

Section 3 (iv) Daily Life Communication vs. Crisis Communication

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It takes years to build trust and a good reputation/image, and seconds to ruin it

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Summary

Well functioning daily routines for communication is the best way to be prepared and manage crisis and crisis communication. Some important assumptions are a communication strategy, communication competence both amongst the leaders and in the communication unit, communication as an integrated part in all key working processes. Routines for exchange of risk information is necessary, as well as routines for dialogue stakeholders.

Communication and crisis management has to be planned, trained and tested under “normal” conditions.

Key principles for communication have to be followed in a risk- and crisis situation. The main conclusion is a common SOP for the EMEA and the NCAs, and maybe including an extranet-service for NCA's, EMEA and commission for exchange of information.

Introduction

The media is working 24 hours in every weekday. News-flow travels fast in electronic networks and via internet. The authorities are faced with growing demands for current and accurate information as well as need for quick measures in crises situations. Delays are hardly accepted in the eyes of the media and the citizens. The process of communication and information about the safety of is becoming more and more unseparable from the Pharmacovigilance activities. It is also time-consuming and demands human resources i.e. expertise in the field.

One of the main goals is, first, to decide what is relevant information for the public and for the media, and second, to transmit all the relevant information in a clear and comprehensive way and at the “right time” to the Healthcare Professionals (HCP), the public and the media, in a clear and comprehensive way, and in the “right time”. It is a problem when the media is publishing information before the Competent Authorities (CA) and most of the times without scientific criteria or deep knowledge of the problem. The NCAs have been forced to react simultaneously with financial markets when multinational companies have done their own decisions and published the information in ways and hours of stock exchange.

In a world where communication is a permanent tool in daily life, where the therapeutic arsenal is hugely increasing in number and specificity, and the public

attention is also focused on pharmacological therapeutic, it is an urgent need to organise these issues in order to achieve a permanent, scientifically correct and useful safety information.

Success in communicating safety on medical issues for the public is also vital to the image and the mandate of medicine control authorities.

Communication and information in daily life

Only if expectations are more realistic can anxiety, and sometimes crisis, be avoided

Good daily routine for communication is a criteria for success in managing crises and the best way to be well prepared for a situation of crisis.

Every NCA will be better prepared with a communication strategy which includes principles for communication, defined target groups, internal roles and responsibilities etc.

Defining roles and responsibility

The head of the agency is responsible for having well established routines for internal and external communication. An excellent daily routine provides a well established system for cooperation between the experts and the communication unit. The head of communication must have a defined role as strategic adviser for communication both in the daily life and during a risk or crisis situation. The head should also guarantee that communication professionals are connected to the processes so that they get all the relevant information necessary for their work.

Communication competence

An assumption for succeeding in communication is a certain competence in communication theory, both amongst the leaders as decision-makers and in the communication unit as advisers. This is also important for the cooperation between them.

The leaders should be familiar with the various tools of communication and possibilities to communicate. Those who give public performances should also be trained and have good personal communications skills.

Communication and Pharmacovigilance

Communication has to be integrated in daily Pharmacovigilance activities as well as other key working processes. It is a challenge to communicate to all stakeholders that medicines are not without risk. Alongside the many who benefit; medicines have caused, do cause and will continue to cause lesser or greater harm to many people. No human activity is absolutely safe or without some element of risk. This applies equally to medical care which is amongst the most complex of human enterprises. Like science itself, medicine is full of uncertainty and unresolved questions, though we do not often understand or admit this. Medical action or inaction always carry some risk.

Only if expectations are more realistic can anxiety, and sometimes crisis, be avoided. Open debate and wide collaboration is essential in order to prevent negative reactions.

The truth about the nature of drugs has long been understood by scientists, but the message has not reached the general public. This message has to be communicated to all the stakeholders to create a consensus about the risk.

In its report for 1969-70 the UK Committee on the Safety of Drugs included the following:

“No drug which is pharmacologically effective is entirely without hazard. The hazard may be insignificant or may be acceptable in relation to the drug’s therapeutic action.

