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WHO Regulatory Strengthening activities Good Regulatory Practice and Good Reliance Practice

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Outline

- **Regulatory strengthening activities**
  - ✓ GBT Plus
  - ✓ Regulatory harmonization, convergence and networking initiatives
- **Good Regulatory Practice**
- **Good Reliance Practice**
- **Conclusion**

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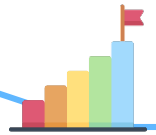
Resolution WHA 67:20

- **Adopted in May 2014**
  - ✓ Recognized the importance of strong regulatory systems to a well-functioning healthcare system and the attainment of health-related SDGs and UHC

WHO supports Member States in reaching and sustaining effective regulatory oversight of medical products through the regulatory systems strengthening (RSS) programme

Objectives of the RSS programme

- *Build capacity in Member States consistent with good regulatory practices*
- *Promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance*

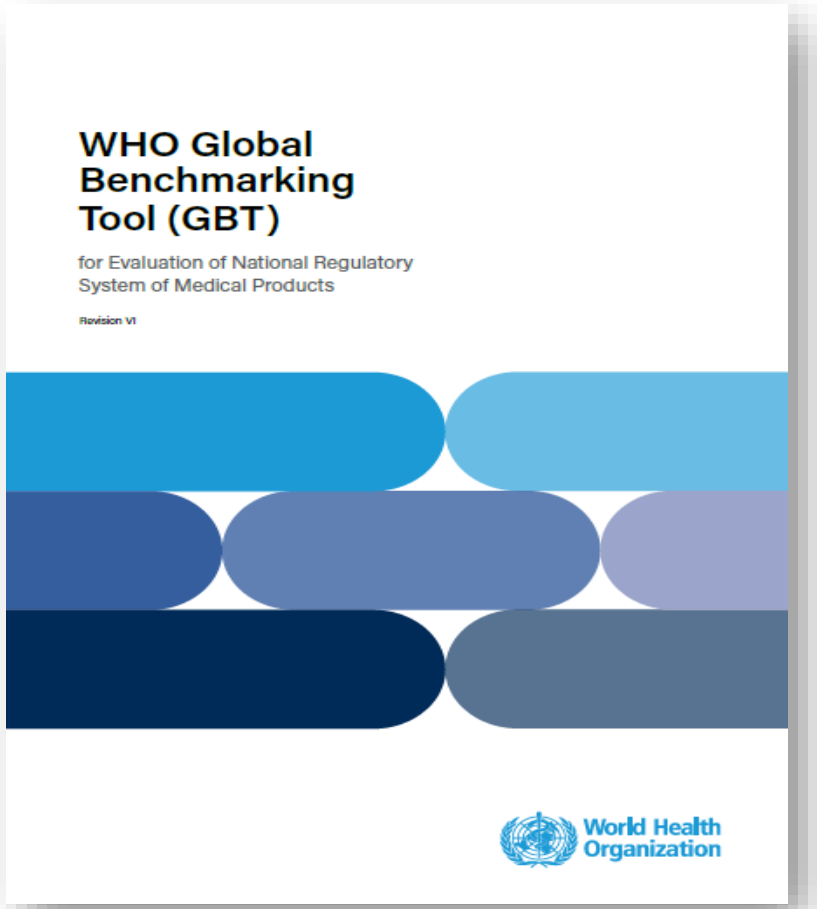


Ultimate goal

- ***Promote access to quality assured medical products***

WHO Global Benchmarking Tool (GBT)

primary means by which the WHO objectively evaluates regulatory systems for medical products



Link: https://apps.who.int/iris/handle/10665/341243

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- Blood (Nov 2019)
- **Medical Devices**
  - ✓ Revision 1 (Apr 2022)
  - ✓ Revision II (Dec 2024)- published

Link: https://www.who.int/tools/global-benchmarking-tools

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GBT+ MD Version 2 published in December 2024

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WHO Global Benchmarking Tool plus Medical Devices (GBT + Medical devices) for evaluation of National Regulatory system of medical products

Revision VI+MD version 2

3 December 2024 | Technical document

Download (5.7 MB)

Overview

The Global Benchmarking Tool Plus Medical Devices (GBT+MD) is an extension of the World Health Organization's GBT framework, designed to support the evaluation and strengthening of regulatory systems for medical devices. While sharing common regulatory principles with other medical products such as medicines, vaccines, and blood products, regulating medical devices presents unique challenges and opportunities that the GBT+MD addresses explicitly.

