



Bundesamt für Sicherheit im Gesundheitswesen **BASG**

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NCA (human) Data Quality activities and uses of ADR data

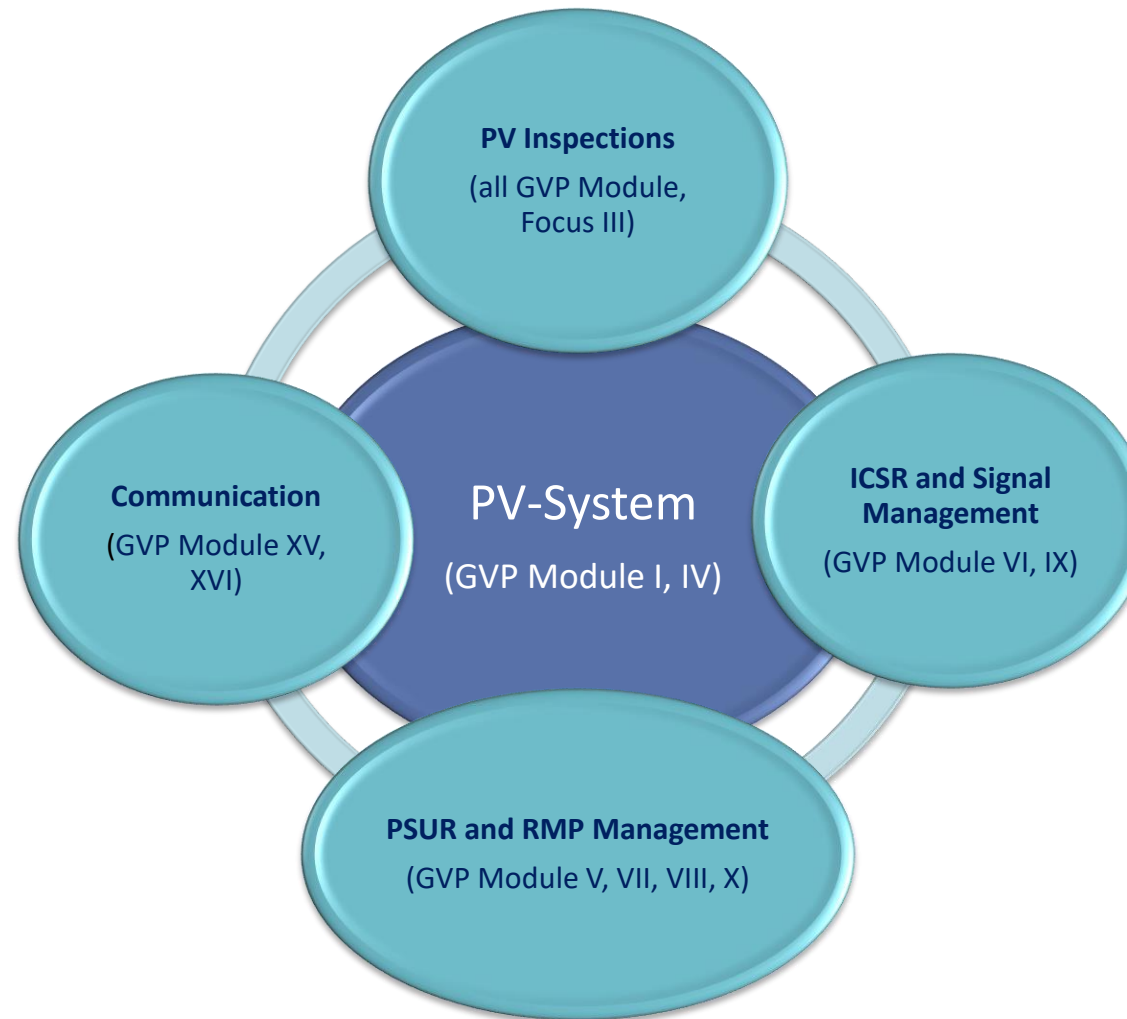
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Scope

- PV-activities – how ADR data are used
- Data Quality activities
- Commonly identified issues

Pharmacovigilance System @NCA



How NCA use ADR data

Routine PV activities

Data collection and reporting to EV

Monitoring of the national ADRs

- Signal management
- Benefit/Risk evaluation
- Other (Statistics, Political Inquiries, etc...)