Furthermore, not all hazards can be known before a drug is marketed; neither tests in animal nor clinical trials will always reveal all the possible side effects of a drug. These may only be known when the drug has been administered to large members of patients over considerable periods of time”.

Routines for exchange of risk information

Risk communication is the interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions. Defined partners and good routines for communication is a part of the Risk Management Strategy of the NCA.

Communication with stakeholders

Clearly defined stakeholders and routines for communication with them must be a part of the daily routines.

Contact with and input from patients/or consumer associations could be useful to improve communication.

Strategic planning of the communication activities

As a part of the communication goals to build a positive image of the agency, daily routine communication activities has to be planned and constantly evaluated. Every NCA should have their own communication strategy, crises management plans and annual operational plans for routine communication.

Some existing mechanisms

As a basic routine for transmitting safety information we have already established several mechanisms such as:

- SPC and Leaflets – all of them should be updated and available in relevant publications and on-line (NCA and Marketing Authorization Holders)
For HCP and public
- Non Urgent Information (NUI) in the EEA (do we need more rules for this procedure?)
Among CA
- EEA Rapid Alert System (RAS) (do we need more rules for this procedure?)
Among CA
- Dear Healthcare Professional Letter (DHCPL) – EMEA guidelines are established
NCA and Pharmaceutical Industry
For HCP
- Publication of information through EMEA and NCA sites
For HCP and public
- Publication of Regular Pharmacovigilance Bulletins
For HCP

- Publication of Regular General Regulatory Bulletins
For HCP
- Regular scientific publications (ex. “Drug Safety”, “Pharmacoepidemiology and Drug Safety”)
For HCP

Concerning these different ways of transmitting information may be we should analyse each of it and try to improve the results we obtain through them - or even create new ones.

To prevent CA to be surprised by an unexpected crisis, one should also include the “crisis prophylaxis”, as a part of the routine process.

Plans for crisis

Communication and crisis management too has to start before a crisis occurs and has therefore to be planned, trained and tested under “normal” conditions before a crisis occurs. Daily life communication, that runs smoothly, is the basis for a successful crisis communication.

In the event of a crisis in pharmacovigilance matters communication should be part of a HMA crisis management plan, defining and communicating roles and responsibilities to all players involved. The crisis management team under the auspices should be composed of pharmacovigilance and regulatory experts as well as of communication experts/public spokespersons. The crisis team should be able to become operational within shortest time.

Identifying some scenarios will be a method for making realistic plans.

Communication has to be an integrated part of the plan.

The common main tasks for the NCA communication plan are:

- to make the communication flow both horizontal and vertical in an organization and between the organization and the players/stakeholders
- To establish an internal organization or group to handle the communication in crisis and
- To keep trustful communication with the media and the public.
- To support the tasks of the NCA with means of communication
- To promote smooth communication flow and interactions within the agency and its stakeholders.
- To improve the knowledge and image of the work of medicine control authorities

Cooperation on an European level

There are systems for cooperation between the pharmacovigilance experts in Europe. To improve the communication on an overall level, a network of communication professionals will simplify the flow of and the access to important information between the NCAs and between the national level and EMEA. The newly established network is to be given an important role in managing a crisis. The network has to be well functioning with well established communication routines.

Communication and information – to deal with a crisis and urgent matters

It's all about trust = competence + openness + justice + sympathy

A crisis-situation (in pharmacovigilance matters) arises with new knowledge about a medicinal product, which could have a serious impact on the health of patients. A crisis, in the public eye, can also evolve as a result of an under-estimated aspect of the safety of a drug.

The management of the crises and the communication about the risk for the patients is vital for the public trust to the authorities and for the reputation of the agencies in particular.

