decision timeframe of 175 working days	Australia	https://www.tga.gov.au/resources/resource/guidance/comparable-overseas-regulators-cors-prescription-medicines
An abbreviated Review Process for new chemical entities from TFDA, Chinese Taipei	Marketing Authorisation	Medicines	National	Shortened review timelines of new chemical entities registration if already authorised by at least two reference authorities	An abbreviated Review Process for new chemical entities in reliance on reviewing by at least two of the three regulatory agencies (US FDA, EMA, or MHLW/PMDA). When applicants provided approvals from two of the three regulatory agencies and with no ethnic difference and agreed to bridging a study waiver as well as providing full review reports, a risk management plan, and updated post-marketing commitment reports, thus the review days could be reduced from 360 to 180 calendar days within fitting above criteria.	Chinese Taipei	http://www.fda.gov.tw/tc/siteListContent.aspx?sid=2984&id=32228
An abbreviated Review Process for drug master file (DMF) from TFDA, Chinese Taipei	Marketing Authorisation	Medicines	National	Abbreviated Review Process for drug master file with EDQM issuing CEP/COS	For applicants submitted for DMF evaluation with CEP/COS (applications containing sterile, biotic and fermented drug substance were excluded), the CTD Module 3 could be exempted and be replaced by the following documents, including an authorisation from the manufacturer, an announcement indicating that no significant changes have been made to the DMF since the CEP/COS was issued by EDQM, a certificate of analysis for at least 3 production scale batches and an outline of the synthesis route/manufacturing process approved by EDQM.	Chinese Taipei	http://www.fda.gov.tw/tc/sitelist.aspx?sid=3001
Reliance procedure for marketing authorisation process in Egypt	Marketing Authorisation	Vaccines & Plasma derived medicinal products	National	Reliance pathway for marketing authorisation procedures	Reliance pathway is performed for products with EMA and/or FDA approval. In this cases applicant must submit full assessment report by the SRA and/or list of question and answer in addition to complete CTD. The analysis of samples for registration can be postponed to the first shipment before placing into market.	Egypt	https://www.edaegypt.gov.eg/media/p0uj2utf/reliance-english-version_1.pdf

Abridged and verification procedure	Marketing Authorisation	Medicines	National	Abridged and verification procedure	EDA relies on Stringent Regulatory Authorities (SRAs) included in the list of reference countries approved by the Technical Committee of Drug Control and also gives significant strength to WHO prequalified products in registration of imported products that are registered and marketed in any of SRAs included in the list of reference countries approved by the Technical Committee of Drug Control.	Egypt	https://edaegypt.gov.eg/media/5ujkjyvo/guidelines-on-reliance-practices-during-registration-of-medicinal-products-version-03-1-_compressed.pdf
Unilateral recognition of marketing authorisation, Mexico	Marketing Authorisation	Medicines	National	Unilateral recognition of marketing authorisations	The Mexican Federal Commission for Protection against Sanitary Risk unilaterally recognizes marketing authorisations from certain reference regulatory authorities. The Mexican government established equivalence agreements (unilateral recognition) for new drugs with prior approvals by the US FDA, Health Canada, TGA, Swissmedic or EMA.	Mexico	https://www.dof.gob.mx/nota_detalle.php?codigo=5271418&fecha=05/10/2012; https://www.dof.gob.mx/nota_detalle.php?codigo=5271419&fecha=05/10/2012; https://www.dof.gob.mx/nota_detalle.php?codigo=5271420&fecha=05/10/2012; https://www.dof.gob.mx/nota_detalle.php?codigo=5271421&fecha=05/10/2012; https://www.dof.gob.mx/nota_detalle.php?codigo=5271422&fecha=05/10/2012 https://www.dof.gob.mx/nota_detalle.php?codigo=5271421&fecha=05/10/2012;
Registration According to Verification and Abridged	Marketing Authorisation	Human and Veterinary medicinal products for the following : - New Products (New Chemical Entity). - Biological Products (excluding biosimilars, blood products, vaccines and	National	Registration According to Verification and Abridged	At Saudi FDA, human medicinal products that have been authorised and marketed by FDA and/or EMA are eligible for verification/abridged registration pathways with shortened times to increase leverage of reference agencies' assessments, minimize duplication of effort, and increase efficiency. To qualify, the product must be identical to that approved in the reference country, and the application must be submitted within two years from the date of approval. Also, the product does not need a more stringent assessment as a result of different local disease patterns and/or medical practices and has not been rejected, withdrawn, or suspended by any drug regulatory agency for safety or efficacy reasons; the manufacturer should be located in one of the following countries: USA, UK, Canada, Australia, Japan, Switzerland, Germany, France, Ireland, Italy, Spain, Portugal, Finland, Sweden, Norway, Denmark, Belgium, Netherlands, Austria, or Singapore.	Saudi Arabia	https://www.sfda.gov.sa/en/regulations/66231