Signal detection in EV

How NCA use ADR data

Data quality activities

Case processing →
duplicate check, QC, FU

Data Quality Issues
identified during the
monitoring of ADRs

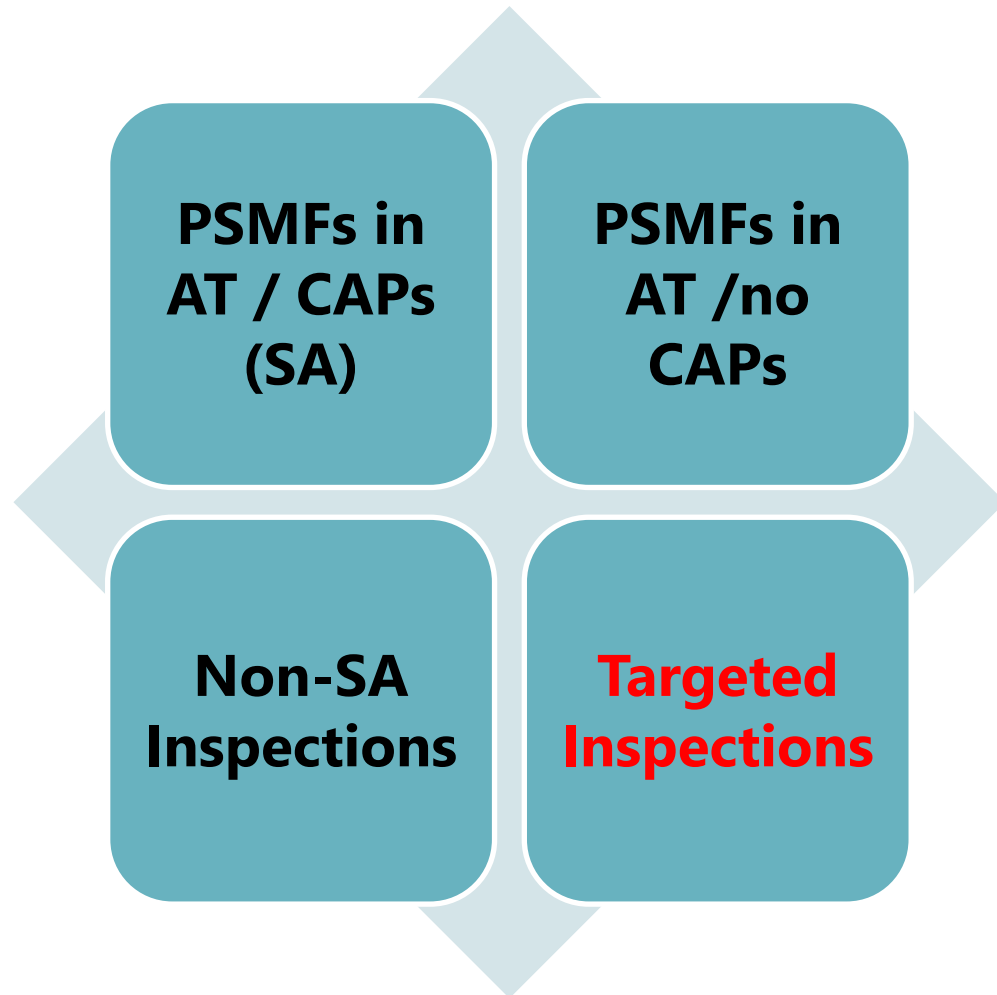
Quality check at the MAH level
→ GVP/GCP Inspections

Quality issues – signal management

- Very few well documented cases → index cases for signal validation
- Noise:
 - Duplicates, retransmission of cases without additional data
 - Overreported cases
 - Non-relevant information
- Data not coded in the structured fields
- Data coded incorrectly
- Literature cases without the reference
- ...

