Impact of the COVID-19 pandemic on inspection activities

FAMHP Vaccine symposium

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PhVig inspections - General

Goals of a pharmacovigilance (PhVig) inspection

- Ensure that a marketing authorisation holder (MAH) has a PhVig system in accordance with the current legislation
- To ensure that requirements for monitoring the safety of medicines are met

National (FAMHP) and international (EMA)

- Risk-based inspection planning
- For cause/triggered inspections

Location

- At marketing authorisation holder sites
- Hospital sites (post authorisation safety studies)

PhVig inspection team: during COVID-19 health crisis (1)

- No site and hospital inspections
- Inspection team involved in other COVID-19-related tasks
- Focus on triggered PhVig inspection (vaccine and non-vaccine related)

Triggered inspections

Request from national authority (inspectors or assessors)/EMA

- Poor quality of provided data in safety report
- Important delays in adverse drug reaction (ADR) reporting
- concerns about the status or fulfilment of risk management plan (RMP) commitment

PhVig inspection team: during COVID-19 health crisis (2)

MAHs of COVID-19 vaccines with PhVig headquarter in Belgium

- Administrative monthly review of MAH's ability to manage ADR processing in a timely manner
- Triggered inspections (vaccine and non-vaccine related medicines – monitoring safety profile of ALL medicines)
- First pre-authorisation PhVig inspection performed in EU by Belgian inspection team
  - E.g. when MAH has not previously operated a PhVig system in the EU and knowledge previous significant safety information on similar medicines
  - Examining the MAH's ability:
    - to manage pharmacovigilance activities
    - meet specific safety conditions

GMP inspection mechanisms (1)

National level

Possible goals of an inspection

- New site/new certification
- New application
- Change in site/certification
- Extension of a certification
- Change in an application
- Certification renewal
- Complain
- Recall
- Enquiry from an authority

GMP inspection mechanisms (2)

National level

Triggers

- Introduction of a dossier by an applicant (licence of marketing authorisation)

- National routine planning (certification renewal) = FAMHP

  ➔ clear signal: we are present

- Registration authorities: EMA, FAMHP, other agency

GMP inspection mechanisms (3)

International level

Possible goals of an inspection

- New application
- Addition of a new site in an application
- Addition of a site by modification of a known site (change in its certification)
- Change in an application (on the process into an authorised site)
- Certification renewal
- Complaint
- Recall
- Enquiry by an authority

GMP inspection mechanisms (4)

International level

Triggers

- Introduction of a dossier by an applicant
- National routine planning (certification renewal) = FAMHP
- Registration authorities: EMA/FAMHP
- EU Commission
- Others: EDQM
- Because our agency is the guardianship agency of many BR sites for EU market.

GCP inspection mechanisms (1)

Possible goals of an inspection

Why?

- Risk based planning
- Campaign
- Question about a dossier during the submission
- Complains

Where?

- PI
  - Hospital and private practices
  - Research centres
- Sponsor
- CRO
- CE

GCP inspection mechanisms (2)

Triggers

National level

- National risk based planning = FAMHP
- Registration authorities: EMA and FAMHP
- Complaints