The WHO Global Benchmarking Tool Plus Medical Devices (GBT+MD) Revision VI+MD version 2, published in December 2024, is the latest release of the GBT for benchmarking medical devices' national regulatory systems. This release comprises six (6) regulatory functions under the overarching framework of the national regulatory system (RS). Additionally, the GBT+MD includes a detailed glossary and fact sheet to provide clarity on key terms and definitions.

Currently, the GBT+MD is available in English. Work is underway to translate the GBT+MD into other official languages of the United Nations (UN).

WHO Global Benchmarking Tool plus Medical Devices (GBT + Medical devices) for evaluation of National Regulatory system of medical products

Support| global and regional harmonization initiatives

- **Global**
  - International Medical Device Regulators Forum (IMDRF)
- **Regional**
  1. Africa Medical Devices Forum (AMDF)
     - Including Medical Devices Assessment Technical Committee
  2. Asia Pacific Economic Coo-peration (APEC)
  3. Global Harmonization Working Party (GHWP)
  4. South East Asia Regulatory Network (SEARN)

Promoting | Regulatory work-sharing and reliance

Good Regulatory Practice

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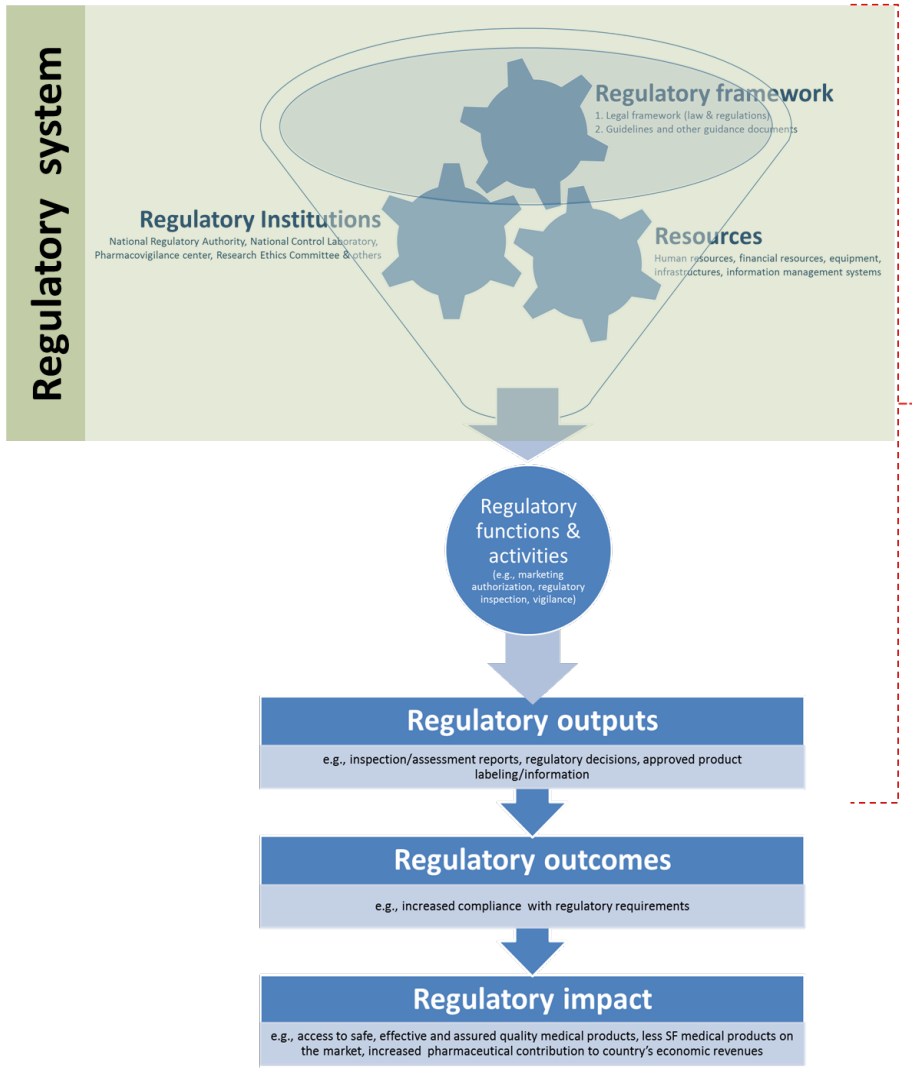
Good Regulatory Practice (GRP)