PV Inspections

National PV-inspection programme

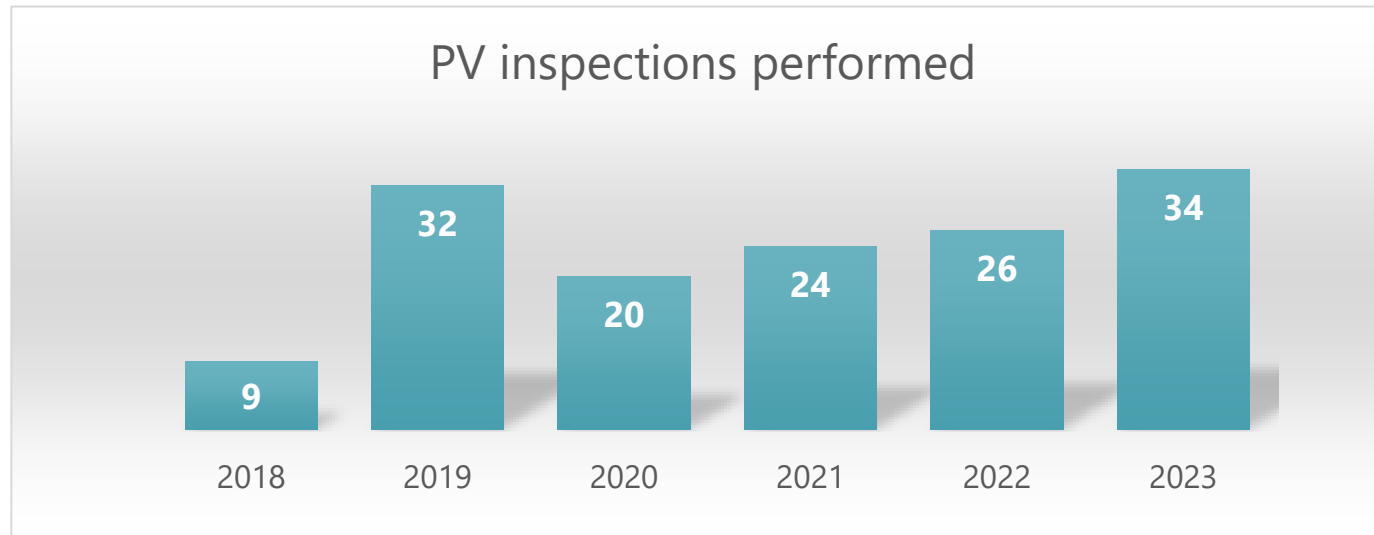


- Signals from the assessors/other inspectorates /EMA can trigger an Inspection or shift focus

PV Inspections

Statistics

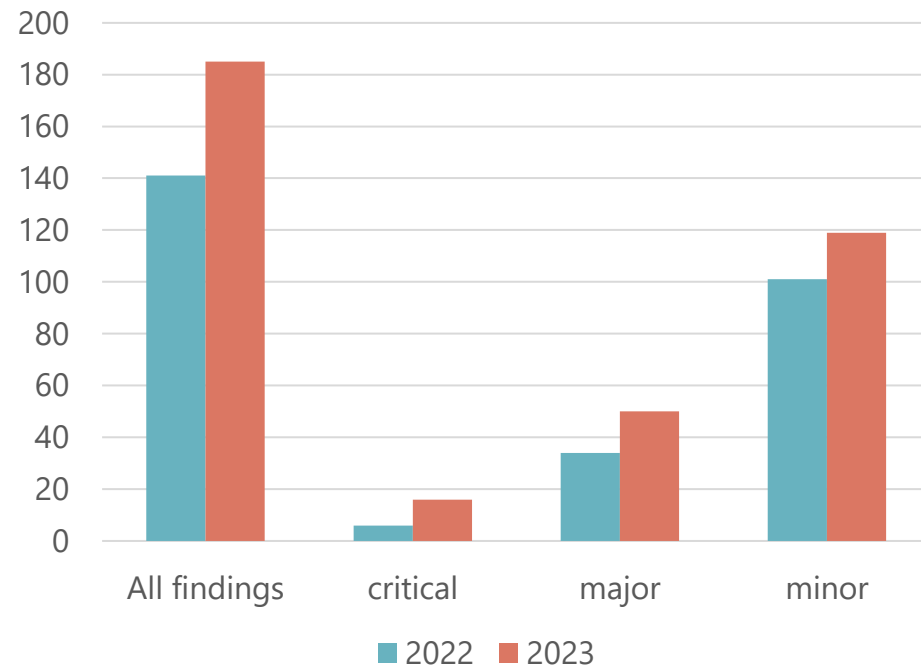
- PV inspection-landscape in Austria:
 - Human: >200 PV Systems, **70+ PSMF in AT, 5 with CAPs (AT is supervisory authority)**
 - (Vet: ~20 PV Systems, **1 with CAPs**)