International level

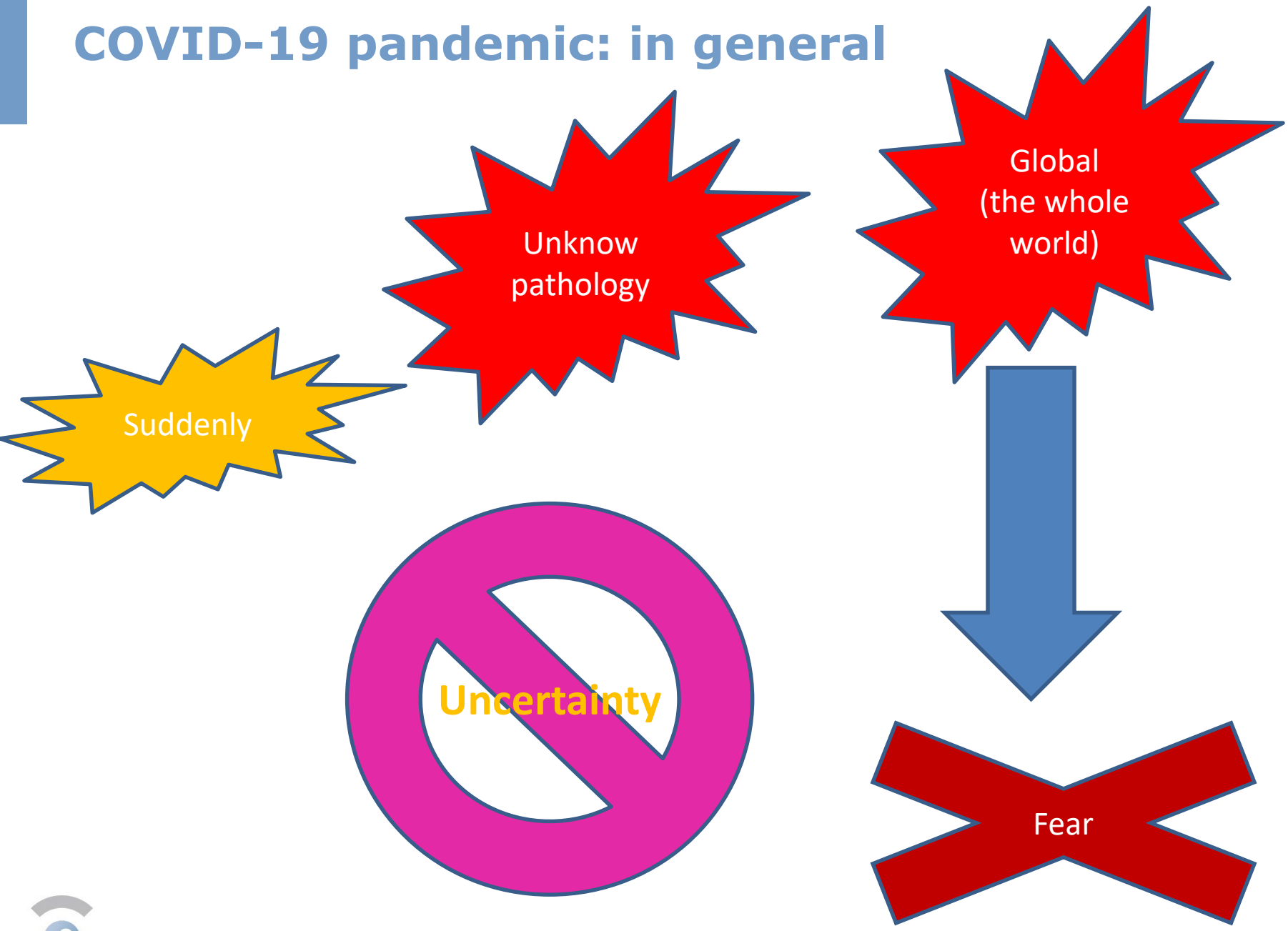
- Registration authorities: EMA and FAMHP

