Post Market Surveillance of Medical Devices and IVDs

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Why?

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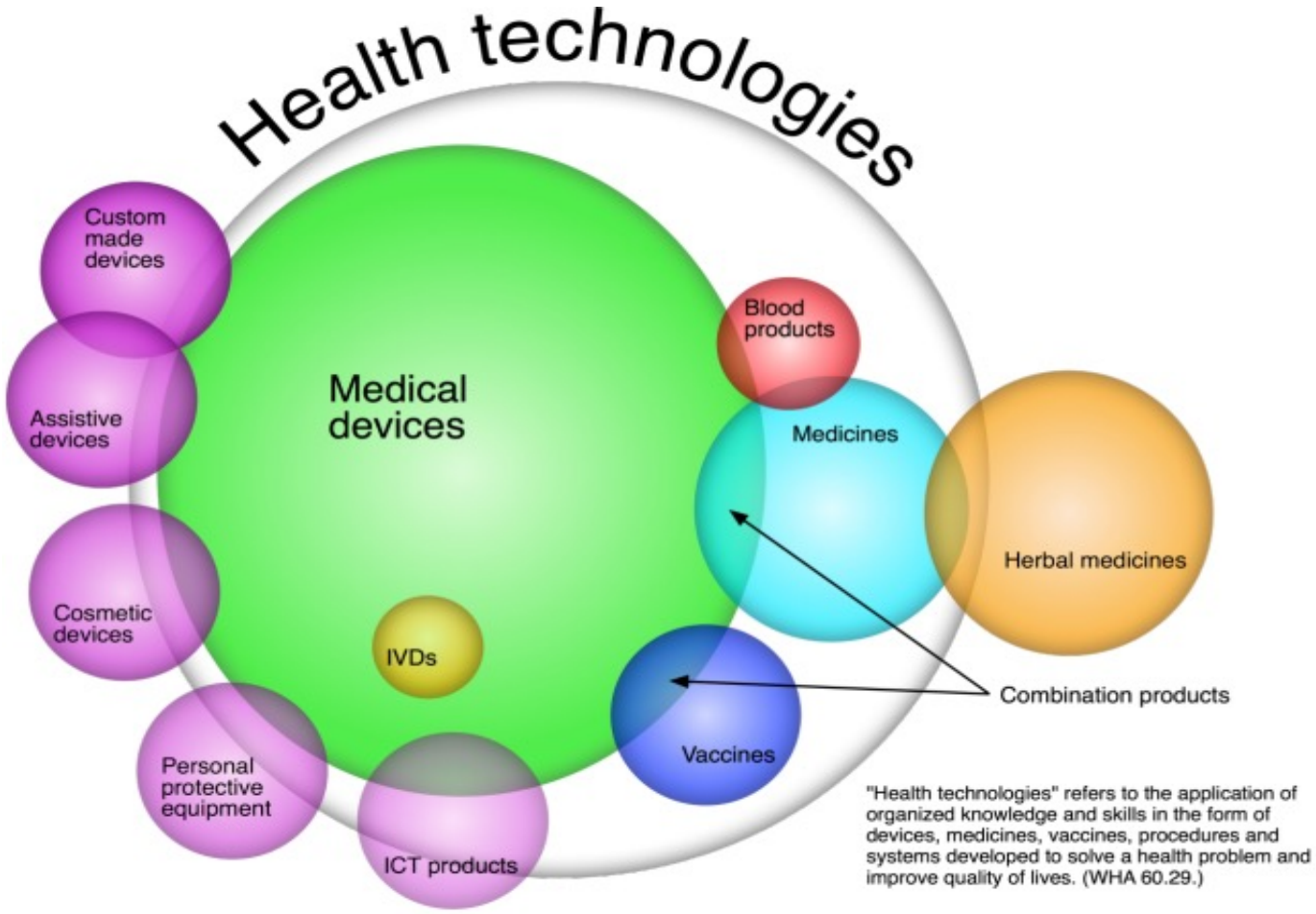
Why?