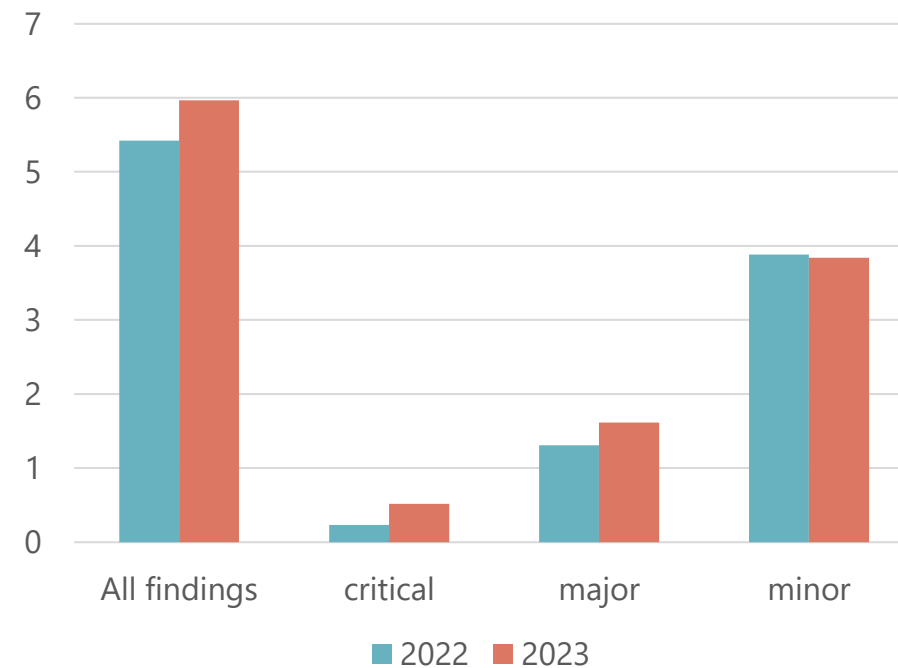
PV Inspections

Statistics -findings

Finding statistics

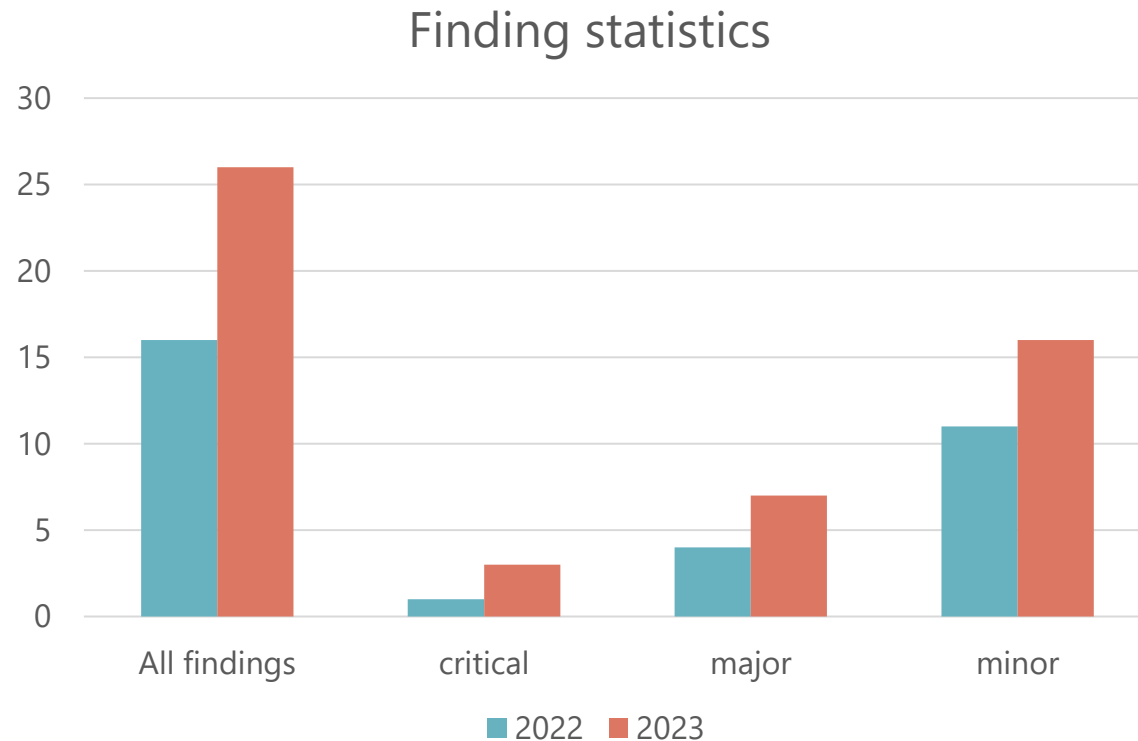


Findings/PV Inspection



PV Inspections

Statistics - ADR Data Quality-related Findings



PV Inspections

What is inspected

- Processes, responsibilities and adequate training
- LL review
- Demo of the cases in the database
- Full case documentation review (check of the data in the case vs source documents)
- FU process and documentation (incl. TFUQ)
- Data integrity and access control

PV Inspections

Common Data Quality – related findings

- Overreporting
 - pregnancy, off-label, death, drug intolerance, not related cases
- Underreporting
- Duplicate check ineffective
- Translation issues → automatic, no QC (can lead to underreporting)
- FU insufficient/inadequate
 - TFUQ overloaded, FU in English only, non-specific FU, no FU of literature cases, no contact consent

PV Inspections

Common Data Quality – related findings

- Seriousness assessment
- Third country cases/partner cases not reevaluated
- Seriousness assessment
- Coding issues
 - Incorrect coding of the events
 - Incorrect coding of the outcome (f.e. death recovered/resolved)
 - Indication or medical history coded as event
 - ...
- Other issues – f.e. Changing WWID

Thank you for your
attention!



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