GMP/GCP inspection characteristics

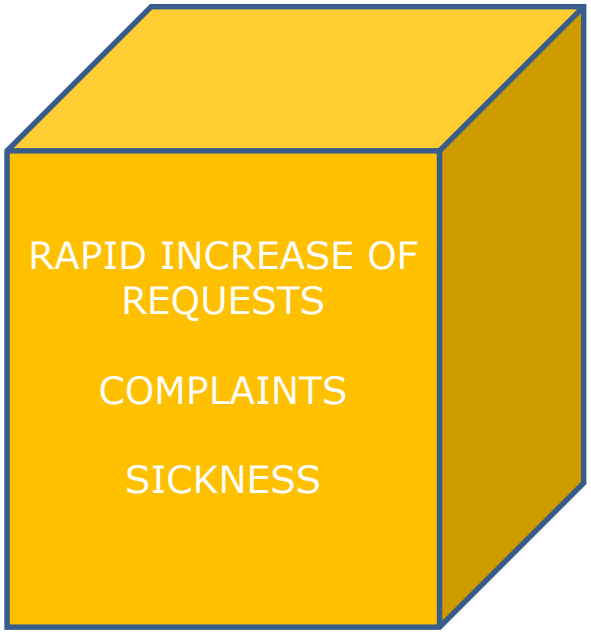
Process

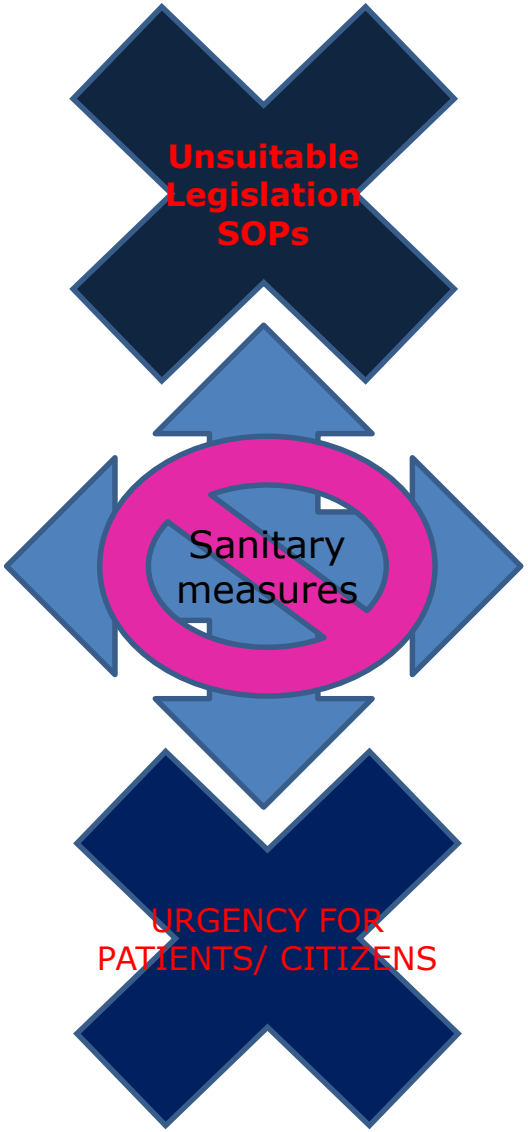
- Selection/planification of the site/the actor
- Preparation
- Execution: **research on the field**
  - observation
  - examination
  - question and answers
- Report
- Following

COVID-19 pandemic: in general



COVID-19 pandemic: for inspections





Specifics for GCP inspections (1)