Stable regulatory systems requires three things Framework, Institution and resources to effectively conduct regulatory functions/activities to get required Regulatory Impact
Well establishment regulatory system is supported by GRP principles and enablers without these regulatory system is weak



GRP Enablers

- Political and government support
- Good organization, governance and leadership
- Effective communication, collaboration & coordination
- Robust and well-functioning Quality Management System
- Sufficient and sustainable financial resources
- Competent human resources
- Pre-set Organizational ethics and values
- Science and data driven regulatory decision making process

GRP principles

- Legality
- Consistency
- Independence
- Impartiality
- Proportionality
- Flexibility
- Clarity
- Efficiency
- Transparency

Principles and enablers of Good Regulatory Practices (GRP) and Components of the regulatory system

WHO Good regulatory practices in the regulation of medical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations: Fifty-fifth report. Technical Report Series, No. 1033, Annex 11; 2021. Link: https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

Take away messages on GRP

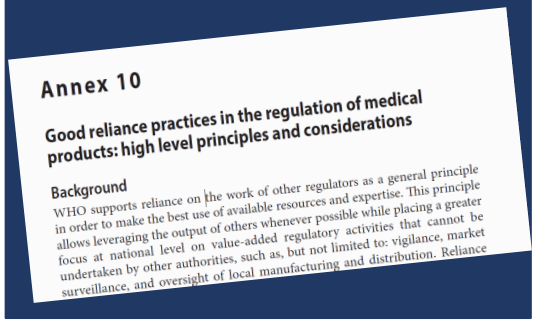
- GRP principles serve as **benchmarks (development, Implementation and review of regulatory instruments**
- Applied in the **whole** regulatory system.
- Guide Member States in **prioritizing** their regulatory activities according to: resources, national goals, public health policies, medical products policies and the medical product environment.
- If GRP principles are implemented **consistently and effectively**, they can result in higher quality regulations, better regulatory decision making, compliance, more efficient regulatory system and better public health outcomes.
- Setting up **requirements and formulating decisions** based on the Principles will help in manufacture, import and distribute quality assured products.

Good Reliance Practice

WHO Good Reliance Practices (GRel)

When timely access to quality-assured products is compromised…

GRel, as a solution for NRAs and public health



Annex 10

Good reliance practices in the regulation of medical products: high level principles and considerations

Background

WHO supports reliance on the work of other regulators as a general principle in order to make the best use of available resources and expertise. This principle allows leveraging the output of others whenever possible while placing a greater focus at national level on value-added regulatory activities that cannot be undertaken by other authorities, such as, but not limited to: vigilance, market surveillance, and oversight of local manufacturing and distribution. Reliance

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NRAs carry great responsibilities in ensuring <u>timely access to quality assured products to their population</u>

Internal factors: low maturity of many regulatory systems, lack of resources and expertise in-house, and ack of collaboration between countries

External factors: increasing complexity of supply chains and global challenges, such as health emergencies

- Overwhelm NRAs - lengthy regulatory approvals of much needed medical products
- Patients' timely access to much-needed quality-assured medicines is compromised

Reliance is meant to facilitate and accelerate the regulatory decisions and the introduction of quality-assured products in countries, through the use of the concepts of reliance and collaboration. When well implemented:

