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GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

Proposed Document

Title: General Procedure of Common Evaluation Reliance Practice

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1. Preface

Regulatory reliance is a hot-button issue drawing global attention. When it comes to medical device registration and evaluation, diverse models of regulatory reliance are available, including abridged evaluation, joint evaluation, unilateral recognition, and mutual recognition. As reliance deepens incrementally, technical-level evaluation consensus and recognition may be extended to the regulatory dimension, whereby the regulatory body makes the approval conclusion based on the evaluation conclusion of the trusted party independently and promptly. This ultimately accelerates the global market access of innovative and clinically urgently-needed medical devices.

Based on the above background, at the end of 2023, the 27th Annual Meeting of the Global Harmonization Working Party (GHWP) approved the establishment of a Special Task Group to carry out the Common Evaluation Reliance Practice (CERP). It aims to develop medical device evaluation guidance documents to foster evaluation recognition, reduce duplicate evaluation, and deliver mutually approval and regulatory reliance.

This Procedure aims to advance the practice of regulatory reliance in the field of medical device technical evaluation. Under this Procedure, the GHWP CERP is committed to promoting convergence, harmonization, and reliance among medical device Technical Evaluation Organizations (TEOs).

2. Work Basis

GHWP has 39 member countries and regions across Asia, Africa and South America, covering nearly 60% of the global population. As an international platform for medical device regulatory-law exchanges with participation from both regulatory authority representatives and industry representatives, GHWP is committed to advancing regulatory harmonization, convergence and reliance for medical devices through dialogue and exchanges among medical device regulators and industries of different countries and regions.

At the end of 2025, GHWP released the Strategic Framework towards 2030. Rooted in global health mandates including the United Nations Sustainable Development Goals and key World Health Assembly resolutions, the Strategy aims to coordinate pre-market technical evaluation of medical devices by leveraging the CERP platform. It also encourages members to conduct joint evaluation for medical devices used in the diagnosis and treatment of both rare and common diseases. GHWP prioritizes developing clear, implementable evaluation-mutual-recognition procedures to reduce redundant regulatory work and optimize global evaluation timelines. It ensures that complete assessment outcomes delivered by mature regulatory authorities can be effectively recognized by other authorities, so as to accelerate patients' access to medical devices.

3. Main Objectives

3.1 Promote Harmonization of Evaluation Requirements and Advance Evaluation Quality Management

Continuously deepen the harmonization of global medical device regulatory rules, and foster consensus among member regulatory authorities on technical standards, evaluation methodologies and risk-determination principles. Disseminate the outcomes derived from internal quality management within evaluation authorities and develop guiding documents for evaluation quality management. Establish regular communication and dialogue channels for evaluation authorities to strengthen evaluation capacity-building, narrow institutional gaps between regional regulatory systems, and build converged regulatory philosophies and technical consensus. This will lay a solid foundation for cross-border medical device evaluation cooperation and support the GHWP initiatives for the harmonization, convergence and reliance of medical device regulations.

3.2 Introduce the Concept of Evaluation Recognition to Reduce Duplicate Evaluation

While fully respecting national regulatory frameworks, technical evaluation reports submitted by counterpart authorities may be recognized to simplify registration-evaluation procedures and shorten technical evaluation timelines, which can be materialized in forms such as abridged evaluation processes or recognition of evaluation conclusions. Local regulatory authorities shall still conduct administrative approval in accordance with legal requirements afterwards. Efforts shall be made to cut resource consumption caused by independent and full-fledged technical evaluations carried out separately by multiple jurisdictions. A joint-evaluation mechanism shall be established to optimize global evaluation workflows and avoid duplicate pre-market technical assessments for the same medical device across different jurisdictions.

3.3 Advance the Implementation of Regulatory Reliance and Improve Global Access to Medical Devices

Constrained by factors including social development and industrial scale, medical-device regulatory capacities vary across countries and regions. Divergences in evaluation-approval requirements and market-access timelines hinder global access to medical devices to a certain degree. CERP actively promotes international cooperation and institutional innovation among GHWP members in the field of regulatory mutual-reliance, explores diversified cooperation models for regulatory mutual-reliance, and develops a clear and

feasible implementation framework. Existing regulatory resources and expertise from various countries and regions shall be fully leveraged to shorten the global time-to-market of medical devices and meet public demand for access to medical devices worldwide.

