

**CMD(h) PANDEMIC PLAN**  
**MAINTAINING CMD(h) CORE AND CRITICAL BUSINESS**  
**DURING A PANDEMIC INFLUENZA OUTBREAK**

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**1. SCOPE**

- 1.1 This plan outlines a framework for maintenance of core and critical business functions within CMD(h) in the event of an outbreak of pandemic influenza according to the WHO pandemic phase system.
- 1.2 The plan will be finalised and published on the CMD(h) website in readiness for its use but it will not be implemented until a decision is taken to trigger the plan in accordance with section 9. An announcement that the plan has been triggered will be given on the website.
- 1.3 The principles outlined in this plan should be aligned where relevant and appropriate with those within the EMEA and other national competent authorities (NCA) plans.

**2. EXCLUSIONS**

- 2.1 This plan does not cover general infrastructure or human resource aspects of business continuity and disaster recovery which are covered in specific EMEA plans.
- 2.2 The plan does not cover business directly related to the pandemic or to support the individual NCAs' response to the pandemic. Nor does it cover specific Risk Management Strategies that should be in place to monitor the safety of pandemic clinical countermeasures across the EU (antivirals, vaccines and antibiotics).
- 2.3 The plan does not cover a scenario when external intervention, at an international or national level would dictate the EMEA's or NCA core functions during an influenza pandemic. The plan therefore assumes that CMD(h) will be obliged to maintain its core business and commitments during the pandemic period.

**3. BACKGROUND**

**Pandemic influenza and impact**

- 3.1 Pandemic influenza occurs when an influenza A virus subtype emerges, or re-emerges, which is

- markedly different from recently circulating strains
- able to infect humans and readily transmissible from person to person
- capable of causing illness in a high proportion of those infected
- able to spread widely because few – if any – people have natural or acquired immunity to it

3.2 A future influenza pandemic could occur at any time (intervals between the most recent pandemics have varied from about 10 to 40 years with no recognisable pattern. There have been three influenza pandemics in the last century; 1918, 1957 and 1968.

3.3 The timing, strain and clinical impact of the next influenza pandemic cannot be predicted. Experts believe that another pandemic is only a matter of time and a new virus may emerge at any time of the year.

3.4 Given the many unknowns, planning has to be based on a series of assumptions, informed by some real data from previous pandemics and epidemics. This has employed mathematical modelling to develop a range of scenarios on the possible impact of a pandemic to inform strategic planning.

***Planning assumptions***

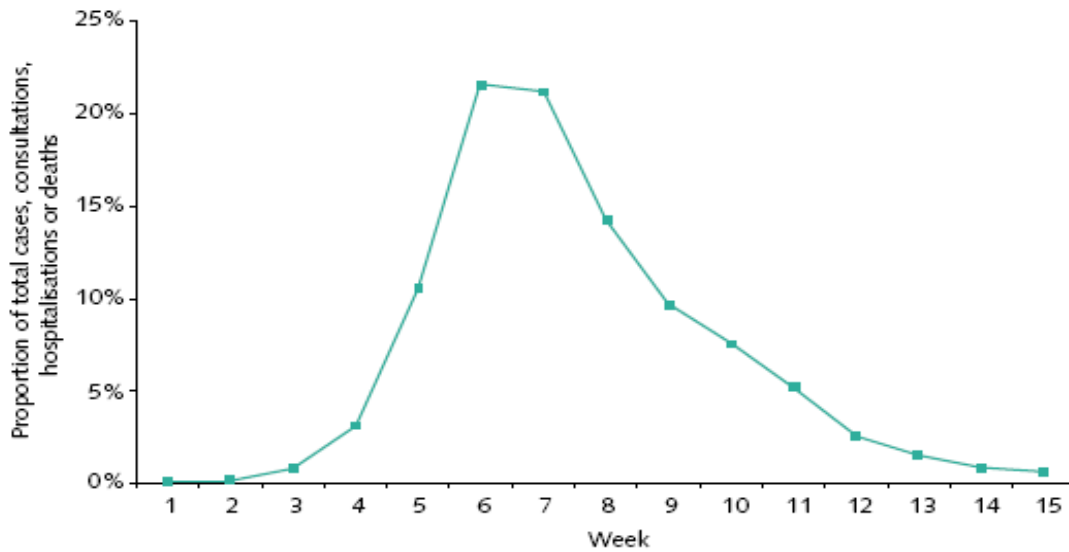
3.5 The following graph and table outline the possible time course and range of scenarios of case fatality and clinical attack rates<sup>1</sup>. An example is given here for one member state, but individual NCAs can apply the same principle calculated for their population. In the UK, based on a population of 60 million, a 50% clinical attack rate would result in around 30 million clinical infections, up to 1.2 million hospitalisations and up to 750,000 deaths (but case fatality could be greater):

**Table 1: Range of possible excess deaths for various permutations of case fatality and clinical attack rates, based on UK population**

Overall case fatality rate (%)	Clinical attack rate (%)		
	25	35	50
0.4	55,500	77,700	111,000
1.0	150,000	210,000	300,000
1.5	225,000	315,000	450,000
2.5	375,000	525,000	750,000

<sup>1</sup> The percentage of the population that will have a symptomatic infection – based on seasonal flu it is thought that 50% of those infected will show no clinical symptoms.