Difficulties

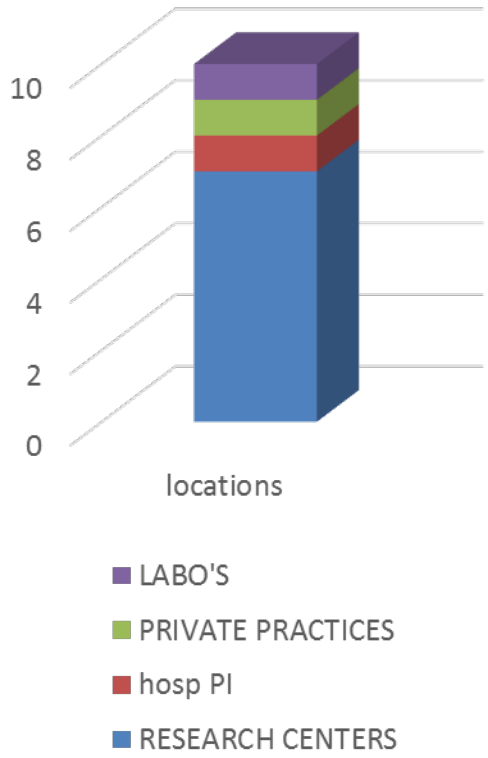
- PI localisation and availabilities

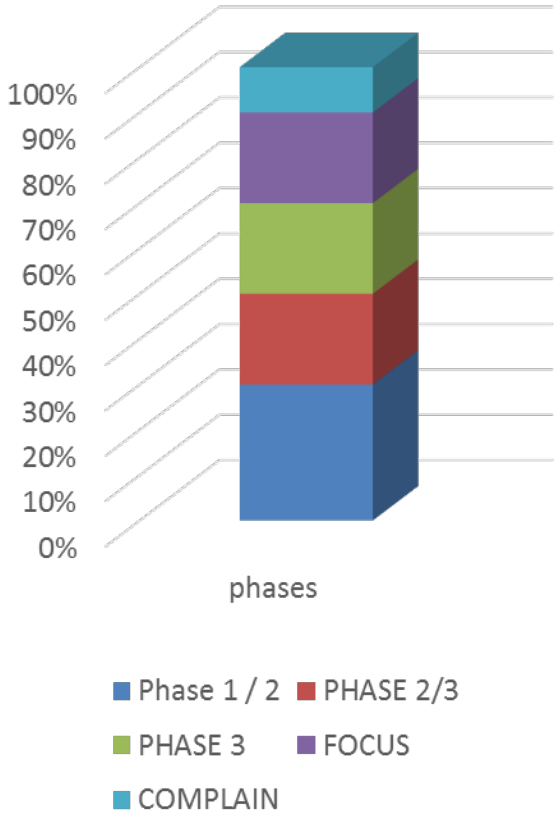
Focus/goals

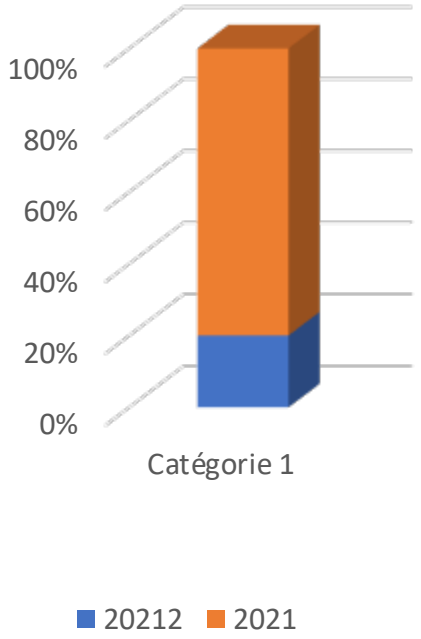
- Give more confidence to COVID-19 vaccines clinical trials.
- Reaction after complaint.
- Prioritisation for medicines against COVID-19.
- Without leaving aside the other medicines/patients.

Specifics for GCP inspections (2)

Result: 10 inspections







New way of working?

In practice no real change but no inspections during the first wave.

After some delay/postponement to perform inspection, especially during the first wave.

Some difficulties to obtain authorisation to reach the field into some hospitals.

Need to appeal to our legal inspection power (very rare).

Same situation in other countries.

Inspector's work when no inspection can be performed: call center, advice, help to cover colleagues, work on documents.

Specifics for GMP inspections (1)

Instructions:

Willingness to show the authority's control.

Respect for the distancing measures.

Respect for the staff's health.

Prioritisation of all "COVID-19 missions".

Act for protection and confidence of the citizens.

Specifics for GMP inspections (2)

Difficulties

- Working from distance not efficient for inspectors.
- Additional measures to access some sites.
- Many manufacturing sites for COVID-19 vaccines are out of the territory and a hight number are unknown.
- Impossible to travel.
- No possibility to ask other EU agencies to help.

But at the same time

- Urgency to give an opinion/certification
- Rolling review process give "uncomfortable" dossiers
- Very high pressure, many interactions/interferences, unusual procedures.

➔ Result: STRESS

Solutions for GMP inspections

Can new way of working help us?

- **New process**
  - new type of preparation: extensive exchange of documentations
  - new type of interaction with the site
  - new technologies (video call, phone call …)

- **New collaborations**
  - with non-EU agencies
  - priority to MRA countries (Canada, Switzerland)
  - including non MRA agencies (US)
  - including WHO

Example of solutions

Distant assessment

Definition: performing an inspection without going in the field.

Extensive exchange of documentation

New way of interactions (phone calls, video calls …)

Advantage

- not on site: no contact

Disadvantage

- **stressful**
- **language**
- **time lag**
- **time consuming**
- **not efficient**

Example of solutions

Remote inspection

Definition: performing an inspection without going on the field but having other inspectors on the field.

Advantage
- not on site: no contact

Points of attention
- link on the colleague's status (MRA or not)
- need to be legally checked

Disadvantage
- **stressful**
- **time lag**
- **time consuming but not as distant assessment**
- **efficient**

Lessons learned (1)

Process/collaboration:

Distant assessment

- Only for following of a (well) known site
- SOP on the CCP

Remote inspection

- More fruitful but need some check/adaptation case to case
- To be described/considered into SOP's/legal framework

Lessons learned (2)

Organisational mesures

- Prepare the teams, the organisations to manage crisis situation
- Technical and skills training
- Mind preparedness
- Promote inspection/collaboration between agencies/ organisations

Legal/procedural improvement

- Extend asap all type of MRA (e.g.: US BIO MRA)
- New legal texts allowing deviation from the “classical cases” with criteria
- New SOP’s in the CCP to execute

Contact

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