4. Work Pathways

CERP promotes regulatory mutual-reliance practice at the pre-market evaluation stage for medical devices through bilateral and multilateral cooperation.In practice, CERP primarily operates through six pathways, namely harmonization of evaluation requirements, abridged evaluation, joint evaluation, quality management system for technical evaluation, unilateral recognition, and bilateral/multilateral mutual recognition.

4.1 Harmonization of Evaluation Requirements

Medical devices feature complex configurations and a wide variety of types with substantial disparities in technical characteristics across different products. Therefore, harmonization of evaluation requirements shall be realized in a categorized and phased manner. Tailored evaluation requirements shall be developed for conventional medical devices, innovative medical devices, clinically-urgent medical devices, and medical devices for the prevention and treatment of rare diseases. Where divergent requirements exist among countries and regions for the same type of medical device — such as performance evaluation items, methodologies, and acceptance criteria for results — such divergences shall be clearly identified, and corresponding harmonization mechanisms shall be established to ensure the compatibility of technical evaluation documents. Once evaluation consensus is reached, conclusions derived from technical evaluation using such technical evaluation documents will be recognized by other regulatory authorities, so as to reduce duplicate evaluation among regulators.

Harmonizing evaluation requirements entails fully collecting and summarizing existing registration regulatory requirements, guidance documents and standards from relevant medical-device regulatory authorities, followed by developing product-specific technical evaluation documents for each product category. Against the trends of global convergence of medical-device regulations, technical evaluation requirements for given products are largely identical or similar across countries and regions. In line with the principle of seeking common ground while reserving differences, aligned requirements shall be set out as “General evaluation Consensus” in technical evaluation documents, whereas divergent technical evaluation requirements shall be specified under “Regional-Specific Requirements”. Regional-specific requirements represent topics for further research and discussion in the process of building technical evaluation consensus, with the ultimate goal of achieving fully-aligned general evaluation consensus. More specific technical evaluation standards contribute to clearer consensus-building among regulatory authorities.

4.2 Abridged Evaluation

At the end of 2024, the 28th GHWP Annual Meeting approved the launch of the Joint Evaluation Pilot Project under CERP. The Joint Evaluation Pilot Project is implemented in phases according to the established schedule, with the focus areas and modes of cooperation for each phase determined based on the preferences of the participating Technical Evaluation Organizations (TEOs). Phase I of the Joint Evaluation Pilot Project explores the streamlined review pathway.

Under this project, medical device Technical Evaluation Organizations (TEOs) from two or more countries/regions reach a consensus on project cooperation and agree to each recommend a limited number of medical devices for inclusion in the project. Once a medical device has obtained marketing approval in one of the participating countries/regions, it may enter the review process through a special pathway established by the regulatory authority in the country/region where marketing authorization is being sought. This special pathway may be an existing streamlined review pathway or specific review simplification measures adopted by the regulatory authority for the project.

During project implementation, participating parties may explore ways to reduce duplicative review efforts and improve review efficiency by strengthening technical exchanges, sharing review approaches, and referring to existing evaluation reports. Each participating party will continue to independently make marketing authorization decisions and conduct post-market regulatory oversight in accordance with its own national laws, regulations, and regulatory policies, ensuring the safety, effectiveness, and quality control of medical devices. Through project cooperation, reviewers will progressively accumulate experience in cross-border regulatory collaboration by focusing on specific medical device products, thereby laying the foundation for expanding the scope of future cooperation and deepening regulatory coordination.

4.3 Joint Evaluation

Phase II of the CERP Joint Evaluation Pilot Project explores the joint evaluation pathway. The joint evaluation pathway consists of five main stages:

Stage 1: The manufacturer submits a medical device registration application to the local regulatory authority. Reviewers conduct application acceptance and technical review in accordance with local regulatory requirements.

Stage 2: Based on the established selection criteria, regulatory authorities recommend medical devices for inclusion in the project, specify the applicable review pathways, and share evaluation requirements with cooperating regulatory authorities. The scope of information sharing is determined by the respective Technical Evaluation Organizations (TEOs).