Source: ICIJ 2018 https://www.icij.org/investigations/implant-files/

Why?



ICT, information and communications technology; IVDs, in vitro diagnostic medical devices.

Source: WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.

WHO **Guidance for post-market surveillance** and market surveillance of medical devices, including in vitro diagnostics

- Covers all medical devices, including IVDs, without prejudice to national legislation
- Describes
  - **Post-market surveillance** activities for manufacturers
  - **Feedback** procedure for users (rather than just complaints)
  - **Market surveillance** activities for regulators
- Reflects new international standards/guidance
  - ISO/TR 20416:2020 Medical devices — Post-market surveillance for manufacturers
  - IMDRF/AE WG/N43 Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes

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WHO **Guidance for post-market surveillance** and market surveillance of medical devices, including in vitro diagnostics

Post-market surveillance

The **systematic process** [carried out by **manufacturers**] to **collect and analyse experience** gained from medical devices that have been placed on the market.

Market surveillance

The activities carried out and measures taken by competent **authorities** (regulatory authorities) to check and ensure that devices **comply with the requirements** set out in the relevant legislation and **do not endanger** health, safety or any other aspect of public interest protection.

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WHO **Guidance for post-market surveillance** and market surveillance of medical devices, including in vitro diagnostics

Obligations for other economic operators

A **manufacturer**, an authorized representative, an **importer**, a **distributor** or the **person**

- **combining different medical devices** into one pack
- or **sterilizing** a system or procedure pack

with the intent to place them on the market

Revised criteria and timelines for manufacturers to report to NRAs*

What to report	Time to report to NRA
Serious public health threat	Immediately but no later than 48 hours
Death, serious deterioration in state of health of patient, user or other person occurred	As soon as possible but no later than 10 calendar days
Death, serious deterioration in state of health of patient, user or other person might have occurred	As soon as possible but no later than 30 calendar days

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*without prejudice to national legislation

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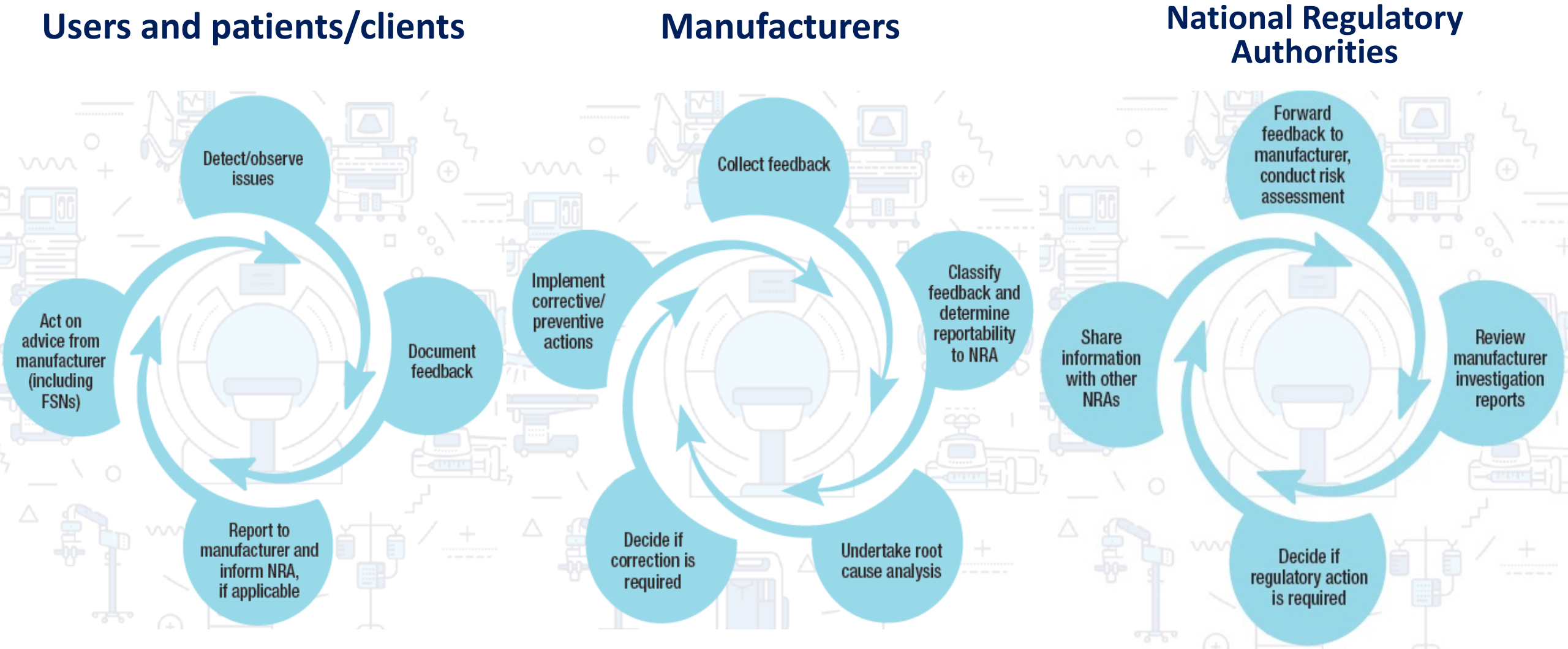
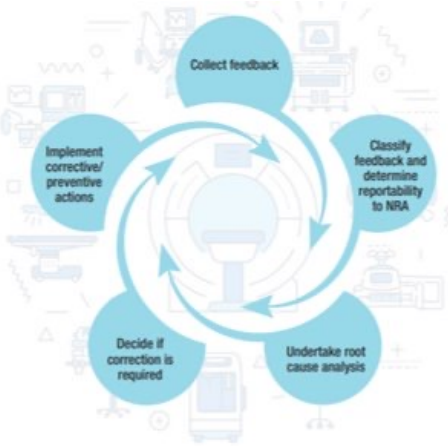


