Post-market surveillance of medical devices including IVDs

WHO support to Member States

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What does WHO normative guidance cover?

- All medical devices, including IVDs
  - Without prejudice to national legislation
- Describes
  - **Post-market surveillance** activities for manufacturers
  - **Feedback** procedure for users
  - **Market surveillance** activities for regulators
- Specific considerations for WHO-recommended IVDs (PQ, EUL, etc.)
- Multilingual (6 UN languages)

https://www.who.int/health-topics/substandard-and-falsified-medical-products#tab=tab_1

Link to document here

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What is new?

- Reflects new international standards/guidance
  - ISO/TR 20416:2020
  - IMDRF/AE WG/N43
- Expansion to all medical devices
- Obligations for other economic operators
- Revised criteria and timelines for manufacturers to report to NRAs, without prejudice to national legislation

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

- Terminology clarity/shifts
  - "Post-market surveillance" for manufacturers
  - "Market surveillance" for NRAs
  - "User feedback" rather than "complaint"

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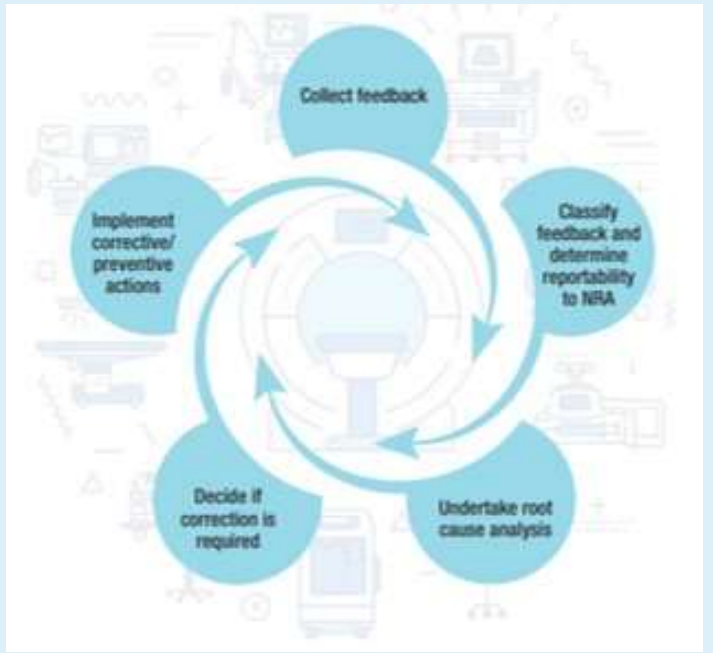
Post-market surveillance expectations of manufacturers

- Post-market surveillance - is the process conducted by the **manufacturer** to **collect and analyze experiences** with a product on the market.
- Manufacturers should have a PMS plan to:
  - Consider all **user feedback** (complaints, technical support callouts, maintenance, etc.)
  - 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)



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Other stakeholder's contributions to post-market surveillance

Regulators

- Forwards user feedback to manufacturer
- Reviews manufacturer investigation reports
- Reviews manufacturer field safety corrective actions
- Oversees testing
- Decides if regulatory action is needed
- Shares information with other NRAs
    - Public repository of field safety notices

Device users

- Detects issues related to devices
- Documents feedback
- Reports feedback to manufacturer immediately
- Acts on advice of manufacturer

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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

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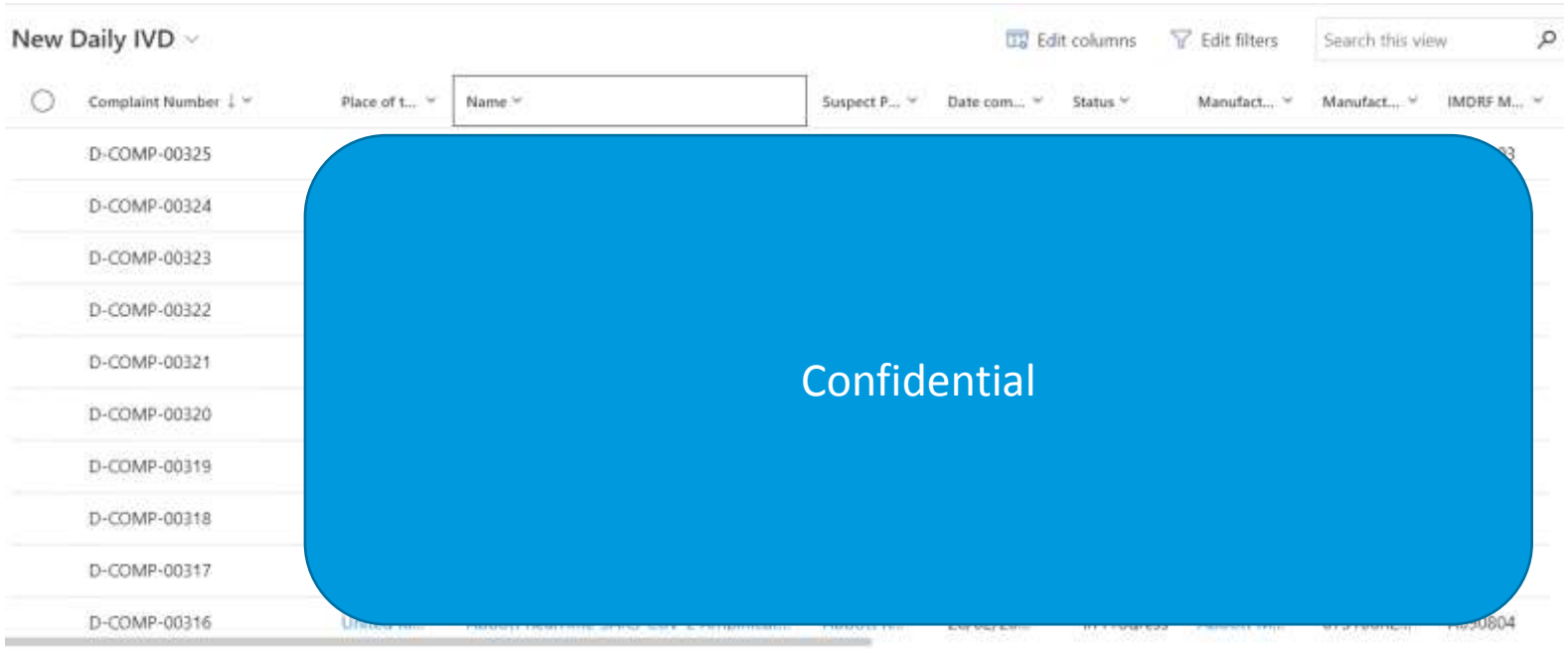
Global Surveillance and Monitoring System for substandard/falsified medical products

