EUROPEAN MEDICINES AGENCY

EU Regulatory Workshop on Medication Errors

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Discussion of legal consequences [of reporting] for healthcare professionals

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Performing a ***high level of quality*** of healthcare is a main objective for European bodies in relation with MS healthcare systems

Quality (healthcare system) → **Security** (patients, staff) → **Prevention** (harm) → **Information** (risk sources) →**Reporting** (adverse events) → **RCA** (evaluate all information scientifically and learn from this) →**Improving preventive measures** (risk minimisation)

Changing views on reporting by healthcare staff

Problems detected in some EU MS to implement an adverse events reporting system by healthcare professionals (including medication errors):

1) *Cultural biases* (“being a snitch”; “reporting brings always complications”; “patient’s safety has nothing to do with my healthcare”).

2) *Corporative culture* (“my colleagues do not ever make mistakes”; “if today I cover you, tomorrow you will cover me”).

Reporting pre-conditions

To improve reporting of medication errors and other adverse events by healthcare professionals some pre-conditions are needed:

- ✓ To create an environment of trust: implementing a confident environment between professional/patient
- ✓ A transparency based system.
- ✓ Facilities for open information.
- ✓ Emphasize the advantages of a reporting system neutral legally
- ✓ An isolated reporting programme from other legal consequences (preventing to extend the adverse events reporting system to other legal duties of communicate harm to concerned authorities (police, courts).

EU legal support of reporting

- ***Amended Directive 2001/83/EC***

  Directive 2010/84/Eu of the European Parliament and of the Council of 15 December 2010 *amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use*.

- ***Other European Legal sources***:

  Council of Europe *Recommendation Rec(2006)7 of the Committee of Ministers to member states on management of patient safety and prevention of adverse events in health care*.

Amended Directive 2001/83/EC (1)

Recital (5)

The definition of the term 'adverse reaction' should be amended to ensure that it covers noxious and unintended effects resulting … from *medication errors* (…).

- a reasonable possibility of there being a causal relationship between a medicinal product and an adverse event, should be *sufficient reason for reporting*.
- the term 'suspected adverse reaction' should be used when referring to *reporting obligations*.
- Member States should ensure *that reporting and processing of personal data* related to suspected adverse reactions, including those associated with medication errors is carried out *on a confidential basis*.
- the principle of confidentiality *should not affect the obligations of the persons concerned to provide information under criminal law*.

Amended Directive 2001/83/EC (2)

Recital (17)

"Member States should operate a pharmacovigilance system to collect information that is useful for the monitoring of medicinal products, *including information on suspected adverse reactions arising from use of a medicinal product* within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, including overdose, misuse, abuse and *medication errors*, and suspected adverse reactions associated with occupational exposure. Member States should ensure the quality of the pharmacovigilance system through the follow-up of cases of suspected adverse reactions. (…)."

Amended Directive 2001/83/EC (3)

Article 1.11.

'Adverse reaction: A response to a medicinal product which is noxious and unintended.'

Article 101.1.

'(…) The pharmacovigilance system shall be used to *collect information on the risks of medicinal products as regards patients' or public health*. That information shall in particular refer to adverse reactions in human beings, arising from use of the medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, and to adverse reactions associated with occupational exposure.

2. Member States shall (...) *evaluate all information scientifically, consider options for risk minimisation and prevention and take regulatory action* concerning the marketing authorisation as necessary (…).'

Council of Europe Recommendation Rec(2006)7

iii. promote the development of a reporting system for patient-safety incidents in order to enhance patient safety by learning from such incidents; this system should:

a. be non-punitive and fair in purpose;
b. be independent of other regulatory processes;
c. be designed in such a way as to encourage health-care providers and health-care personnel to report safety incidents (for instance, wherever possible, reporting should be voluntary, anonymous and confidential);
d. set out a system for collecting and analysing reports of adverse events locally and, when the need arises, aggregated at a regional or national level, with the aim of improving patient safety; for this purpose, resources must be specifically allocated;
e. involve both private and public sectors;
(…)

The need for a legal support for a reporting and register of adverse events

- An adequate legal framework has a great importance in order to ease and to give the necessary support to the establishment of a system of reporting and register of incidents and adverse event. The Directive 2001/83/EC provides a supporting core for the essential legal framework on reproting medicament errors.