**Figure 1: Single wave national profile showing proportion of new clinical cases by week**



- 3.6 There may be one or more pandemic waves weeks or months apart, each lasting 12-15 weeks depending on the season. Figure 1 represents the possible national profile of a single wave; local profiles could be shorter or longer (with higher or lower peaks respectively) depending on local demographics.
- 3.7 Spread from the source country outside Europe to a NCA through movement of people is likely to take around a month. Experience of the dissemination of severe acute respiratory syndrome (SARS) from Hong Kong suggests modern travel may result in even more rapid international spread. Upon arrival in a NCA it will probably be a further one to two weeks until sporadic cases and small clusters, that will act as initiators of local epidemics, are occurring across the whole country.

### **Business continuity**

#### ***‘Reasonable worst case scenario’***

- 3.8 All NCAs should have plans in place to maintain critical business during a pandemic. National planning may be based on a reasonable worst case scenario (**i.e. case fatality 2.5%, clinical attack rate 50%**).
- 3.9 A regular information exchange on the status of the business continuity planning of the NCAs relating to functions relevant for the functioning of the CMD(h) should be established. This relates especially to the key tasks-prioritisation, the personnel roles, IT communication technology, travel restrictions.

#### ***Staff absence***

- 3.10 On this basis, up to 50% of the (national) workforce in the affected NCA could be absent for 6 to 10 days each during the whole pandemic (i.e. over one or more waves). According to modelling, absence rates (for illness alone) could reach 15-20% in the peak 3 weeks of a single wave.

- 3.11 However, additional staff absences would be likely for other reasons (e.g. caring for dependents, travel disruption etc). Small organisational units (5 to 15 staff) or small teams within larger organisational units may suffer higher percentages of staff absences – up to 30–35% over a 3 week period at the local peak.

### *Virtual team*

- 3.12 A “virtual CMD(h) crisis team” should be established including the Chair, Vice chair and secretariat responsible for information exchange within the CMD(h) and between CMD(h), EMEA, CHMP, working parties, responsible for decisions to be taken (e.g. cancellation of meetings, on priorities, communication with EMEA-IT etc). Until such a time as the pandemic situation is declared, this “virtual CMD(h) crisis team” will operate as the CMD(h) Pandemic Task Force and members will represent CMD(h) interests in the EMEA Pandemic Task Force.
- 3.13 The CMD(h) member should inform the CMD (h) crisis team about the personnel situation at the NCA relevant for the CMD(h) activities/ procedures. A deputy role for the CMD(h) Member should be established.

### *Infrastructure*

- 3.14 As well as staffing levels, the availability of internal infrastructure (IT systems, building access etc) may become a factor in maintenance of critical business.

## **4. KEY ELEMENTS OF PLAN**

- 4.1** The fundamental objective of this plan is to ensure that CMD(h)’s critical business and key public health functions are maintained for the time period of the pandemic, as well as during the pandemic recovery period (or between waves).
- 4.2** For the purpose of this plan, **core business** is defined as CMD(h)’s usual operational functions. **Critical business** is defined as the core operations which **MUST** remain functional in the face of a worst case scenario of staffing levels (e.g. in WHO phase 6; see also section 9).
- 4.3** The plan is focussed on identifying agreed priority activities of CMD(h) and any procedural changes necessary to support them. The principle of member state work sharing or agreement of a changed RMS will be fundamental to its success.
- 4.4** There may be a requirement for a reciprocal arrangement of amended procedures with external stakeholders (e.g. industry may wish to include only minimal information to support priority safety variations or packaging changes, provide short expert reports of safety changes etc).
- 4.5** The plan should identify essential inter-dependencies such as the information line between the CMD(h) member and the NCA, maintaining a functional IT communication system, maintenance of mail boxes, and CTS tracking.

## **5. POLICY AND GUIDANCE AMENDMENTS**

- 5.1** Within the core and critical functions there is a requirement to consider which specific tasks can be removed or ‘streamlined’ to minimise workload (e.g. to minimise ‘processing’ work and focus on assessment).

