Enhanced surveillance of medicines

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Alongside the signal assessment-based approach, we are engaged in the proactive surveillance of certain medicines. In order to optimise the prevention and anticipation of risks, we establish an enhanced surveillance programme which identifies and monitors potentially dangerous situations and ensures the implementation of preventive risk-reduction measures. This programme is based on a risk analysis combining the exposure and severity of certain situations, the type of population concerned and the characteristics of certain classes or products without there necessarily being an identified signal.

We employ several surveillance tools:

Pharmacovigilance surveys

A national pharmacovigilance survey consists in carrying out a retrospective and/or prospective assessment or reassessment of the risk of an adverse reaction to a medicine or a class of medicinal products, in order to confirm a potential signal, characterise a proven signal and monitor the safety profile of a medicine.

The survey is conducted by an expert from a regional pharmacovigilance centre (CRPV) at the request of ANSM. The conduct of the survey must meet the objectives set within the allotted time frame.

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: pharmaco-epidemiology studies 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.

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Monitoring of medicine sales and reimbursements

The implementation of reliable monitoring of health product sales is key in the field of medicines and public health. This is firstly because this data provides a sound base of information required to manage the supply of health products to the population, and secondly because it offers, within an epidemiological framework, depending on the level of detail, an initial estimation of populations’ exposure levels to this products.

Since 2019, EPI-PHARE’s activity has included the collection of sales data, or more broadly use data, along with the processing, analysis and dissemination of this data to bodies within and outside ANSM.

This data particularly pertains to:

- sales – generally from sales reports from pharmaceutical companies, wholesalers or pharmacy panels,
- prescription,
- and reimbursements, retrieved from online databases relating to inter-scheme Health Insurance medicine

expenditure.

This data taken from several complementary databases is used to investigate pharmacovigilance cases, review the benefit-risk balance, supply tension or shock shortages in particular.

Statistical signal detection

Signal detection is mainly based on reported pharmacovigilance signals. While qualitative analysis is essential, a statistical approach can contribute to signal detection. It consists in identifying abnormally frequent medicine/effect combinations.

This detection system was established by ANSM using the national pharmacovigilance database (BNPV). This approach is then consolidated by cross-referencing with other available data to confirm the identified risk and prevent any bias.

Learn more about statistical signal detection +

This quantitative approach is essential but not sufficient on its own for signal detection. When applied to large databases (over 900,000 cases for the National Pharmacovigilance Database), its statistical power can highlight even minor disproportionalities. However, these results can be biased, leading to false negatives or false positives. Therefore, this type of statistical detection requires further validation.

To address this, the results of statistical signal detection are incorporated into cross-analysis of signals, pharmacovigilance surveys, and pharmacovigilance expertise. This aims to enhance the sensitivity of the signal detection process.

The ANSM utilises an algorithm developed by theINSERM - HiDiBiostat research team (Biostatistics in large dimensions for drug safety and genomics). This algorithm is based on the Bayesian Gamma Poisson Shrinker method. It generates statistically significant signals for a pair (medicine, adverse effect) according to the statistical model.

Monitoring of reports

ANSM then takes the reported signals, reviews them using its medical, scientific and technical expertise, and communicates with the healthcare professional and patient representatives concerned.

Surveillance database monitoring

The French national pharmacovigilance database (BNPV) was created by the first CRPV in 1985 in the Hospices Civils de Lyon, and subsequently transferred to the French Medicines Agency in 1993. The application in its current form was commissioned in June 2007.

The French national pharmacovigilance database now represents a significant source of information containing all spontaneous reports input, validated and reviewed by regional pharmacovigilance centres since 1985.

This allows the database to be queried daily, with a view to helping assess reported cases of adverse reactions, responding to questions from healthcare professionals or patients, compiling the information needed for a pharmacovigilance survey and for a review of the benefit-risk ratio of a medicine.

The French national pharmacovigilance database is a key tool in monitoring adverse reactions occurring with medicines. It is in continual use to ensure the safety of use of medicines by patients. Monitoring is carried out using qualitative or statistical approaches.

Medicines subject to enhanced surveillance

The European Union (EU) has set up a new scheme to identify medicines subject to particularly close monitoring.

These medicines are identified by a black inverted triangle printed on their package leaflet, together with a short phrase: “This medicinal product is subject to additional monitoring.”

All medicines are carefully monitored after they are placed on the EU market. However, medicines labelled with

the black triangle are monitored more closely than other medicines. This is generally because there is less information available on them than on other medicines, for example because they are new to the market. It does not mean that the medicine in question is unsafe.

- **View the list of medicines subject to enhanced surveillance**

Surveillance of risks associated with the use of medicines during pregnancy

Pregnancy is a particular time when, as a general rule, the use of medicines should be avoided. However, there may be exceptions, particularly in cases of chronic illness or if the medicines have been prescribed in the context of pregnancy.

In order to ensure the safety of the mother and that of the unborn child, it is essential to provide tools for monitoring and assessing the risks associated with medicines and their exposure during pregnancy and breastfeeding, and also with their effects on fertility (reproduction).

This surveillance makes it possible where applicable to take the necessary health safety measures to ensure that the expected benefits are always greater that the risks to which the mother and her unborn child are exposed.

To find out more about the surveillance of risks associated with the use of medicines during pregnancy refer to the subject-specific file.