Analysis of responses to ENMCA questionnaire on the alert mechanism - ANONYMISED

Background

1. In March 2014 the European Network of Medical Competent Authorities (ENMCA) issued a questionnaire to participating competent authorities (reproduced at Annex 1) to feed into ENMCA's engagement with the development of an alert mechanism under Directive 2013/55/EU.

2. The findings have been collated below. For further information please contact: contact@enmca.eu

Overview

3. A total of 12 competent authorities from 11 EEA countries replied to the questionnaire.

4. In general, respondents welcomed the introduction of an alert mechanism although it was apparent that opinions differ on the types of sanction that should be included and the methods of storing received alerts received. Respondents also highlighted serious concerns with the three day deadline to transmit an alert and raised a number of issues that require further consideration in the Implementing Act.

Summary of findings

Main advantages of the proposed alert mechanism

5. Competent authorities from 11 countries outlined what they believed to be the main advantages of the new alert mechanism. All comments focused on similar issues relating to the benefits to patient safety due to the increased information flow about doctors who may pose a risk to the public. One authority welcomed the direct contact between competent authorities which it believes will avoid delays in transmitting information.

Types of sanctions included

6. All respondents agreed that permanent prohibition and suspension should be included in the alert. All but two respondents believed that use of fraudulent documents should also be covered. Six authorities thought that criminal proceedings affecting a professional's right to practise should be included. One authority would be unable to provide information on criminal sanctions as they only have information on proceedings that result in the restriction of a right to practise. Nine competent authorities believe that sanctions related to supervised practice should also be included.

7. One competent authority queried whether medical competent authorities would be able to send an alert related to the use of fraudulent documents as the Directive limits this provision to decisions taken by 'national courts'. It is not clear whether a decision taken by a competent authority on the authenticity of documentation would come under the definition of 'national courts'.

8. A different authority called for an additional category to be included in the alert – that of persons under investigation where there is a reasonable expectation that sanctions will be imposed.

Information on past sanctions

9. Five competent authorities highlighted the need for the continued exchange of Certificates of Good Standing at the point of registration alongside the alert mechanism. An additional three authorities called for a continued dialogue between competent authorities, outside of the alert mechanism, to check a professional's good standing.

10. Seven authorities called for a searchable repository of information within the IMI system that competent authorities could consult when a professional applies to join their national register. Concerns were raised that the once a sanction has expired, the alert should be amended or deleted accordingly.

11. One competent authority questioned how an alert or searchable database would work should a professional change their name and unless other unique identifiers are included in the alert. Another authority questioned the feasibility of creating and maintaining a system containing details of historical sanctions.

Storing information received in an alert

12. Opinions differed on the methods of storing alerts received by an authority. One authority strongly believes that the decision to store alerts outside of the IMI system should be one for each individual competent authority. Seven authorities stated the need to store alerts on their national systems in addition to IMI whilst two authorities maintained that this would not be necessary.

13. One competent authority asked about the interaction of the alert with article 14 of the IMI Regulation (2012/1024) which covers the retention of personal data received via IMI.

Time frame for sending an alert

14. A theme common to the majority of responses was the need to clarify whether the wording of the Directive ("at the latest within three days from the date of adoption of the court decision…") relates to three working days or three calendar days (72 hours).

15. Five authorities strongly believe that the three day deadline would be impossible or very difficult to meet. This is mainly due to delays in the transmission of court decisions. Often

these are taken by bodies separate from the competent authority. Three authorities stated that if the definition is three 'working days' it should be possible.

16. One competent authority stated strongly that compliance with the three day rule will not be possible. In their opinion, the resources spent on meeting this deadline would not be proportional to the improvements it would provide in terms of enhanced patient safety as most data will involve health professionals who have no intention of leaving their current country.

17. Another authority stated that the federal structure it some member states might make it difficult to comply with the timeframe.

18. Two authorities queried what the sanctions would be if a competent authority failed to meet the three day deadline or failed to send an alert.

Further clarification needed

19. One competent authority will only be able to send alerts once a decision is non-appealable which may be some time after the decision to prohibit practice is made. In addition, confusion may be caused should a professional appeal a decision to send an alert before the proceedings have been completed. Concerns around the interpretation of a professional's right to appeal are also shared by three other authorities.

20. The same authority highlighted that disciplinary procedures can only be initiated if a doctor is registered with the competent authority. A professional presenting fraudulent documents at registration will not be registered and thus disciplinary proceedings cannot be initiated. No alert will be sent in this case. The authority is concerned that the Directive does not capture this scenario which represents a danger to patient safety.

21. A different authority has grave concerns about the burden on competent authorities and the amount of data that an authority will potentially receive. They believe that an authority should not receive information regarding health professionals unless it has specifically requested information on that individual.

22. A further authority also has some concerns about the management of a large volume of alerts and is keen to learn how other competent authorities currently manage such communications.

23. One competent authority asked whether the alert would be cross-professional (e.g. a doctor may hold dual registration as a pharmacist and dentist). They also stated that the alert mechanism will be ineffective unless competent authorities have powers under national legislation to take action on a doctor's registration when a fitness to practise decision in another country comes to light.

24. As different rules apply in member states regarding the revocation of licenses to practise or the issuing of a warning, one authority called for further guidance as to how competent

authorities should interpret information provided by competent authorities in other member states.

ENMCA, July 2014

Prepared for the ENMCA Utrecht meeting on 7 April 2014

March 2014

Questionnaire on the implementation of the alert mechanism under Directive 2013/55/EU

The aim of this questionnaire is to collect ENMCA participants' views on the development and implementation of the IMI alert mechanism.

The legal basis for the alert mechanism is Art. 56a of Directive 2013/55/EU published in the European Union's official journal on 28 December 2013. The article is reproduced in full at Annex A.

We would be grateful if you could take the time to think about the answers to the questionnaire ahead of the ENMCA meeting in Utrecht as they may form the basis of our discussion.

Following the meeting, we would appreciate written responses to the questionnaire **by Friday 18 April**. Please send your completed forms to contact@enmca.eu.

Thank you very much in advance for responding to this questionnaire.

ENMCA Coordinators

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CONTACT DETAILS

ENMCA participant:

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Name of respondent:

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Person to contact in case of questions:

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I. IMI FILE AND APPLICATIONS

1. What, in your opinion, are the main advantages of the proposed alert mechanism?

2. Which sanctions would you like to see transmitted between competent authorities using the alert mechanism? i.e. the scope of information.

☐ permanent prohibition	☐ temporary prohibition	☐ suspension
☐ supervised practice	☐ criminal proceedings	☐ fraudulent documents
☐ other, please state here:		

3. In your opinion, what would be the most effective way for competent authorities to find information on past sanctions?

4. In your opinion, how should information received in an alert be stored by competent authorities? Should authorities be able to save the alert in case the doctor subsequently applies for recognition?

5. Will the time frame for sending an alert ("at the latest within three days from the date of adoption of the court decision…") be achievable for your organisation and do you foresee any difficulties with compliance? Please give details.

6. Are there any aspects regarding the introduction of the alert mechanism via IMI that you think require further clarification? If yes, please provide details.

7. Please indicate if you are content for ENMCA to share an anonymised summary of the findings from this questionnaire with the European Commission.

☐ Yes	☐ No