

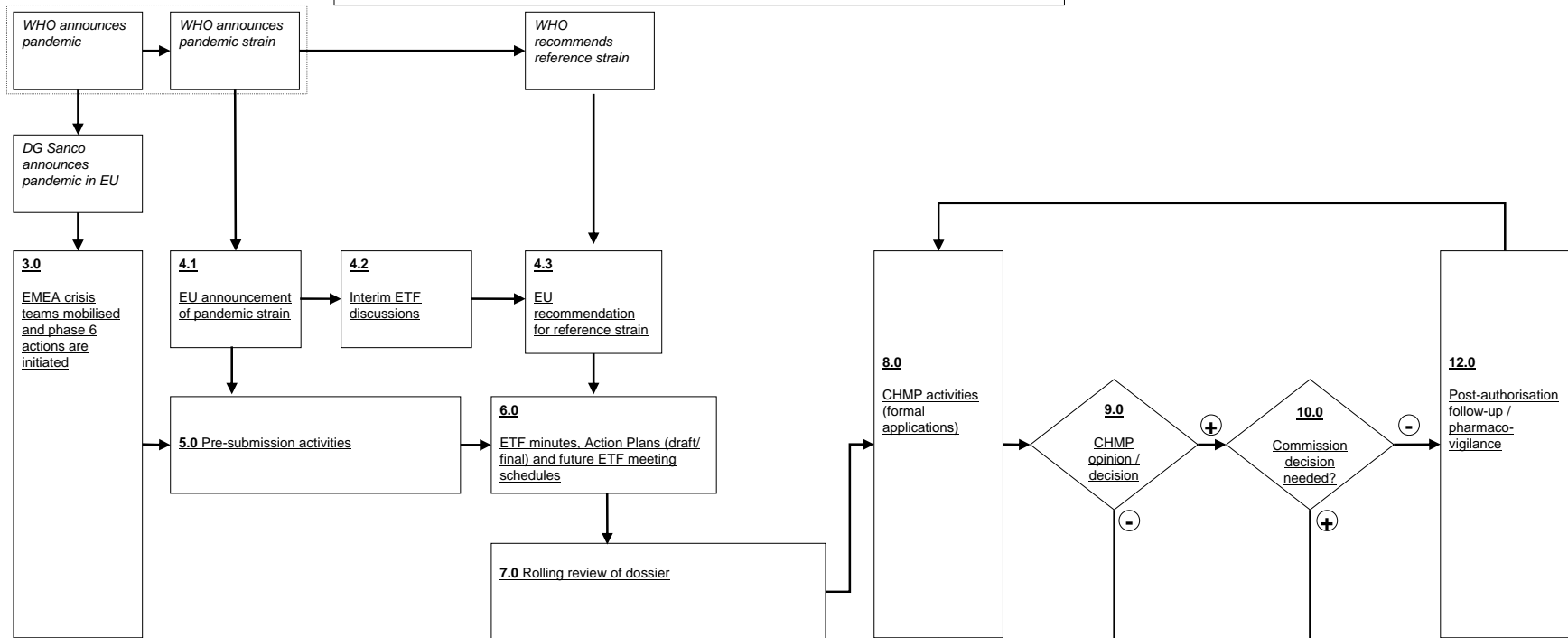
## Pandemic influenza vaccines

### Phase 1-3\*

- 1.1** Establish JEIF
- 1.2** Organise JEIF meeting
- 1.3** Hold JEIF meeting
- 1.4** Establish ETF and EPT
- 1.5** Establish EMEA Crisis Teams

### Phase 4-5\*

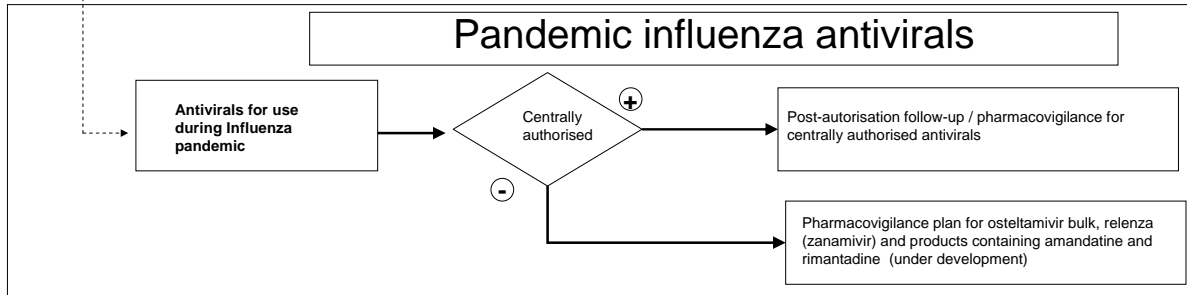
- 2.1** Organise JEIF meeting
- 2.2** Hold JEIF meeting
- 2.3** EMEA follow up actions



- Inputs**
- 1.1-1.5: Agency need
  - 2.1-2.3: Phase 4, 5 or 6 alert
  - 3.0: Phase 6 alert
  - 4.1: WHO announcement of pandemic strain
  - 4.2: EU pandemic strain announcement and scientific input from known sources
  - 4.3: WHO recommendation of reference strain and review of possible EU reference strain candidates
  - 5.0: Mobilisation phase 6 activities; EU endorsement of reference strain
  - 6.0: Pre-submission activities; EU recommendation of vaccine strain
  - 7.0: Action plan
  - 8.0: Start of a formal procedure (Including those based based on favourable rolling review of interim data)
  - 9.0: Assessment reports; CHMP discussion
  - 10.0: Type of procedure
  - 11.0: Positive CHMP Opinion needing a Commission Decision
  - 12.0: Commission Decision

- Outputs**
- 1.1-1.5: JEIF list; Crisis Team list; ETF and EPT lists; Minutes yearly meetings
  - 2.1-2.2: Minutes and report describing current status of the pandemic alert and of the manufacturer's activities, adopted by CHMP and to be distributed widely
  - 2.3: EMEA follow up actions including preparing press-release for when the pandemic is announced (phase 6) and assigning staff to products.
  - 3.0: Publication of pandemic press-release, Trigger EMEA pandemic activities
  - 4.1: EU announcement of pandemic strain
  - 4.3: Publication of EU recommendation of vaccine strain
  - 5.0: ETF reports(s)
  - 6.0: Action plans; ETF minutes & ETF future meeting schedule
  - 7.0: ETF report(s)
  - 8.0: Assessment reports
  - 9.0: CHMP Opinion
  - 10.0: Commission Decision
  - 11.0: Commission Decision

## Pandemic influenza antivirals



\* Phases as defined in the WHO Global influenza preparedness plan (doc. WHO/CDS/CSR/GIP/2005.5)