

Section 3 (v) “Solutions”

Introduction and scope

The HMA road map document indicated the need for improved communications between EU member states, particularly on emerging drug safety issues. The communications group’s view is that improved communications will be characterised by:

- Better and, where possible, more timely communication between member states. This could include, for example, the sharing of communications tools such as press statements and background briefing.
- A more detailed understanding of the different “communications environments” faced by each member state. For example, the attitude and approach of newspapers and journals across the EU varies – the media in some countries are routinely more aggressive on drug safety issues than in others. This will have an impact on the timing, style and tone of communications with different media outlets in different member states. Member states are best placed to communicate within their territories, as they understand the communications environment.
- Recognition that communications on sensitive subjects require confidentiality and swift action, and that the timing and content of communications will be dictated to some extent by these considerations. This makes it inevitable that some communications will take place at short notice, making efficiency of communication all the more important.
- The development of communications mechanisms which address the need for good ongoing communications in “day-to-day” situations, as well as in more acute crisis situations.

This paper responds to these needs by suggesting a series of tools which can be developed across EU member states. The list should not be seen as exhaustive and other possibilities for development will inevitably come to light as the communications network across the EU grows. However, the tools outlined below represent a sound way to develop more “joined up” communication across Europe in the short to medium term.

Principles for good communication between EU member states

There are likely to be two channels of communication between agencies across member states on any emerging issue:

- Communications between those *regulatory officials* (eg in pharmacovigilance or licensing functions) responsible for initiating action in relation to a medicinal product.
- Liaison between *communications leads* in member states for the purpose of discussing handling strategy, sharing briefing documents etc.

There are already some strong links between *regulatory officials* in member states. The tools set out here aim to facilitate those interactions, and also to build better links between *communications leads* which have historically been less well developed. The aim is that these two channels of communication should work in parallel; in particular, the growth of a communications network should not be seen as a substitute for ongoing communication between regulatory officials.

The group identified a number of challenges to effective communication, and these are covered in other sections of the report. However, it is worth highlighting some key practical considerations here, as they have a bearing on all the communications tools which follow:

- Language – the different languages of EU member states have a particular impact on communication, and mass communication via the media especially. News items which originate in English tend to travel more rapidly as English is widely spoken across the EU; news items which originate in other languages may travel more slowly, simply because journalists, patient groups etc in other countries are unable to access them. This is an issue for member states to consider, not just when dealing with difficult news stories but also when promoting good news.
- Communications culture and systems – the media climate and “culture” is very different in different member states, and the same story may therefore be reported in quite contrasting ways. Similarly, the healthcare infrastructures differ, and so communications with healthcare professionals and patients will need to be tailored for each country. *Communications leads* are best placed to assess how an issue will “play out” in their own country, and to manage the communications with their audiences.
- Time difference – There is up to a two-hour time difference across the EU. A communication issued in the mid-afternoon in western Europe will therefore hit Eastern Europe at the very end of the day; similarly, an early release in the east may hit the west before staff are in the office. Careful consideration needs to be given to the timing of announcements.
- Resources – good communication takes time and money. Communications tools need to be proportionate to the task in hand, and manageable both in financial terms and staffing terms. For example, translation is costly, and judicious use will need to be made of translation to ensure that resources are effectively used. Similarly, regular meetings of *communications leads* are costly, and alternative channels of communications will need to be identified.

Tools recommended by the group

The group recommends the following communications tools to address the issues outlined above:

- The creation of a formal network of *communications leads* in each agency
- The formation of a series of small “standing groups” to consider ongoing communications issues and make recommendations for how they are addressed
- Agreement of some guidance on the sharing of information, including what is shared, when and with whom
- In any incident or emerging issue, the designation of a member state(s) responsible for producing and circulating briefing materials
- The development of a communications “toolkit” which provides a set of model resources for handling communications on medicines issues
- The creation of a routine distribution mechanism for circulating briefing materials

Model

This section expands on the suggestions for improving communications outlined above.

Formal network of communications leads

The management of communications issues varies between member states. Some have a dedicated full-service communications function including media relations, stakeholder communications and public affairs staff. Others are likely to have a more focussed function specialising principally in media relations, whilst others have no dedicated communications staff at all.

However, it is proposed that every Agency designate a *communications lead*. This person can function as a “gatekeeper” for information and briefing, passing relevant information from within their own Agency to *communications leads* elsewhere in Europe, and cascading information they receive from elsewhere to others within their own Agency.

It will be important to note that:

- These individuals will need to establish strong and effective working relationships, not least in order to assess accurately the subjects on which it is likely to be helpful to share information between member states
- Communications between these individuals will not substitute for communication between *regulatory officials* (see above). Indeed, if communication is to serve the interests of public health, contact between *communications leads* should be closely linked in to that between the *regulatory officials*.

The Dutch medicines agency has already taken the first steps in trying to bring *communications leads* from agencies across member states together, and it is now proposed to create this network as a formal HMA group with meetings twice each year. Work is being done separately on defining the role and remit of the group, but it is proposed that this group should form the basis of the formal network of *communications leads*.

Formation of communications standing groups

Communication is not just about crisis communications; there need to be mechanisms for good ongoing communication on a day-to-day basis, or to tackle difficult long-term issues. To some extent, this will be addressed through ad-hoc contact between *regulatory officials*, and increasingly between *communications leads* as they build relationships.