Post-market surveillance expectations of manufacturers **post-market surveillance**



- **Collect and analyze experiences** with a product on the market
  - **Classification**: IMDRF terminology
- Manufacturers should have a PMS plan to:
  - Consider all **user feedback** (complaints, technical support callouts, maintenance, e
  - Review **scientific literature** and other information sources
  - Review **production** records,
  - Conduct **post-market performance follow-up**
  - Etc.
- Determine if an incident/event is **reportable to any regulator**
- Undertake a **root cause analysis**
- Decide on any **correction** (repair, modification, adjustment, relabelling, destruction or inspection (including patient monitoring) of a product without its physical removal to some other location); and/or
- Decide on any **corrective or preventive action** (to eliminate the cause of detected nonconformity or undesirable situation or identify opportunities for improvement before a problem is identified)

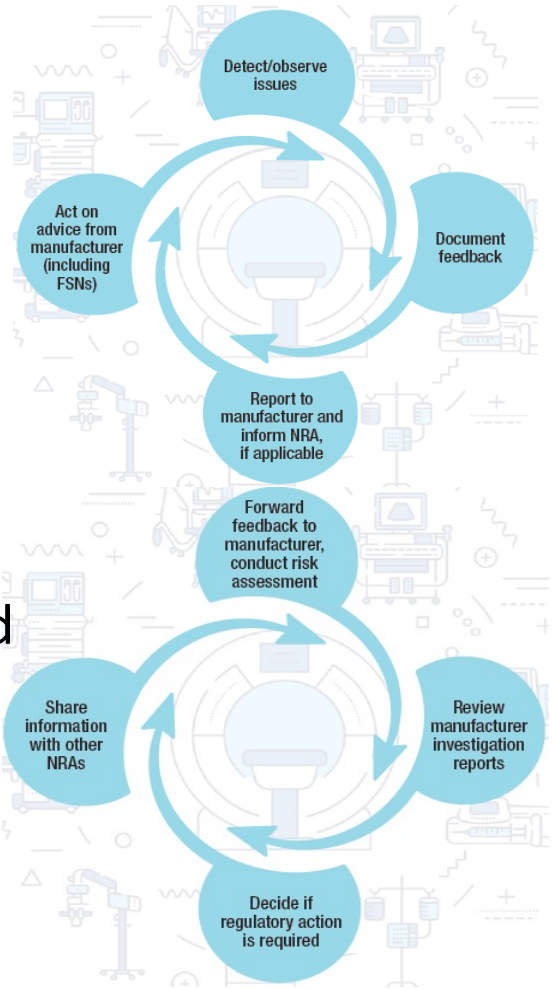
Contributions from **regulators** and **users** to manufacturers's post-market surveillance