- *NRAs leverage on the work performed by others, improving efficiency of the regulatory systems by avoiding duplication of regulatory efforts and work*
- *NRAs optimize the use of human and financial resources and increase expertise and build capacities*
- *NRAs reduce the time nedeed to process a product application and reduce workload and backlog at NRAs*
- *NRAs perform science-based and transparent regulatory decision-making, while maintaining national independence on their decisions*
- *NRAs ensure timely access to priority quality-assured products in countries.*

Adopted by WHO Expert Committee on Specification for Pharmaceutical Products in October 2020, published in March 2021 https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

WHO collaborative registration procedure for IVDs- Overview

CRP for IVDs

Accelerate the registration and availability of WHO prequalified in vitro diagnostics (IVDs) in countries

Involved parties:

- *WHO, the manufacturer/applicants, and participating NRAs*
- *Facilitates information sharing while respecting regulatory autonomy*

How it works

- ✓ *Involves WHO-prequalified IVDs*
- ✓ ***Manufacturer Consent**: The manufacturer submits consent for WHO to share its full assessment. performance and inspection reports with NRAs*
- ✓ ***Information Sharing:** WHO shares comprehensive reports with NRAs*
- ✓ ***Streamlined Registration:** NRAs use WHO reports to expedite their own review and registration process*
- ✓ ***Outcome:** Faster regulatory approval and access to quality-assured IVDs*