### **Assessment reports**

- 5.2** There will be a requirement on a NCA to prioritise<sup>2</sup> assessment work. There will also be a requirement to abbreviate assessment reports as much as possible in order to reduce the time and effort in producing the reports, as well as that of the CMS in reviewing the report. CMS will take national decisions as to the extent (if any) they will undertake further review. A pandemic specific amendment to the CMD(h) best practice guide (BPG) has been prepared taking into account the guidance available for centralised procedure for pandemic vaccines.
- 5.3** Only prioritised applications (see 6.1) should be assessed in the pandemic period (WHO phase 6; see also section 9). Non-urgent submissions may be delayed until the pandemic recovery period (and prioritised accordingly).
- 5.4** Abbreviated assessment reports should be produced. These should include minimal background and discuss only the key points and data for consideration. This procedure should also be adopted when assessing the back-logged non-urgent submissions in the recovery period (see also section 9.6).

### **Timetables**

- 5.5** All MSs, as well as EMEA, are encouraged to adopt a reciprocal system of prioritising applications and producing pragmatic timetables which take account of staff shortages across Member States.
- 5.6** Full timetables should be maintained for the priority functions listed below. Recommendations on the timetables will be included in the amendment of the BPG for pandemic situations taking into account the guidance available for pandemic vaccines

### **Change of RMS**

- 5.7** A simple procedure should be agreed for the change of RMS where the RMS has identified it can not undertake the work in the required timeframe. The amended procedure may be by reciprocal arrangement between 2 MSs or coordinated by the CMD(h) crisis team based on the information about the availability of the MS (see 3.13)

### **Worksharing**

- 5.8** Whenever possible a worksharing procedure based on the existing procedural guidance (e.g. proposed CMD(h) Art. 20 BPG, paediatric worksharing) should be used.

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<sup>2</sup> The priority here is simply to read/scan for important data and conclusions and not conduct a detailed assessment or prepare an AR unless it is considered urgent/important

## **Annex**

**5.9** A full list of amended procedures to be used in a pandemic is detailed in the Annex to the Plan.

## **6. CMD(h) PRIORITY (CRITICAL) FUNCTIONS AT PEAK LEVEL OF PANDEMIC (WHO phase 6 in the EU; see also section 9)**

### **6.1** Prioritised procedures

MRP/DCP and pandemic related variations for the following products:

- (viral) vaccines
- antivirals
- antimicrobials
- other medicines used for influenza-type illness
- other medicines on national ‘critical lists’

### **6.2** RMS-led Safety variations

### **6.3** Processing Urgent Safety Restrictions

### **6.4** Rapporteur-led identified important EU paediatric work sharing procedures

**6.5** CMD(h) referrals – which may utilise telecon, Vitero facilities. CMD(h) referral procedures should be suspended in phase 6 except when the referral concerns a prioritised procedure and the reason is a safety issue. The timelines should be agreed as proposed in 5.6. The discussion should be performed by e-mail and telecon preferably by Vitero. An amendment to the SOP should be prepared.

### **6.6** Maintenance of CTS records and EudraNet-mailboxes (e.g.MRNA, MRVE)

### **6.7** Maintained liaison with PhVWP on critical safety issues.

### **6.8** Maintained information exchange with EMEA, CHMP, VWP

### **6.9** CMD(h) activities

- no regular CMD(h) meetings because of travel restrictions
- but maintained information exchange via e-mail and telecon preferably by Vitero

## **7. RESPONDING TO NON-URGENT EXTERNAL ENQUIRIES**

It will be important to inform external stakeholders that CMD(h) will respond only to urgent requests for information in the pandemic period. Wherever possible this should involve auto-response e-mails from mail boxes outlining policy on dealing with enquires.

## **8. ACTIVITIES BEFORE AND IN THE PRE-PANDEMIC AND WARNING PHASE**

- 8.1 Preparation of pandemic related amendments to the BPGs
- 8.2 Input to legislative change preparation where timelines are fixed or procedures are suspended.
- 8.3 Agreement on the main principles for the pandemic period (phase 6; see also section 9) e.g. prioritised procedures, suspension of procedures (e.g. delay of ongoing procedures except products in accordance with point 6.1, no start of new procedures, PSURs, paediatric worksharing if not pandemic relevant, etc.), worksharing procedures, accelerated assessment, abbreviated assessment reports
- 8.4 Establishing of information lines between CMD(h) members and between the virtual CMD(h) crisis team and EMEA/CHMP (e.g. reachability of the CMD(h) member, CMD(h) crisis team contact point)
- 8.5 Check of maintenance of CTS, EudraNet-mailboxes and Vitero
- 8.6 CMD member: clarifying whether necessary technology and network for rapid communication and access to CTS and EudraNet, Eudralink and intranet is in place for homework facilities (e.g telephone-/video/Vitero, internet, Citrix).