Device Users

- Detect issues related to devices
- Document feedback (Incident reports, complaints, technical support callouts, maintenance, etc.)
- Report feedback to manufacturer immediately
- Act on advice of manufacturer

Regulators

- Review manufacturer investigation reports
- Review manufacturer field safety corrective actions
- Oversee testing
- Decide if regulatory action is needed
- **Forward user feedback to manufacturer**
- **Share information with other NRAs**
- Public repository of field safety notices



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Going further

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Risk-based approach: reflecting on the specificities of some devices

- **Risks of IVDs?**
  - **Direct harm** to user
    - E.g. Infection or lesion from the sample collection instrument
  - **Material integrity problem**
    - E.g. broken, cracked, damaged elements which may lead to further risks
  - **Use errors**
    - E.g. inadequate or unclear instructions for use
  - **Performance**
    - E.g. false negative, false positive, inaccurate results

- **Risks of Assistive products?**
  - primary purpose: maintain or improve individual's **functioning and independence**
    - E.g. spectacles, artificial limbs, wheelchairs
  - **'Low' risk. But**:
    - Used by vulnerable populations
    - Often locally produced
    - => considered? Reporting encouraged?

Role of WHO

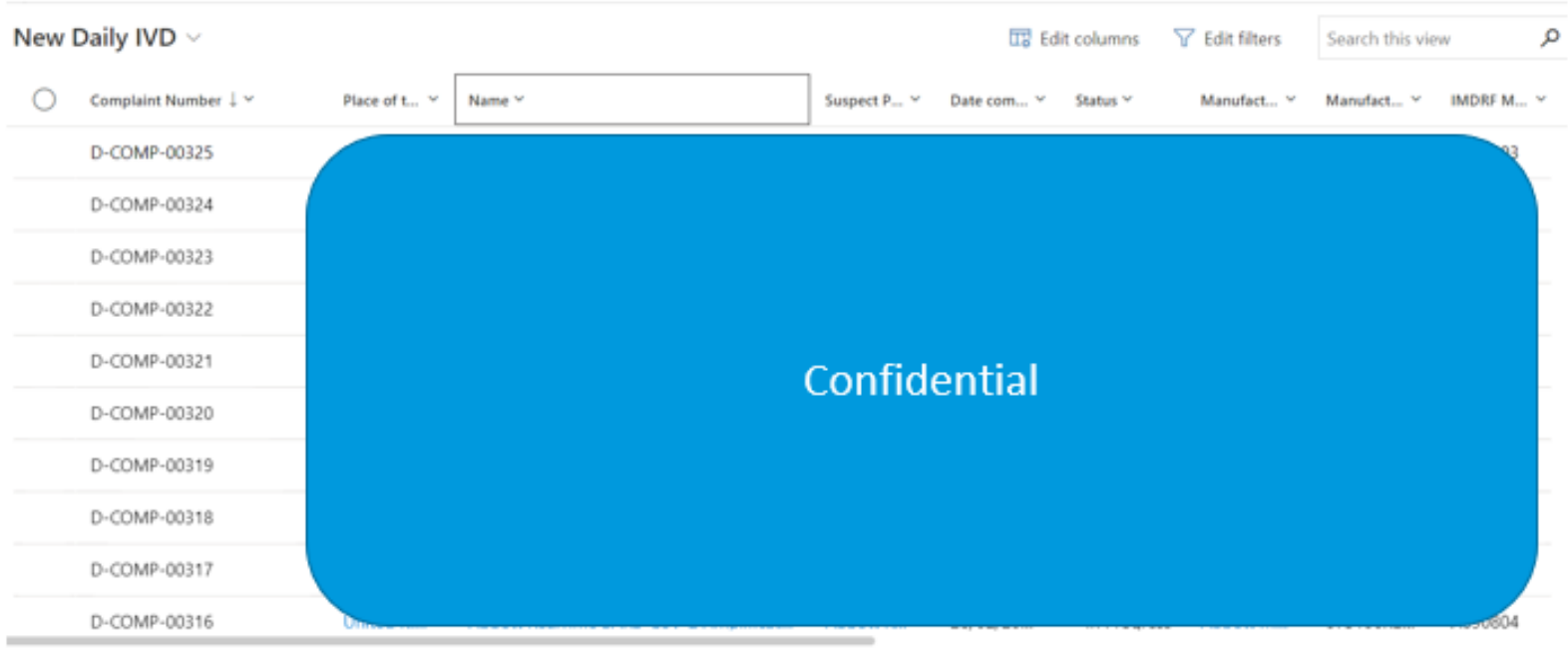
- WHO accepts any user feedback and forwards to manufacturer
- Manufacturers of any WHO-listed IVDs (PQ, EUL) must fulfill certain reporting requirements, outlined in Part IV
  - WHO receives and reviews
    - manufacturer investigation reports
    - field safety corrective action reports
  - Follow-up reports expected no later than 15 calendar days after the initial investigation report is sent or after the previous follow-up report
  - Periodic summary reports each year reviewed annually