However, there will also be particular issues which require more detailed consideration – for example, particular ongoing safety issues about a product or class of products; issues around communication of benefit and risk with the public; or the development of protocols and guidelines on information sharing. Issues such as these may require the formulation of joined-up action plans across Europe, or the development of recommendations for the HMA to consider.

In these situations, it would be impractical and unwieldy to bring together large groups to address the issues – the cost and time would be too great. It is therefore proposed that a number of smaller “standing groups” are set up. There would be initially perhaps four standing groups, each made up of 4-6

communications leads from across EU member states. The standing groups would be sub-groups of the network of communications leads.

A standing group could be called into action on a particular issue either by the chair of the communications network, or potentially at the direct request of the HMA. Whoever calls the group into action would specify the remit of the work required, the output expected, the timescale, and to whom the output is to be delivered. Although some groups will be inactive some of the time if there are no ongoing projects, the groups will be permanently constituted so that they can be called into action easily whenever needed.

The standing groups will therefore be able to:

- Further develop good working relationships between member states
- Share expertise between member states
- Convene relatively quickly
- Work rapidly and, if necessary, remotely
- Tackle ongoing and “day-to-day” issues

It is envisaged that the standing groups could be used to develop some of the tools identified below (eg guidance on information sharing, communications toolkit).

Guidance on the sharing of information:

It is unrealistic to agree hard and fast rules about what information should be communicated, when it should be communicated, and with whom. The range of different issues which occur and the variety of communications environments in different member states make entirely prescriptive arrangements unworkable.

However, it should be possible to agree some guidance and rules on information sharing which includes:

- Confidentiality agreements which govern the exchange of information between agencies; these would, by definition, need to be reasonably tightly defined. Further discussion is needed on what arrangements would need to be set out in such agreements to allow agencies to function optimally.
- Some guidance on the timing of communications with different groups, including the relative timing of announcement to those groups (ie who is informed first)
 - When Agencies inform each other of issues
 - When healthcare professionals are informed
 - When companies are informed
 - When patients and the media are informed
- Guidance for companies on what communications they are expected to initiate with regulators during crisis situations

It may be possible to develop this in the form of a single guidance document, and this could be an early task for one of the standing groups.

Production and circulation of briefing materials

When an issue emerges about which widespread communication is likely to be necessary, it is normal for a member state(s) to emerge as the natural choice to take the lead on developing communications materials. There may be a number of drivers behind this choice:

- Media pressure. If a member state anticipates being asked a number of questions by the media on any given subject, it is likely to want to develop its own briefing material.
- Healthcare professional issues. If a member state anticipates being asked questions by its healthcare professionals on any given issue, it is likely to want to develop its own briefing.
- Patient issues. If there are likely to be a number of questions from patients, perhaps because a medicine is more widely used in one country than in another, then a member state is likely to want to develop its own briefing.
- Rapporteur status. A country which was a rapporteur for a centralised license application is likely to wish to produce its own briefing.

The choice about who produces briefing should not be seen as an attempt to designate a single member state as responsible for producing briefing. Instead, this should be an opportunity for discussion amongst *communications leads* on what the pressures in their own country are likely to be, and what types of briefing are likely to be developed where.

Briefing documents could then be shared between *communications leads*. This will lead to greater opportunities for sharing of information, and earlier recognition of any areas of potential conflict, whether real or perceived.

It is envisaged that the developing communications network will lead to the creation of an e-mail distribution list which, in the first instance, could be used for alerting other *communications leads* to forthcoming issues and sharing information.

Language will be a key issue here. It is not proposed to translate every document into English. Instead, it is proposed that:

- A short briefing (initially, most likely to be in the form of an e-mail) will be circulated to *communications leads* in English by any country producing briefing on a significant media issue.
- Any supplementary briefing documents will be produced and circulated in whatever language the country in question generally uses for its briefing materials. It will then be up to individual member states to decide whether to have that material translated.
- Any relevant supplementary briefing documents which have for any reason been produced in English will also be circulated.

Communications toolkit

[Note: this section will need to be revisited in the light of the section on stakeholders, as there may be other stakeholder groups which need to be addressed within the toolkit].

It has been noted above that different member states have different levels of communications expertise at their disposal. In this light, it may be helpful to develop a communications “toolkit” containing some models and templates for the communications resources needed in a mass communications exercise, and some guidance on how to use them. This could include:

- Key messages documentation
- A press release
- A question and answer document for media interviews
- A patient information sheet
- An “evidence base” document
- A question and answers document for patients
- A telephone helpline briefing sheet
- A web-based communication resource template
- A communication to healthcare professionals
- A communication to key opinion formers (eg members of government, parliament etc)

It is not intended that the toolkit should be proscriptive – different countries will have different approaches and formats for documents. Instead, it will aim to define good practice in each type of document, and raise questions/issues which need to be considered in the development of such a document. In effect, it will be a detailed checklist which can be used as an aide memoire in developing communications tools.

The development of this toolkit could be another early task for one of the standing groups.

Distribution list

For this model to work effectively there needs to be a mechanism for rapid dissemination of information amongst communications leads. Initially, the way of doing this will be to establish an e-mail distribution list through which communications resources can be shared. However, it would be more effective to develop a secure web area, accessible only to *communications leads* – this could include downloadable communications resources posted up by the leads, as well as a discussion area for exploring issues arising as the communications around a particular issue develop.

It is recommended that such a resource is developed, and is hosted by one of the member states.

Conclusion

This paper briefly outlines a proposed model for building communications between member states, particularly around drug safety issues. The HMA is invited to discuss and approve this model.