Principles for communication in a risk- and crisis situation

- Quick and open information is a matter of keeping trust during a crisis situation.
- Transparency, predictability and coordination of the communication from the medicines agencies and other governmental authorities are matters of concern for the consumers
- Information about the safe and effective use of medicinal products is a public health responsibility and such information must be communicated to HCP and relevant partners at all stages of risk management
- All new or emerging safety information and change in the benefit-risk balance evaluation should first of all be disseminated to HCP in first place and at the right time (In practice Dear-doctor-letters are not reaching the doctors before the news are already in the media/public)
- The information must be clear, concise and as complete as possible, objectively presented and not misleading
- This communication needs the cooperation and coordination of all partners, also including the media and patients organisations
- The information (facts and messages)transmitted should be as harmonised as possible among EEA, through a common communication and information plan for CA
- In order to evaluate wheter the information has been effective, received in time, understood and adhered to: the impact of the information transmitted must be measured and analysed.

In a situation of crisis:

National level (routines for reporting to EMEA is a part of the communication)

- The NCAs has a plan for crisis management
- The Head of the agency is responsible for the communication. The Head of communication is advisor for the Head of the agency and the crisis organization
- Open, active and quickly communication. To avoid a situation where the media is ruling, the agencies are encouraged to be proactive. The cases of crises communications could be discussed in the communications network to improve the crises management process.
- To allow health care professionals to provide immediate and adequate information when consulted by patients, information from the NCAs must reach them in time.

- Focus on facts and the measures/actions that has been done, what will be done and the considerations of risk these actions are based on
- The agency has the responsibility for the communication on their special field (important to stress this when the crisis suddenly becomes a political case)
- Cooperation with the Ministry of Health and other relevant governmental authorities follows certain national routines
- Cooperation between experts and the communication staff in the national agency and the Ministry of Health
- Daily status report to the players/stakeholders (“no news” are also news)
- The internet will be the main channel for quick and fresh information
- Consensus-building between NCAs should not go on the cost of the content of information.

European level

EMA is responsible for the coordination of the information in cases of centrally approved products (there are situations when the crises starts at a certain country/countries. The Pharmacovigilance group has rules of procedure for different situations. Could we suggest that in cases of national procedure or mutual recognition procedure the member who has the relevant or best information of the crises is responsible for providing/coordinating the information?)

National cultures and national media should be recognised. Harmonized texts for common press releases are often difficult to write and it takes too much time (for example time zone differences). To prepare the national press releases and answers to media inquiries the facts and agreed points of views should be available to the communicators and pharmacovigilance people of EMA and the various NCAs.

- The information flow between the players through the established system (a description of this?) In order to avoid escalation of a crisis, profound information should be shared as soon as possible between the NCAs themselves and also between NCAs and the relevant stakeholders.
- Information to/communication with the stakeholders before, if possible, or at the same time as the medias
- The media messages are focused on the situation of the patients (sympathy), clear directions for stakeholders on necessary actions.
- Press releases should be coordinated between NCAs (not texts but facts, points of views and timing)
- All information is to be found on a website where all the players/stakeholders know that the last news and all the facts are published (the question of languages...perhaps there could be at least permanent link list to NCA's webpages/press releases where you could see all published news even if they are not yet translated to english. Preparatory work, facts and points of views should be in english)

Main conclusions

The EMA together with the NCAs should develop a common SOP, including may be an extranet-service for NCA's, EMA and commission for exchange of information.

Extranet is a necessary tool for changing information confidentially, before publishing it at the national websites.

If a safety problem arises in a Member-state, the NCA should immediately inform other NCA through the extranet-site.

In every NCA one should have a group of two persons (one – Pharmacovigilance and one - Communication) to check the new information regularly.

If a crisis occurs, the NCAs ought to cooperate with the stakeholders to ensure that harmonised information is available. The media and the stakeholders should be informed that the latest news about the matter will be published on the NCAs internet site (“no news” is also news).

Five main questions linked to crisis and risk communication:

- **What do we know?**
- **What don't we know?**
- **Why don't we know it?**
- **What measures are being taken to reduce the risk?**
- **When do we come back with more information?**