## **9. TRIGGERING THE PLAN**

- 9.1 The CMD(h) Pandemic Plan is envisioned to become effective at the height of the outbreak and in the immediate period leading up to it, when resources will be most stretched. The plan anticipates that WHO pandemic phase 6 will have been declared, but the announcement of phase 6 does not automatically trigger the implementation of this plan.
- 9.2 The CMD(h) Chair, with deputy cover (from EU presidency member state), will have responsibility to declare when the plan should be triggered. This will normally be the case when in one or more Member States the emergency situation is officially declared. Ideally, if time allows, this will be by consensus of the full CMD(h) following consultation and agreement using e-mail communication. Triggering the plan will have the effect of changing the responsibilities of the CMD(h) Pandemic Task Force to those of the Virtual CMD(h) Crisis Team (see point 3.12), and applying the Annex amended procedures, as detailed below.
- 9.3 As the extent of the pandemic situation differs across geographical areas, it may not be necessary for all aspects of the plan to be triggered simultaneously. It will be for the CMD(h) member (or nominated deputy) of the national competent authority to inform the virtual CMD(h) crisis team when CMD(h) - emergency procedures are required to be introduced. The virtual crisis team will give approval to that MS in order that a clear picture of activity is retained. Good communication will therefore be essential in order to share information as to the pandemic situation in each MS.

- 9.4 Once emergency procedures are effective within a region, the MS may use **all** the abbreviated procedures detailed in the annexes **for all products, although these will affect primarily products which fall under the definition according to point 6.1**. It is anticipated that only work in the identified priority areas (see section 6 above) will be undertaken, but nevertheless this does not preclude use of abbreviated procedures and templates for all work undertaken in the declared pandemic period if this is deemed necessary by the RMS on the grounds, for example, that the procedure is for a product which is deemed to be a critical product in either the RMS or any CMS. As not all MS may have declared the emergency situation in their territory, it follows there will be a mix of both full and abbreviated processes running. This is acceptable. But a MS who has not yet declared the emergency situation, **must** accept the abbreviated process triggered by another affected MS. RMS and CMS and, if required, the CMD(h) crisis team should prior to the start of the procedure agree whether a procedure should be prioritised.
- 9.5 A common sense approach to the practical implementation of this plan will rely on good communication between MS and a flexible arrangement to take account of the needs of individual MS. The plan is intended as a framework that CMD(h) has agreed all MS will work within. Therefore if there is a request from a CMS to take priority action on a procedure, then the RMS should accommodate. Likewise, the RMS should not expect participation of a CMS in a procedure if that CMS has declared the emergency situation as national plans to rely entirely on the RMS assessment may be in place.
- 9.6 The situation will continue for a recovery period following the peak of the pandemic and the virtual crisis team will declare when the Pandemic Plan should actively cease. Procedures that have commenced with an abbreviated process will be allowed to continue to completion. Other non-PSRPH questions/concerns which have not been discussed/solved in the abbreviated processes may be solved after the end of the pandemic phase as commitments or in subsequent procedures (e.g. variations).

**Co-ordination Group for Mutual Recognition and Decentralised procedures, human – CMD(h)**

## **ANNEX I Amended Procedures to be used in a pandemic**

<b>Annex</b>	<b>Procedure</b>
A1	CMD(h) procedural advice on changing the RMS
A2	Procedural advice on Repeat Use procedure
A3	BPG on Decentralised and Mutual Recognition Procedure
A4	BPG on Break-out sessions
A5-1	DCP/MR Assessment Report Templates - Quality
A5-2	DCP/MR Assessment Report Templates - Clinical
A5-3	DCP/MR Assessment Report Templates – Non Clinical
A5-4	DCP/MR Assessment Report Templates – Overview and List of Questions
A6-1	PVAR Template
A6-2	FVAR Template
A7	Urgent Safety Restriction MSs SOP
A8	PhVWP-CMD(h) BPG on Communication and Implementation of Safety Information (during a pandemic period)
A9	CMD(h) SOP – Referrals to CMD(h)
A10	Information on maintenance of CTS and availability of CTS helpdesk during a pandemic situation

### **II Composition of the CMD(h) Pandemic Task Force**

Chair  
Vice-Chair  
CMD(h) Secretariat  
SE  
DE  
UK  
IT

### **III Link to the EMEA pandemic plan and procedures**

The plan, procedures and guidance documents are published on the EMEA external website.  
<http://www.emea.europa.eu/htms/human/pandemicinfluenza/background.htm>