Post-approval changes management, HSA Singapore	Marketing authorisation, post-authorisation changes	Medicines	National	Abridged pathway for post-approval changes	The Health Sciences Authority in Singapore applies an abridged (if one approval has been obtained) or a verification route (two approval obtained) with shortened times for approving post-approval changes to quality and product labels, to increase leverage of reference agencies' assessments, minimize duplication of effort and increase efficiency as part of work that includes effective life cycle management of registered therapeutic medicinal products if these variations have been authorised already by one or two reference authority(ies). To qualify, the proposed changes must be identical to those approved by one of the Authority's five reference agencies, with proof of the approval and the approved product label of that reference agency.	Singapore	https://www.hsa.gov.sg/therapeutic-products/guidance-documents#toggle=togglepanel-product-registration-and-post-approval-variation
Reliance in the WHO Emergency Use Listing process	Emergency Use Authorisation	Medicines, vaccines, medical devices	Global	Reliance on assessment and inspection from the National Regulatory Authority of record for the WHO EUL process	The WHO Emergency Use Listing (EUL) is a risk-based procedure for assessing unlicensed vaccines, therapeutics and in-vitro diagnostics during public health emergencies, with the ultimate goal of expediting the global availability of these products. If the product submitted for EUL has been assessed by a Stringent Regulatory Authority (SRA), WHO does not duplicate work and relies on assessments already available. In addition, WHO assesses the product suitability from a global public health perspective.	All regions	https://www.who.int/teams/regulation-prequalification/eul
PAHO Guidance on Reliance for emergency use of medicines and other health technologies in a pandemic	Emergency Use Authorisation	Medicines, vaccines, medical devices	Global	Guidance on practical ways to implement reliance for emergency use of medicines and other health technologies	This document provides guidance to national regulatory authorities (NRAs) and regulatory systems on practical ways to implement reliance for emergency use of medicines and other health technologies in a pandemic situation.	All regions	https://iris.paho.org/handle/10665.2/52027
Abridged and verification procedure	Post-authorisation changes	Medicines	National	Abridged and verification procedure	Same reliance principles and mechanisms adopted in the initial marketing authorisation, EDA may also broadly apply those mechanisms assessing post-approval changes that are already approved by another reference countries.	Egypt	https://edaegypt.gov.eg/media/5ujkjyvo/guidelines-on-reliance-practices-during-registration-of-medicinal-products-version-03-1-_compressed.pdf
Reliance for post approval changes	Post-authorisation changes	Vaccines & Plasma derived medicinal products	National	Reliance for post approval changes	Reliance pathway is preformed for post approval changes. In this cases applicant must submit full assessment report by the SRA in addition to all section related to the submitted change. Also for inspection, facilitate applying post approval changes of products by relying on approval of NRA.	Egypt	https://edaegypt.gov.eg/media/n4rjpc4y/guideline-on-the-regulation-of-post-approval-changes-to-a-registered-bio-therapeutic-products.pdf
International Mutual Recognition Agreement between countries/regions for inspections	Regulatory Inspection	Medicines, vaccines	Global	National Regulatory Authority relying on each other's inspections	Mutual Recognition Agreements between the European Union and Australia, Canada, Japan, Switzerland and the USA	All regions	https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/mutual-recognition-agreements-mra

PIC/S	Regulatory Inspection	Medicines, vaccines	Global	Reliance on regulatory inspections from other National Regulatory Authorities	PIC/S is a non-binding, informal cooperative arrangement among regulatory authorities in the field of good manufacturing and good distribution practices of medicinal products for human or veterinary use and, more recently, also in good clinical and good vigilance practices. Its aim is to facilitate cooperation and networking among competent authorities and regional and international organizations, thus increasing mutual confidence in inspections.	All regions	https://picscheme.org/en/picscheme; https://picscheme.org/docview/2475
Mutual Recognition Agreement between countries/regions for inspections in Association of Southeast Asian Nations	Regulatory Inspection	Medicines, vaccines	Regional	National Regulatory Authority relying on each other's inspections	The ASEAN Sectoral MRA on GMP Inspection is an agreement signed by the ASEAN Economic Ministers which aims to facilitate the movement of medicinal product in ASEAN through the mutual exchange and recognition of GMP inspection reports and certificates.	Association of Southeast Asian Nations	https://asean.org/wp-content/uploads/2016/06/31.-October-2015-FAQ-on-the-ASEAN-MRA-on-GMP-Inspection-of-Manufacturers-of-Medicinal-Products.pdf