WHO Information notice for users and field safety notices

Click here

Global Surveillance and Monitoring System for substandard/falsified medical products

- Developed for medicines and vaccines and IVDs (any interest for medical devices?)
- Example of back-end



- WHO Member State mechanism on substandard/falsified medical products
- Management of incidents related to IVDs with PQ or EUL or otherwise recommended for procurement by WHO
- Uses IMDRF coding for adverse event reporting

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Traceability of medical devices

- Available in all 6 UN languages
- Mainly written for medicines and vaccines, but principles are applicable to medical devices.
- Landscaping the varying states of implementation of national traceability systems is on-going.

- "*Globally accepted ISO/IEC coding standards implemented by global organizations, such as GS1, HIBCC and ICCBBA, meet the criteria of the UDI and manufacturers shall be permitted to choose which system to use. These organizations have responsibility for maintaining the global uniqueness of their coding systems.*"

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Strengthening the overall regulatory system

Global Benchmarking Tool + medical devices

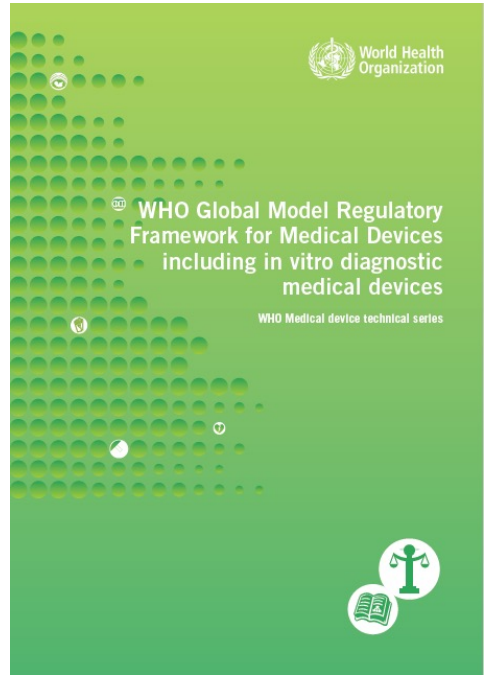
- self-assessment
- evaluation

https://www.who.int/tools/global-benchmarking-tools/evaluation-of-national-regulatory-systems-of-medical-devices-in-vitro-diagnostics

WHO Global Model Regulatory Framework for Medical Devices including IVD

- Under revision
- **Risk-based**

Link



Good regulatory practices in the regulation of medical products (link)

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

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Terima kasih 🙏

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