HAI EUROPE RESPONSE

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Stichting Health Action International Europe
Overtoom 60/II
1054HK Amsterdam
The Netherlands
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This response has been prepared by Health Action International (HAI) Europe. HAI Europe is a non-profit, European network of consumers, public interest NGOs, health care providers, academics, media and individuals with over 25 years experience in representing the voice of civil society, and poor and marginalised people in medicines policy debates.

Our authority rests on our integrity and independence from commercial and political party interests, our research excellence and evidence-based advocacy.

- HAI advocates for access to essential treatments that satisfy the priority health care needs of a population.
- HAI Europe promotes better access to medicines by advocating for EU trade policies that are coherent with the EU's commitments on health and development; by campaigning for changes to the EU's internal market laws that hamper access to medicines in Europe; by advancing EU actions on the exploration of new models of medical innovation.
- HAI Europe is committed to ensuring the rational use of medicines through greater controls on medicines promotion, independent medicines information, greater patient involvement in the reporting of adverse drug reactions so that harmful or ineffective medicines are identified more quickly, thereby reducing the threat to public health.
- HAI Europe advocates for the highest levels of transparency, independence and accountability in all aspects of pharmaceutical policy and regulation, as well as the wider participation of patients and consumers in decisions that will affect their health and wellbeing.

Summary

Regardless of their origin, health threats are frequently tackled using medicinal products. Medicines not only play a central role in treating illness, but they can also be crucial to preventing the onset and spread of disease. Therefore, any strategy to promote health security in the EU needs to consider, among other things, how medicines can be used rationally to achieve the best health outcomes and widest social benefits.

As a civil society organisation committed to citizen-centred pharmaceutical policies, Health Action International (HAI) Europe supports the highest levels of transparency and accountability in decisions that affect citizen health. We maintain that any strategy to promote health security in the EU should be founded on:

Executive Agency for Health and Consumers

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- an objective assessment process of potential health threats;
- the implementation of a policy to handle and resolve conflicts of interest of those giving advice;
- the appropriate evaluation of medicines intended for use in health emergencies;
- an inclusive and effective communication strategy;
- ensuring that health security is compatible with civil liberties;
- developing measures to ensure the health security of vulnerable population;
- the transparency of decisions about health threats.

Objective assessment process

The identification and assessment of health threats in the EU needs to be established through an objective process that is independent of international health authorities. In the case of the H1N1 influenza, the World Health Organization's (WHO's) official declaration of a pandemic, issued shortly after an amendment to the definition of pandemic, triggered a hasty response from EU governments. This resulted in the unfortunate diversion of already limited public health resources on medicines and vaccines.

To ensure an appropriate response to health threats in Europe, HAI Europe calls for the EU to reinforce the powers of the European Center for Disease Prevention and Control (ECDC) as the public health authority in Europe. As an expert European agency, it is best able to assess the health threats and to advise on a calculated response suited to the EU context.

Establishing policies to handle and resolve conflicts of interest

Independence in scientific and expert advice is crucial to balanced decision making. Conflicts of interest can bias regulatory affairs, and compromised decisions could result in the market approval of medicines of questionable efficacy or unproven safety, which would ultimately put citizens at risk.

Following the public declaration of an A/H1N1 Influenza pandemic in 2009, and the subsequent handling of the outbreak, important concerns have been raised about the management and decision making surrounding this 'pandemic'. Questions have arisen about the role played by the pharmaceutical industry, particularly regarding whether commercial interests had any influence on decisions made by EU Member States.[1]

The European Parliamentary Committee on the Environment, Public Health and Food Safety (ENVI) presented key recommendations to improve cooperation, independence and transparency in their *Report on the evaluation of the management of H1N1 influenza in 2009-2010 in the EU.* In particular, the ENVI Committee has stated that:

> "*The conflicts of interest among experts who advise European public health authorities lead to suspicions of undue influence and harm the overall credibility of these public health authorities and their recommendations"*[2]

[1] Dr. Wolfgang Wodarg, medical expert specialising in epidemiology and former Chair of the Sub-committee on Health of the Parliamentary Assembly. Statement presented to the Social, Health and Family Affairs Committee of the Parliamentary Assembly of the Council of Europe in Strasbourg on 26 January 2010. URL: http://www.assembly.coe.int/CommitteeDocs/2010/20100126_Statement%20Wodarg.pdf

[2] Committee on the Environment, Public Health and Food Safety of the European Parliament. *Report on the evaluation of the management of H1N1 influence in 2009-2010 in the EU. (2010)* Point 26. URL : http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A7-2011-0035+0+DOC+PDF+V0//EN

The conclusions from this reflection on the EU's response to the H1N1 influenza should be applied to the wider context of health security.