Mutual acceptance of data for chemicals (including pharmaceuticals) in the European Union	Regulatory Inspection	Medicines, vaccines	Regional	Mutual acceptance of data for chemicals (including pharmaceuticals) in the European Union	The OECD operates a system for mutual acceptance of data in the assessment of chemicals (including pharmaceuticals), in which data generated in any member country in accordance with OECD test guidelines and the principles of good laboratory practice are accepted by any other member country for assessing products for the protection of human health and the environment.	European Union	https://www.oecd.org/chemicalsafety/testing/mutualacceptanceofdatamad.htm
Supervisory authority for pharmacovigilance activities in the European Union	Regulatory Inspection	Medicines, vaccines	Regional	One authority responsible for ensuring compliance with pharmacovigilance requirements for the European Union	In Regulation EU No 1235/2010), the European Union introduced the concept of a supervisory authority for pharmacovigilance, to be responsible for verifying on behalf of the Union that the marketing authorisation holder for a medicinal product satisfies the pharmacovigilance requirements as per European Union legislation	European Union Member States	https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-iii-pharmacovigilance-inspections_en.pdf
Relying on other authorities inspection reports and decisions for registration and re-registeration procedures	Regulatory Inspection	Biological products, vaccines, blood products	National	National Regulatory Authority relying on each other's inspections	Facilitate products registration and re-registration procedures through assessing the level of GMP compliance of an overseas facility, can be confirmed remotely without an on site inspection.	Egypt	https://www.edaegypt.gov.eg/media/mt5bj1qc/%D8%A7%D9%84%D8%AF%D9%84%D9%8A%D9%84-%D8%A7%D9%84%D8%AA%D9%86%D8%B8%D9%8A%D9%85%D9%8A-%D9%84%D9%84%D9%82%D8%B1%D8%A7%D8%B1-%D8%B1%D9%82%D9%85-343%D9%84%D8%B3%D9%86%D8%A9-2021.pdf; https://www.edaegypt.gov.eg/media/2jadmwwp/regulatory-guideline-on-organizing-the-rules-and-procedures-of-registration-of-human-pharmaceutical-products-in-accordance-with-the-different-cases-based-on-egyptian-drug-authority-chairman-decree-no-450-of-1.pdf
WHO National Control Laboratory Network for Biologicals (WHO-NNB)	Lot release	Vaccines	Global	Reliance on batch releases by NRAs and national control laboratories that are members of WHO-NNB	Launched in 2017, the WHO National Control Laboratory Network for Biologicals (WHO-NNB) brings together national control laboratories and NRAs of vaccine-producing and vaccine recipient countries, WHO contract laboratories, manufacturers' associations, WHO regional offices and other stakeholders, including donors. WHO-NNB ensures effective use of global resources by providing a platform and infrastructure for collaboration and exchange of information on quality and technical aspects. Its main objective is to facilitate access to and the availability of prequalified vaccines (and other biotherapeutic products) through reliance on batch releases by NRAs and national control laboratories that are members of WHO-NNB, thereby reducing redundant testing and encouraging more cost–effective testing and more effective regulatory oversight.	All regions	https://www.who.int/teams/regulation-prequalification/regulation-and-safety/laboratory-networks-and-services/regulatory-harmonization
Risk based lot release system in Egypt	Lot release	Vaccines & Plasma derived medicinal products	National	Reliance on batch releases by NRAs and national control laboratories that are mentioned WHO list for SRAs	Full or partial exemption of independent testing may be granted to products upon submission of lot release certificate issued by a reference NRA / NCL.	Egypt	https://www.edaegypt.gov.eg/media/vkzpwnjl/lot-release-guidline_1.pdf
General European Official Medicines Control Laboratories Network	Testing and lot release	Medicines, vaccines	Regional	Mutual recognition among its members of tests conducted by national official medicines control laboratories	The network of official medicines control laboratories supports regulatory authorities in controlling the quality of medicinal products on the market. Collaboration within the General European Official Medicines Control Laboratories Network (GEON) makes the best use of resources by pooling resources and avoids duplication of work and testing. Some of the main goals of the GEON are to ensure mutual recognition among its members of tests conducted by national official medicines control laboratories, coordinate activities among official medicines control laboratories and facilitate sharing of knowledge and work.	European Union	https://www.edqm.eu/en/omcl-background-and-mission
Abridged assessment of pharmacovigilance in Egypt	Pharmacovigilance	Vaccines & Plasma derived medicinal products	National	Abridged pathway for pharmacovigilance activity	PV administration reviews the published risk management plan and periodic safety reports by other regulatory authorities such as EMA, MHRA, FDA, and/or Japan. Additional activities and risk minimisation measures tailored to the domestic context. For the EU pharmacovigilance system master file, only oversight on national assiliate is performed.	Egypt	https://www.edaegypt.gov.eg/media/kg2dtie2/guideline-on-good-pharmacovigilance-practice-gvp-in-egypt-for-pharmaceutical-products_.pdf