- 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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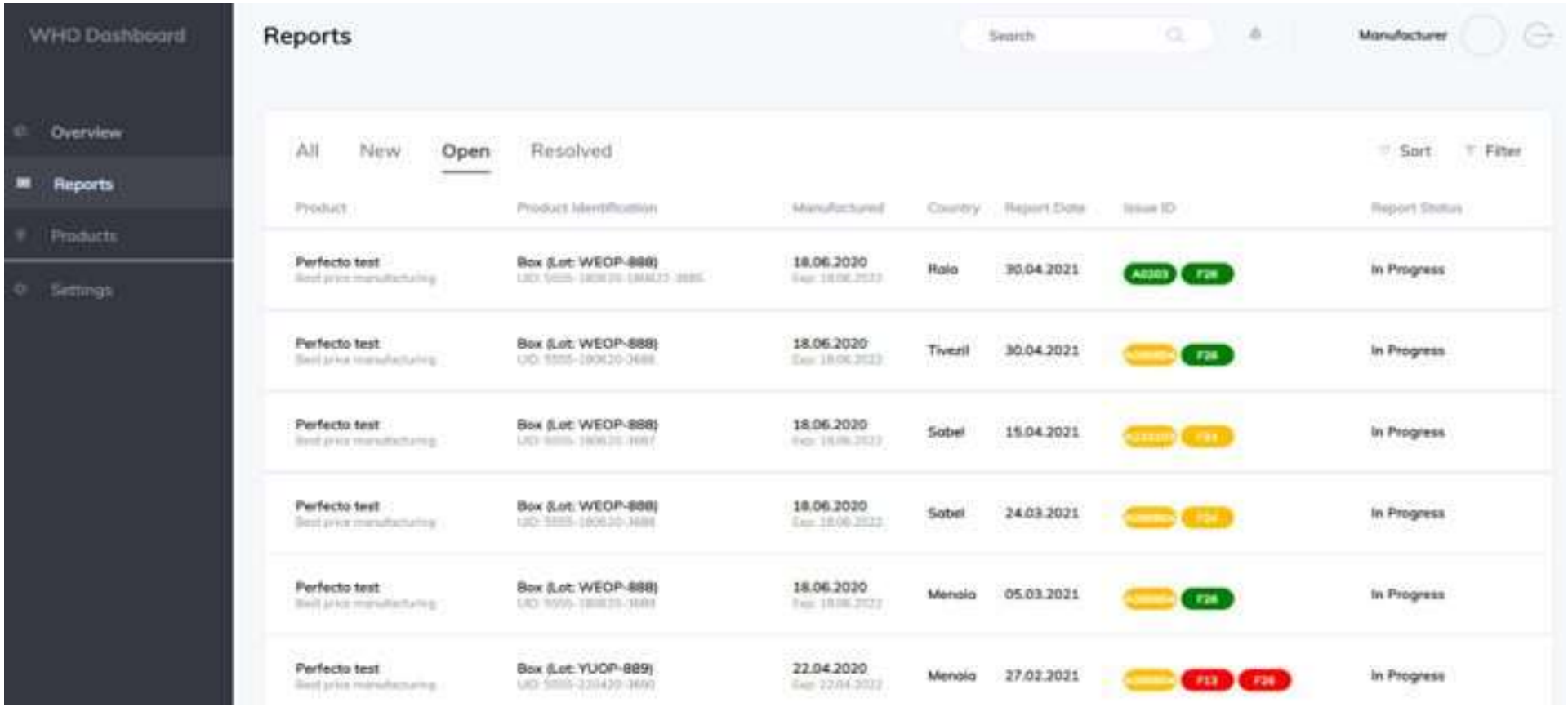
WHO Innovation Challenge: Enhancing feedback on quality and safety of IVDs

- Prototype of application to collect user feedback and to authenticate device to detect falsified or substandard devices
- Dashboards to monitor feedback and to submit incident reports
- IMDRF coding



https://ivd.void.pt/

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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Suggestions for implementation

- Implement the following processes and procedures:
    1. Users to report issues with medical devices for Cervical Cancer related devices to manufacturers.
    2. Manufacturers (or their local authorized representatives) to report IVD incidents to respective NRAs.
    3. Manufacturers (or their local authorized representatives) to report FSCA for IVDs to respective NRAs.
    4. NRA report incidents and FSCA for IVDs to WHO Global Surveillance and Monitoring System for substandard/falsified medical products (GSMS).
- Global Benchmarking Tool + medical devices self-assessment and/or evaluation

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

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Thank you

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