Health security at the EU level can be strengthened by ensuring the most robust policy for handling advisors' conflicts of interest in relation to decisions about medicines or other therapies intended for use in health emergencies. To this end, HAI Europe supports the ENVI Committee's call for EU public health authorities to develop:

> *"A European code of conduct relating to the exercise of the function of a scientific expert in any European authority in charge of safety and of the management and anticipation of risks"*[3]

Specifically, HAI Europe supports a coordinated and comprehensive approach to handling conflicts of interest by:

- Adopting a common definition of conflict of interest among agencies, committees and other informal bodies advising on health threats.[4]
- Instituting the mandatory declaration of the details regarding the activities of experts and decision makers in relation to any of the following: employment, strategic advisory roles (gainful or not), consultancy, representation (gainful or not), financial interests, ownership of a patent or product, researcher, employment or involvement at an institution receiving a grant or other funding.
- Requiring that experts and advisors to EU authorities declare their (potential) competing interests before taking up any duties.
- Making participation in EU advisory groups and decision making regarding health threats conditional on the full disclosure of any potential competing interest.
- Mandating the EU authorities to publish all declaration of interest forms.[5]
- Creating a procedure to identify and resolve any competing interest. In some cases, impartiality could be achieved by limiting the advisor's involvement in the decision making process.[6]

A conflict of interest can jeopardize the credibility of the decision making body and the public trust afforded to its decisions. The rigorous application of a policy for handling conflicts of interest can safeguard EU decision-making from undue influence, ultimately supporting public security and patient safety.

Appropriate evaluation of medicines intended for use in health emergencies

Regulatory agencies evaluate the safety, quality and efficacy of a medicine. In health emergencies, regulators may feel additional pressure to expedite the market approval of a medicinal product. HAI Europe cautions against accelerated authorisation procedures for medicinal products designed to respond to health crises. As medicinal products are tested on a relatively small number of people before they are approved for use by the wider population, previously undetected adverse reactions can emerge. HAI Europe reinforces the overarching need to ensure the correct assessment of the benefit-harm profile of a medicinal product before

[3] ENVI Report. Point 19
[4] ENVI Report. Point 27
[5] ENVI Report. Point 29
[6] ENVI Report. Point 20

authorising it to enter the European market. Part of correctly assessing a medicinal product is ensuring that all of the clinical information about safety and efficacy is publicly available.

Appropriate evaluation also includes the basis for making decisions about stockpiling medicines in anticipation of a health emergency. Stockpiling should only be undertaken for medicines that have a solid basis of clinical evidence showing that they significantly impact the disease that they are designed to treat. Where evidence is questionable or unavailable, as was the case with Oseltamivir[7], limited public health budgets and Member State resources should not be used to build up supplies.

Effective communication about health threats

Effective communication about health threats should provide timely, accurate information in an accessible way. To this end, HAI Europe recommends involving civil society organisations in decisions about the appropriate format and dissemination channels for communicating risk and harm information. By including the target audience in these preparatory steps, EU authorities can enhance the readability and accessibility of their messages and ultimately, raise public awareness of the health threat in question through a variety of dissemination techniques so that they are accessible to the widest possible European audience.

Ensuring that health security is compatible with civil liberties

During a health emergency it is important that measures taken to ensure health security do not infringe on the rights of individuals, especially those in vulnerable populations. As one example, guarding the health of homeless people may lead authorities to take measures to put these people into shelters even against their will. Mechanisms need to be developed to guard against forcing people to undertake activities while at the same time helping them protect their health.

Developing measures to ensure the health security of vulnerable populations

Certain groups of people, for example the elderly, are especially at risk during a health emergency for a variety of reasons. Any plan for health security needs to ensure that the specific needs of these populations are taken into consideration.

Transparency of the EU's strategy for health security

An EU strategy for health security needs to ensure transparency at every level of decision making. In particular, the rationale behind the declaration of a health emergency and the authorisation of large-scale medical interventions is crucial to the public understanding of how and why these decisions are made within Europe. Given the significant public resources involved, it is vital that European citizens have the opportunity to scrutinize the decisions made on their behalf.

[7] Doshi P. Neuraminidase inhibitors: the story behind the Cochrane review. BMJ 2009;339:1348-51