Signal identification and processing

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Source of signals

Noteworthy cases

The Regional Pharmacovigilance Centres (RPCs) draw ANSM's attention to reports of adverse reactions that are potential signals, in the form of noteworthy cases. The adverse reaction is deemed to be a noteworthy case if it is unexpected or occurs in at-risk individuals.

Noteworthy medication errors

The RPCs also draw ANSM's attention to reports of noteworthy medication errors that are potential signals, in the form of noteworthy medication errors (the errors involving the most risk).

Medicine use surveillance

The purpose of medicine use surveillance is to understand how medications are used in real-life conditions. It thus helps detect, quantify, and assess the potential consequences of any type of misuse and use not in compliance with the terms of the MA and/or guidelines.

This surveillance process is implemented at different levels :

- **by conducting pharmaco-epidemiological studies**

  Within the framework of overarching health product surveillance, in late 2018, ANSM and CNAM (French health insurance system) set up the EPI-PHARE scientific interest group, an independent public body with epidemiological expertise in respect of health products.

  EPI-PHARE carries out, manages and coordinates pharmaco-epidemiological studies which examine the use, efficacy, and risks of medicines under "real-life" conditions on large cohorts.

  This approach particularly makes it possible to identify the risks associated with health products more quickly and accurately, confirm an alert signal, and quantify it where applicable, and thus inform public authorities' health safety decisions.

  Go to EPI-PHARE

- **by recording reports of non-compliant medicine use**

  Any use that does not comply with the terms of the MA or a compassionate prescription framework (Cadre de prescription compassionnelle - CPC) exposes the patient to an excess risk. For this reason, ANSM places a particular focus on reports of non-compliant medicine use. The purpose of this surveillance is to identify cases of misuse and collect the information needed to evaluate their public health impact, in order to put appropriate measures in place to prevent or reduce these practices.

  The reports recorded by ANSM come from multiple sources :

  - the RPC network, which collects reports of non-compliant use and misuse with adverse reactions, made by

healthcare professionals and patients, and information on practices in the field ;

- patient associations and healthcare system users, as well as organisations representing healthcare professionals (learned societies, organisations, etc.), key sources of information about real-life practices ;
- ANSM's discussions with its institutional partners, especially the French health insurance system ;
- ANSM surveillance and evaluation activities ;
- manufacturers, who must monitor and collect information on use for the medicines under their responsibility, especially through educational and pharmacovigilance activities, and pass on this information to ANSM.

50 % This figure represents the increased risk of an adverse reaction occurring when a medicine is used off-label

N.B.

For manufacturers, the legislation stipulates that a company that manufactures a medicine must help ensure that it is used properly and implement every educational measure deemed necessary to inform healthcare professionals when it observes prescriptions and uses that are non-compliant with proper use. It must also notify ANSM without delay.

Scientific literature monitoring

On a daily basis, we monitor the scientific and medical literature, a key source of information for assessing the safety profile of medicines.

Potential signals are detected in any publication suggesting a risk with the use of a medicine or findings relating to the benefit-risk ratio of a medicine.

Signal processing

Signal processing through risk management

We include risk management as a core principle in all our decisions. Every incoming signal is the subject of a risk analysis which helps determine those with a greater risk and requiring specific processing.

This analysis is based on medical, scientific, public health, sociodemographic, social and environmental criteria.

Four risk levels can be assigned to the potential signal:

- low risk,
- moderate risk,
- significant risk,
- high risk.

The potential signal will be processed differently according to the risk level.
Certain signals require more in-depth analysis using additional tools for better characterization (e.g. implementing a pharmacovigilance investigation, a pharmaco-epidemiological study, an impact study, or a usage study, etc.).

Signal processing: collective assessment with our stakeholders

All signals are processed collectively at ANSM through our medical, scientific and technical expertise.

We use all of the safety data available for cross-referencing purposes (e.g. good pharmacovigilance practices statistical signal detection, periodic safety update reports, etc.). We analyse the data to confirm or refute the signal. This data is shared between different divisions who communicate during the initial signal analysis phase.

This collective process extends beyond ANSM, by enlisting experts, representatives of patient associations and healthcare professionals or through referrals to bodies outside ANSM.

It is particularly organised within the framework of standing scientific committees. These committees use a double-review process to confirm the risk level of signals, particularly signals assessed as having a low risk. For signals with a greater risk, the collective review is used to enhance the characterisation, if needed, and discuss ANSM’s action plans. In this way, patient representatives and healthcare professional experts help safeguard signal assessment, and also follow-up actions.

Some signals require a more in-depth analysis with the use of supplementary tools to obtain a better characterisation (e.g. setting up a pharmacovigilance survey, a pharmaco-epidemiological study, an impact study or a utilisation study, etc.).