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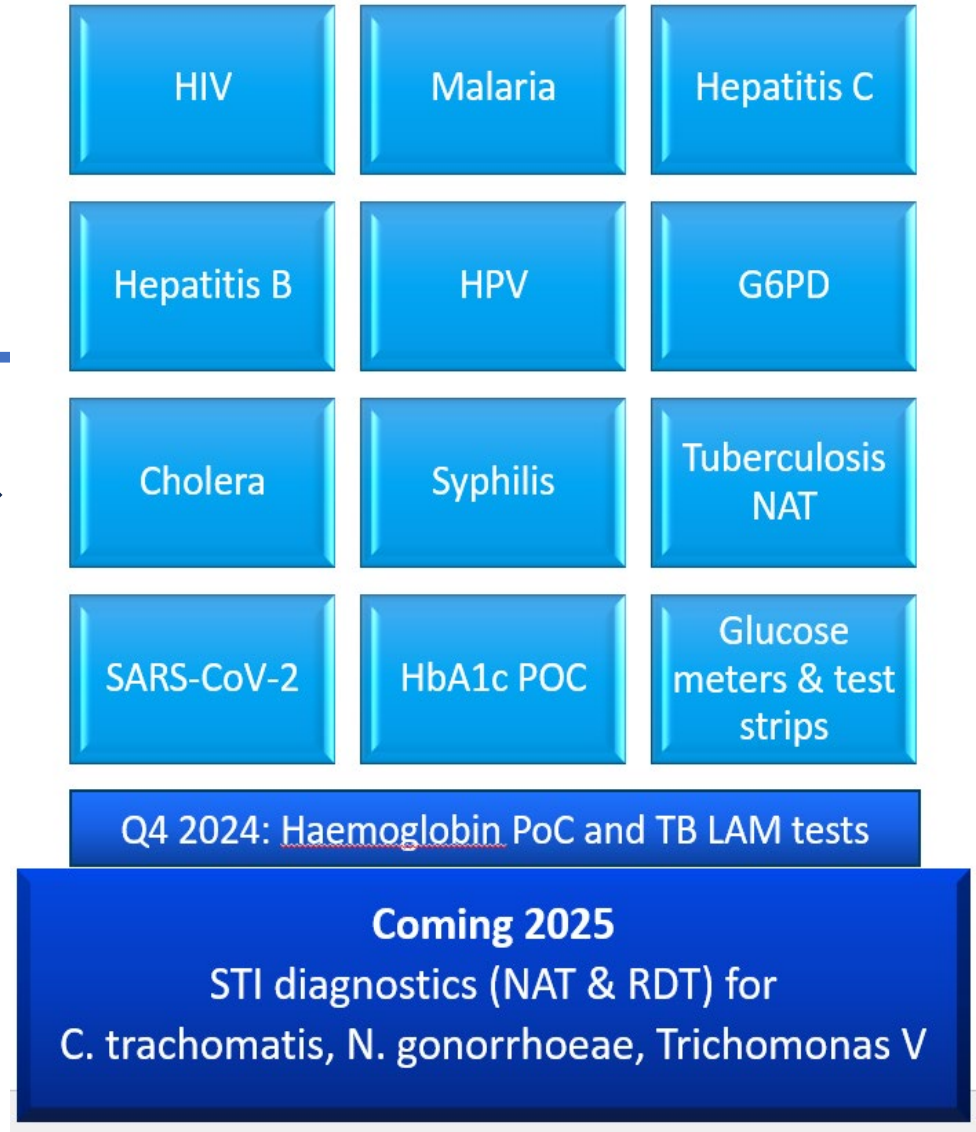
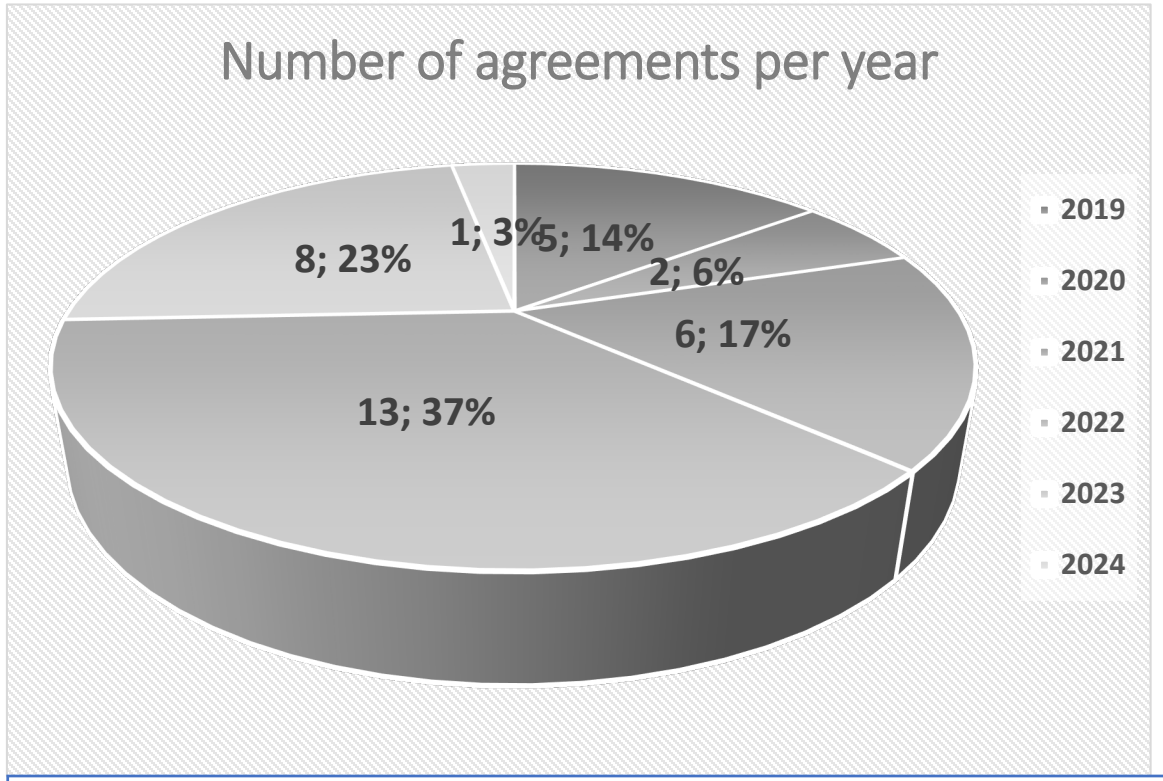
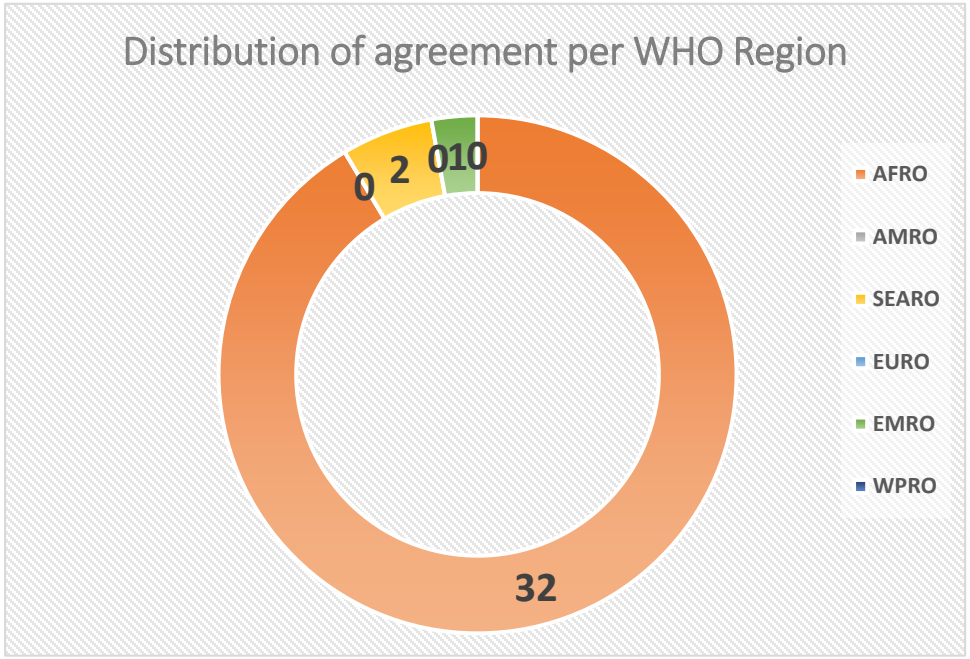


