

Section 3 (ii) Defining Communication Roles

In the past few years, communication has become a major challenge for all national authorities, due to different reasons. First of all, most of the final stakeholders (general public, health professionals, journalists, politicians) have become increasingly sensitive to health products issues and request more access to information relating to the product evaluation process (efficacy, safety and quality). Besides, we face a growing yearning for transparency of the decision making process in general, which applies in this field. Finally agencies are summoned to develop their accountability in front of these stakeholders.

This situation leads to two major challenges for national authorities : convincing internally that information and communication are key objectives which must be considered as part of the job of regulators, and developing a communication policy which makes the system and its responsibilities understandable for stakeholders.

Making information and communication part of the duty of regulators

National competent authorities rely on scientific competence and resources. Their staff is mainly preoccupied with the intrinsic quality of the evaluation process (sometimes also inspection and laboratory control). The scientific staff in charge of the marketing authorisation process was chosen upon its technical skills, often high level, and was not asked to take information and communication issues into account, at least initially.

More globally, national authorities were not interested in information and communication issues until recently. We, as a whole, used to consider that the job was carried out at that very moment of the decision making, concerning marketing authorisation as well as restrictions of use or even withdrawal. Therefore the production of information and communication resources were scarce and were not considered as crucial. Besides, most national competent authorities (NCA's) are authorities for much more than medicines e.g. clinical trials, medical devices, distribution, inspections, laboratory control, this means than public demands could be on many other areas than medicinal products.

Over the past few years, chief officers and staff in contact with outside world have been increasingly aware of the importance to inform and explain decisions and make the information available to final stakeholders. This situation has led to the creation of communication departments in most national authorities and to a growing share of time dedicated by Heads of medicines agencies on communication issues. Up till now, this evolution has not completely reached the scientific staff. In many cases, this staff considers information and communication efforts as irrelevant, time consuming and not in the right timetable. The legitimacy of the questions coming from the outside, especially from journalists, has not been fully accepted yet.

The contradiction between new communication policies of the national authorities' top management and the reluctance of the scientific backbone must be addressed, because scientific staff is needed to provide good information and moreover because an efficient communication policy relies on the implication of scientists.

Steps forward would be to:

- initiate a real debate with the scientific staff on the information and communication challenges, making them aware of its relevance
- address the difficulty of releasing information on an incomplete decision process by drafting a standardised procedure
- increase the communication skills of scientific officers, by specific training

Making the medicine regulation system understandable for final stakeholders

In the meantime, we have to increase the global understanding of the regulatory system, and put boundaries to our responsibility and accountability towards public opinion. As a matter of fact, patients, journalists and health professionals are often genuinely convinced that either the role and powers of the national authorities are far bigger than in the real world, or that we are completely helpless.

This leads to major misunderstandings, such as :

a) considering that regulators are almighty:

- asking if we conduct and realise the clinical trials ourselves and being disappointed when hearing the answer
- asking why products considered as “me-toos” or minor innovations get market approval and why the older products stay on the market when a new class gets access

b) considering that we are helpless :

- dismissing the role of the national authority considering that the competence and abilities have completely been transferred to EMEA
- considering that we are unable to properly evaluate products because of the industrial links declared by the external experts we rely on.

Therefore, pedagogy is increasingly needed to perform our task. The regulatory system itself is very procedure focussed, complex and difficult to understand. An effort must be made to tell about the system itself, otherwise all contacts with – especially journalists- will have to start with telling basic knowledge instead of using the time to talk about the ‘real’ issue.

First of all, it is important that the context in which we take actions is well-understood by our final stakeholders, especially in a period in which all decisions are scrutinized by the outside world. Besides, if we want to succeed in convincing our scientific staff to be more transparent and communicative, we have to protect them from the basic questions relating to powers and competence. Finally, when confronted to a crisis, it is crucial that the outside world is able to sort out the responsibilities of the different bodies involved. During the Vioxx crisis, we have experienced that it was not clear for the general public that the owner company of a product could legitimately withdraw its product out of the market for industrial reasons, even if public health reasons were advanced.

In that field steps forward would be:

- to develop communication and information tools on the role and powers of national authorities
- to initiate special information sessions for journalists
- to create links with interested parties eg. Patient associations.