- Main purpose is to establish the legal issues which can be relevant in order to determine the position of the different legal professionals (judges, lawyers) in relation with such a reporting and register system especially when the later includes the communication of adverse events with harmful consequences for any person (patients or staff).

The purpose of reporting by HCP. 1

- The guarantee for the efficiency of reporting is based on the confidence of the healthcare professionals, so if they consider that the aforementioned system can be used with control and/or sanctioning purposes (namely for the reporter), the number of reports will be kept certainly low.
- The establishment of a national reporting system of adverse events in this fields must be linked exclusively with the improvement of the *healthcare quality*.
- A goal of a reporting system should be isolated from any other labour, court or legal issues.

The purpose of reporting by HCP. 2

- Finally it should be stated what is the status of the members of the committees responsible for the Root Cause Analysis. Due to the analysis performed of the adverse event by these committees its members could achieved an in-depth knowledge of the adverse event, being capable of identifying the persons involved in the adverse event resulting in harm.

Summary of conclusions. 1

1) One of the main results of an healthcare quality plan is the need to reinforce the confidence relationship between HCP and patient.
2) The availability of a report and register system for adverse events related with the security of the patient represents one of the main goals of the health systems in developed countries and it includes medicaments
3) The experience in some countries shows the increasing importance of adverse events reporting systems, based on different national/regional models and, at the same time, founded in some common aspects:
   - the non-punitive character of the reporting system.
   - Its exclusive orientation to a learning process by health.professionals and to the prevention of harm.

Summary of conclusions. 2

4) If we adopt a national point of view we have to start by assuming that the medical profession is submitted to different fields of legal responsibility (mainly torts and penal negligence).
5) The analysis of the rulings passed by the courts of different jurisdictions (in Spain) shows that a substantial part of them could have been avoided if having in place a reporting system (i. e., prescribing and medication management and other like hospital infections, failed diagnosis).

Summary of conclusions. 3

6) The possible link between an adverse event and a case of legal responsibility which is known by the health professionals, constitutes a problem in order to create an adverse events reporting system, especially when there is a legal duty to declare as witness in a process and to report to the authorities (to police or to the courts) any crime they are aware of.

7) From an strictly legal point of view, in some countries (Denmark, USA) legal provisions have been established so as to guarantee the indemnity of the reporter in relation with his/her work and judicial environment as well as of the staff working at the reporting register office.

Summary of conclusions. 4

8) The reporting system should be established on a confidentiality basis of the reporter's identity. A matter for discussion has been whether reporting should be kept anonymous.
9) Furthermore both the creation and the come into operation of a register with the reports resulting from the adverse events system could be subject to the legal regulation on personal data protection.

Summary of conclusions. 5

10) Related to the information registered in an hypothetical system of adverse events it should be guaranteed that it will not be accessible to third persons, specially insurance companies and judges and courts (particularly from the criminal jurisdiction) if one of the parts of the process asks for the inclusion of a piece of information registered in an adverse events reporting system.

11) A reporter should be entitled to avoid to report to the authority (the police or the judge) and to declare if the declaration is imposed by a judge according to the law.

Summary of conclusions. 6

12) The same solution can be caught for the members of the teams in charge of the Root Cause Analysis and of the revision of the reported adverse events.
13) To ensure a succesful implementation of a reporting system of medicament errors and to encourage reporting by HCP in a first step it should be voluntary (not compulsory), anonymous (reporters not being identified) and confidential.
14) To improve the RCA both adverse events (medication errors), causing harm or not (near misses) should be a matter for reporting.
15) In the specific cases of errors of authorised medicaments for the market that occur at patients home a specific solution for reporting should be given.

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Thanks for your attention!!

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