WHO CRP IVDs progress and achievements: Participation agreements



- Agreements from 2022-2023: Increase in number of agreements from ***2 in 2020*** (roll out of CRP) to ***13 in 2023.***
- New advocacy strategy and NRAs engagement approach **+** experience of use of reliance by countries during COVID-19 pandemics.
- In 2024 : *less agreements-shift of focus to product registration.*



- 35 agreements, AFRO participation is ***91%*** showing strong engagement/interest.
- Moderate engagement in SEARO and EMRO
- No participation in AMRO, EURO, WPRO regions indicating potential for increased involvement

- ***More balanced participation among all regions to enhance global access to quality – assured IVDs***
- ***2024: 38 products registered, median = 81 working days***

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Reliance in facilitating national regulatory decisions…summary

- Provided there is evidence of product's quality, safety and performance

- Implemented through WHO Collaborative Registration Procedure (CRP)
  - ✓**Scope:** medicines, vaccines, **in-vitro diagnostics (IVDs)** & vector control products
  - ✓35 regulatory authorities signed to CRP IVDs, launched in 2020
    - In 2024, 38 products registered through CRP with average time of **81 working days** (target 90 days!)

- WHO CRP annual meetings, a unique platform for advocacy and addressing challenges
  - ✓12-14 Nov 2024, Jakarta, Indonesia

- Useful tools for implementing CRP for medical products
  - ✓WHO guidelines on CRP for IVDs, TRS 1030, 2021 (Annex 4)
  - ✓WHO Good Practices of NRAs in implementing CRP for medical products
    - **Revised to include IVDs - to be published in 2025**

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… in conclusion

Rollout of GBT+MD will transform regulatory landscape for medical devices…….along with implementation of the principles of WHO GMRF

Regulatory co-operation, networking, work-sharing and reliance remain a priority for the WHO

Alignment and ***harmonization*** *of 'regulatory harmonization* initiatives' to minimize duplication

Revision of WLA Policy to expand scope to integrate MDs, including IVDs…….**building on the lessons from the use of the GBT+MD**

Thank you for your attention!

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