Pharmacovigilance recognition activity in Egypt	Pharmacovigilance	Vaccines & Plasma derived medicinal products	National	Recognition pathway for pharmacovigilance activity	Recognition is performed for safety signals confirmed by other regulatory authorities, safety variations, and/or emerging safety issues published by the WHO and/or other stringent regulatory authorities (SRAs) and ensures RMMs` implementation in Egypt. However, validated signals that arise in Egypt are assessed. This approach is used in case of products under " emergency use licensing EUL".	Egypt	https://www.edaegypt.gov.eg/media/kg2dtie2/guideline-on-good-pharmacovigilance-practice-gvp-in-egypt-for-pharmaceutical-products_.pdf
Recognition in Australia of registrations and certification from other countries under Mutual Recognition Agreements (MRAs)	Medical Devices Oversight	Medical Devices	Global	Mutual acceptance of conformity assessment for medical devices	Australia has MRAs with a number of countries which provides for the mutual acceptance of conformity assessment for medical devices.	Australia	https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-devices-reforms/medical-devices-reforms-mutual-recognition-agreements-mra
Reliance in Australia of registrations and certification from comparable overseas regulators	Medical Devices Oversight	Medical Devices	National	Reliance in Australia of registrations and certification from comparable overseas regulators	Australia takes into account registrations and certifications from comparable overseas regulators and assessment bodies, including notified bodies designated by the medical device regulators of European member states, the Pharmaceuticals and Medical Devices Agency of Japan, the US Food and Drug Administration, Health Canada, Singapore's Health Sciences Authority, and auditing organizations participating in the Medical Device Single Audit Program	Australia	https://www.tga.gov.au/comparable-overseas-regulators-medical-device-applications
The Medical Device Single Audit Program	Medical Devices Oversight	Medical Devices	Global	Single regulatory audit of the quality management system of medical devices manufacturers by a third party organization for several regualtory authorities	The regulatory authorities of Australia, Brazil, Canada, Japan and the USA established a robust system of oversight by recognized third party auditing organizations (AOs), who audit the quality management systems of medical device manufacturers. The AO's conduct a single QMS audit that satisfies the requirements of the regulatory authorities participating in MDSAP. The 5 regulators pool resources to: establish and maintain oversight of AOs, resulting in more streamlined and effective use of limited regulatory resources; accept a single QMS certificate to streamline processes efficiently without compromising public health; and promote better aligned, more consistent regulatory requirements.	Australia, Brazil, Canada, Japan and the USA	https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap
International Medical Device Regulators Forum (IMDRF) Guidance for exchanges of information on the safety of medical devices among participating National Regulatory Authorities	Medical Devices Oversight	Medical Devices	Global	Exchanges of information on the safety of medical devices	The IMDRF has also issued guidance for exchanges of information on the safety of medical devices among participating NRAs. The system reports incidents that represent a serious threat public health beyond national borders. The IMDRF provides consistent terminology for reporting and coding adverse events for categorized reporting.	IMDRF members	https://www.imdrf.org/
Abridged evaluation of medical device conformity assessment certification in Australia	Medical Devices Oversight	Medical Devices	National	Abridgement of applications for TGA conformity assessment certification	Comparable overseas regulator or assessment body evidence can be utilised for abridgement of TGA conformity assessment.	Australia	https://www.tga.gov.au/resources/resource/guidance/comparable-overseas-regulators-medical-device-applications
Abridged evaluation of medical devices in Singapore	Medical Devices Oversight	Medical Devices	National	Abridged evaluation of medical devices already authorised by other authorities	In Singapore, medical devices and in vitro diagnostics that have been authorised through specific pathways in Australia, Canada, Europe, Japan or the USA are eligible for abridged evaluation. To qualify, the proposed intended use must be identical to that approved in the reference country. Typically the documentation includes proof of approval from the reference regulatory authority and summary technical documents to satisfy requirements for supporting documentation	Singapore	https://www.hsa.gov.sg/medical-devices/registration/overview#toggle=togglepanel-overseas-reference-regulatory-agencies
Vigibase Uppsala Monitoring Centre for all countries	Vigilance	Medicines, vaccines	Global	Exchange and sharing of Vigilance data	More than 100 Member States share data on the safety of medical products in the WHO database of individual case reports of safety, VigiBase, developed and maintained by the Uppsala Monitoring Centre. Member States use this database (and thereby each other's data) as a single source of pharmacovigilance information to confirm and validate any signals of adverse events associated with medicines and vaccines that they have observed.	All regions	https://who-umc.org/vigibase/