Stage 3: Technical Evaluation Organizations (TEOs) convene meetings to jointly discuss product risks and risk control measures, and exchange views on the evaluation of the safety and effectiveness of the medical devices.

Stage 4: Where supplementary information is required, the TEOs notify the participating manufacturers to submit additional documentation in accordance with the applicable laws and regulations of their respective countries/regions. Upon receipt and review of the supplementary information, the TEOs issue their technical evaluation opinions and share relevant information from their evaluation reports. The scope of information sharing is determined by the respective TEOs.

Stage 5: The regulatory authorities issue their respective regulatory approval decisions.

The joint evaluation pathway generally applies to medical devices that have not yet obtained marketing authorization in any of the participating countries/regions. The regulatory authority in the country of origin must have formally accepted the medical device registration application, while the manufacturer must also submit a registration application to at least one other regulatory authority participating in the project outside the country of origin.

Manufacturers participating in the project may take part in project-organized technical exchanges, progress updates, communication, and coordination activities.

4.4 Quality Management System for Technical Evaluation

Recognition reflects state-level will, whereby a country accepts marketing authorisation certificates issued by a reference jurisdiction in accordance with its laws, regulations or policy documents. The precondition for recognition is reliance in the technical evaluation capacity and quality-management system of the reference jurisdiction; that is, the reference evaluation authority shall be capable of effectively implementing the full set of evaluation procedures as specified in this guidance and safeguarding the safety, effectiveness and consistent quality of medical devices.

CERP is developing the Medical Device Technical Evaluation Quality Management System document. It aims to guide technical evaluation authorities to establish, implement and continuously improve their in-house quality-management systems, and enhance the quality and credibility of pre-market evaluation work both within and across authorities. The guidance sets out fundamental principles for the quality-management system of medical device technical evaluation, for internal use by authorities conducting medical device technical evaluations, and may also be used for external institutional assessments by international technical working groups. Entities undertaking medical device technical evaluations include, but are not limited to: regulatory authorities, technical support bodies authorised by regulatory authorities (i.e. technical evaluation authorities), conformity-assessment bodies, notified bodies

and other relevant stakeholders. GHWP member countries and regions may adopt this guidance directly to guide quality-management-system development for technical evaluation authorities within their jurisdictions, or may add supplementary requirements based on domestic medical-device regulatory provisions.

4.5 Unilateral Recognition

Unilateral recognition is implemented at the sole discretion of one regulatory authority and does not require bilateral or multilateral agreements with the reference regulatory authority. The authority implementing unilateral recognition retains independent decision-making power and bears statutory regulatory responsibilities. Reciprocal acceptance of its own evaluation outcomes by the reference jurisdiction is not a mandatory requirement. The implementing authority may independently define the scope of recognition, product categories, list of reference regulatory authorities, abridged evaluation workflows and other relevant arrangements.

Based on its confidence in the recognized party's medical device technical evaluation capabilities, internal quality management system, and the quality of medical devices exported from its jurisdiction, the recognizing party may, through the issuance of relevant policies, include the recognized party in its "List of Reference Regulatory Authorities" and unilaterally recognize the technical evaluation conclusions issued by the recognized party. Meanwhile, depending on the cooperation arrangements, the recognized party may provide training, share technical evaluation reports, and undertake other collaborative activities to support the recognizing party.

4.6 Bilateral/Multilateral Mutual Recognition Mutual Recognition

Bilateral/Multilateral mutual recognition is normally implemented under formal agreements reached by participating parties for reciprocal acceptance of evaluation conclusions. Experience accumulated through abridged evaluation and joint evaluation can lay a foundation for bilateral mutual recognition between two or more regulatory authorities. Ultimately, the scope, procedures and legal effect of recognition are formalised in writing via agreements or MoU concluded between regulatory authorities or respective governments. Authorities will subsequently incorporate the bilateral-mutual-recognition mechanism into domestic medical-device regulations through appropriate measures consistent with their national legal systems. It should be noted that reaching consensus and pursuing regulatory-mutual-reliance cooperation through agreements or MoU does not equate to bilateral mutual recognition.

