

## ROADMAP

Title of the initiative: Council Recommendation / **Commission Communication on pandemic influenza preparedness and response planning in the European Union**  
Type of initiative (CWP/Catalogue/Comitology): legislative / non legislative  
Lead DG: SANCO  
Expected date of adoption of the initiative (month/year): first half 2011 (Council Recommendation - Commission Communication package)  
Date of modification: 12 March 2010  
Version No: 1

### Initial IA screening & planning of further work

#### **A. Context and problem definition**

(i) What is the political context of the initiative? (ii) How does this initiative relate to past and possible future initiatives, and to other EU policies? In 2005 the Commission adopted a Commission Communication on pandemic influenza preparedness and response in the European Community. In 2008 and 2009 the Council adopted conclusions inviting the Commission to take into account the inter-sectorial dimension of preparing for pandemic influenza by reviewing the arrangements that cover this area and by updating the communication of November 2005 on pandemic influenza preparedness and response planning in the European Community. The initiative will provide for an update of the 2005 Community pandemic influenza preparedness plan.

What are the main problems identified? Lack of coordination at EU level, different levels of preparedness between MS and insufficient interoperability within and between MS including inter-sectorial coordination are seen as key problem areas.

Who is affected? The problems affect the whole EU population at risk in the event of an influenza pandemic.

(i) Is EU action justified on grounds of subsidiarity? (ii) Why can the objectives of the proposed action not be achieved sufficiently by Member States (necessity test)? (iii) As a result of this, can objectives be better achieved by action by the Community (test of EU Value Added)? The MS are responsible for preparedness planning and response. However, without coherent coordination at EU level on multi-sectorial issues specific areas of internal market may be affected, for example free movement of goods (vaccines, pharmaceuticals, medical devices) and people (human resources in the health sector). Trans-boundary spread of pandemic influenza and the need of congruency of Community preparedness planning with WHO guidance are major reasons why this initiative is necessary. The added EU value will be that the EU will provide political weight and visibility putting pandemic preparedness at the centre of MS health priorities and that effective knowledge will be shared through exchange of best practice.

#### **B. Objectives of EU initiative**

What are the main policy objectives? The general objective of this initiative is to ensure the best level of health protection for the general public and different sectors of the society through effectively addressing preparedness and response planning for pandemic and indirectly also for inter-pandemic (seasonal) influenzas at EU level. Specific objectives are to increase the level of EU coordination, to address differences in levels of preparedness between MS and to increase inter-operability within and between MS systems including coordination of the cooperation of key sectors such as transport, energy, telecommunication which have been identified by the Council as the first core areas to be looked at to ensure sustainability of these services during a pandemic.

Do the objectives imply developing EU policy in new areas or in areas of strategic importance? Additional actions are foreseen in sectors other than health, for example policies on school

closures, travel advice, closure of borders, business continuity planning in the energy sector and other measures.

### **C. Options**

(i) What are the policy options? (ii) What legislative or 'soft law' instruments could be considered? (iii) Would any legislative initiatives go beyond routine up-date of existing legislation? Policy options are I: no further EU action – status quo; II: strengthened cooperation with the MS and other bodies supported by technical guidance; III: strengthened cooperation with the MS and other bodies supported by a soft law instrument such as a Council Recommendation or a Commission Communication and technical guidance; IV: strengthened cooperation with the MS and other bodies supported by a soft law instrument under co-decision procedure such as a Council and Parliament recommendation and technical guidance; V: strengthened cooperation with the MS and other bodies supported by a regulatory instrument such as a Commission Decision and technical guidance.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments? Yes as emphasis is on inter-sectorial coordination, in particular with regards to key sectors such as transport, energy and telecommunication.

Explain how the options respect the proportionality principle. Considering that MS are responsible for the implementation of national preparedness strengthened by using hard law instruments may be too far reaching and therefore soft law instruments would be preferred.

### **D. Initial assessment of impacts**

What are the significant impacts likely to result from each policy option (cf. list of impacts in the Impact Assessment Guidelines pages 32-37), even if these impacts would materialise only after subsequent Commission initiatives? With regard to achieving coordination: Options I and II: no impact on improving coordination of activities at EU level; Option III: will ensure attention at highest political level combined with relatively short lead time until adoption; Option IV: disadvantage of long lead time, Option IV: disadvantage of low political acceptance. Options II to IV are all intended to reduce health risks from pandemic flu, improve the targeting of public authorities spending, and in the event of an outbreak may reduce risks of economic disruption.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation? No impacts on EU budgets are expected.

Could the options have significant impacts on (i) simplification, (ii) administrative burden or on (iii) relations with third countries? Not foreseen

### **E. Planning of further impact assessment work**

When will the impact assessment work start? Kick off meeting took place 5 February 2010.

(i) What information and data are already available? (ii) Will this impact assessment build on already existing impact assessment work or evaluations carried out? (iii) What further information needs to be gathered? (iv) How will this be done (e.g. internally or by an external contractor) and by when? (v) What type and level of analysis will be carried out (cf. principle of proportionate analysis)? European Centre for Disease Prevention and Control carried out a study on pandemic influenza preparedness assessment in the EU. The UK Health Protection Agency has carried out an evaluation of the response to the H1N1 pandemic covering the period April to August 2009. A second part covering the period from September 2009 is awaited in June 2010. ECDC will provide scientific data to support the initiative. Currently SANCO is preparing a consultation paper analysing critical areas during the response to the pandemic (H1N1)2009. The paper is meant to facilitate the impact assessment process and to feed into the BE presidency conference of 1-2 July which will examine the lessons learnt from the H1N1 pandemic. A decision which legal format the initiative

will take will only be taken after the conference.

Which stakeholders & experts have been/will be consulted, how and at what stage? The consultation will involve a drafting group set up by representatives from interested MS as well as the flu section of the Health Security Committee and the committee itself. Furthermore an open web-based consultation is planned that will involve all interested stakeholders such as the pharmaceutical industry, patient groups, health professional groups and EU level stakeholder associations in relevant sectors such as transport, energy and tele-communication on top of those mentioned in the comments.