A typical global practice of bilateral mutual recognition involves regulatory authorities of two or above jurisdictions entering into a conformity assessment mutual recognition agreement. Subsequently, one party issued a statement of

intent on the international recognition policy for medical devices, designating multiple regulatory authorities as reference authorities based on device type, risk class and prior approval status. The other party issued revised regulatory documents, allowing applicants to submit conformity assessment certificates issued by the notified bodies designated by the counterpart as evidence of conformity to access the local simplified evaluation pathway.

5. Roles and Responsibilities of Participants

Roles and Responsibilities of Participants

Participants	Role	Responsibilities
Regulatory Authorities	Regulator	• The regulators shall perform their duties in accordance with the laws and regulations of their respective jurisdictions; • The regulators agree to maintain confidentiality of the commercial confidential information obtained through communications, testing and feedback exchanges ; • The regulators agree to fulfill their responsibilities within the agreed timeframes, communicate promptly when issues arise, and provide and receive feedback as appropriate . • Carry out clear and transparent communication with applicants (manufacturers) regarding applicable regulatory provisions, compliance obligations and regulatory requirements for pilot products, and keep relevant records to support CERP-related activities.
Regulated Industry	Manufacturers / Applicants	• The applicant（ manufacturer） shall submit complete and accurate application dossiers and fulfill the relevant regulatory obligations shared earlier within the agreed timeframes; • Communicate any issues promptly as they arise, provide and receive feedback as required, and maintain confidentiality of any information disclosed during the communication, testing or feedback exchanges related to the pilot.
CERP-STG Members	Coordinators	• Support the development, evaluation, and refinement of guidance documents and position papers related to collaborative evaluation and regulatory reliance practices; • Provide strategic input and recommendations to improve the design, scalability, and sustainability of reliance-based mechanisms; • Support capacity-building activities, such as workshops, training sessions, or knowledge-exchange initiatives; • Call for products recommendation in the project and coordinate with regulatory authorities, and complete the relevant work within the agreed timeframes.
CERP-STG Secretary	Coordinators	• Assist in the daily organization, coordination, and management of CERP activities; • Facilitate communication and liaison among working group members, participating regulatory authorities, and manufacturers; • Organize and coordinate technical exchanges and other related activities conducted under CERP; • Draft, compile, organize, and archive project documents, meeting minutes, work reports, and other relevant materials; • Monitor project implementation progress and assist in ensuring the effective execution of project tasks; and undertake other relevant assignments entrusted by GHWP.

6. Others

6.1 Adjustment and Optimisation

Taking into account the implementation outcomes of specific projects under each CERP work path (hereinafter referred to as CERP Projects), as well as feedback from participating regulatory authorities and other stakeholders, this document will be adjusted and optimised in a timely manner where appropriate. Possible revisions include streamlining procedures, refining wording, adding case studies, and updating progress updates. Such adjustments aim to ensure the efficient and smooth delivery of CERP Projects and foster sustained and steady advancement of CERP initiatives.

6.2 Information Sharing

Subject to the removal or protection of confidential and commercially sensitive information, aggregated or anonymized feedback related to pilot Ⅱ, experience accumulated by regulatory authorities during technical evaluations, and general experiences encountered by participating manufacturers in registration processes across different jurisdictions may be shared and disclosed to the public for transparency and capacity-building purposes.

Registration application documents submitted by manufacturers shall be shared among all participating regulatory authorities and shall be used exclusively for the purposes of this pilot.

6.3 Confidentiality

All non-public, proprietary, or commercially confidential information belonging to regulatory authorities or manufacturers shall be handled in accordance with applicable national laws and regulations and shall be treated as confidential.

Participating parties shall ensure that such information is protected against unauthorized disclosure throughout the duration of the pilot and thereafter, as required.

6.4 Publication of Pilot Documents

Meeting minutes, records and evaluation reports generated during the pilot may be published in document form, provided that confidential, proprietary, or commercially sensitive information is removed or appropriately protected, in accordance with applicable laws and regulations.

6.5 Project management

The Joint Evaluation Pilot shall be implemented on a project basis, and any regulatory authority that endorses this pilot framework may indicate its participation and consent through appropriate formal acknowledgment, in accordance with its internal governance and national regulatory procedures.