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Pharmacovigilance for COVID-19 vaccines: A 1-year experience in France

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ABSTRACT

As of February 2022, more than 130 million Covid vaccine doses had been distributed in France. During the first year of relevant vaccination, 128,766 adverse events (AE) were reported and analysed, as compared to an average of 40,000 per year for all drugs combined in the pre-pandemic years. A weekly monitoring committee was set up. Through enhanced pharmacovigilance, by February 2022, 49 safety signals had been identified nationwide and submitted to the EMA. For example, very few cases of myocarditis and pericarditis were reported. In children, 9 multisystem inflammatory syndromes were reported.

Organization of pharmacovigilance (PV) in France

Pharmacovigilance and COVID-19 vaccines

At a nationwide level

As of February 2022, more than 130 million vaccine doses had been distributed in France.

During the first year of vaccination against COVID-19 in France, 128,766 adverse events (AE) were reported and analyzed (compared to an average of 40,000 per year for all drugs combined in the pre-pandemic years). ANSM has implemented an enhanced pharmacovigilance system, carried out by CRPVs (31 regional pharmacovigilance centers in France) including routine PV and specific weekly/bimonthly/quarterly reports for the 4 authorized vaccines (Cominarty, Spikevax, Vaxzevria and Janssen), for heterologous regimen, and for vaccination during pregnancy (Fig. 1).

Following implementation of the enhanced pharmacovigilance system, ANSM set up a weekly monitoring committee including ANSM representatives, CRPVs and experts. The committee reviews the follow-up investigations and the safety profiles of COVID-19 vaccines. If a safety signal is validated by the committee, ANSM takes measures aimed at reducing the risk associated with the safety signal. The conclusions of each committee meeting are published on the ANSM website.

Through enhanced pharmacovigilance, by February 2022, 49 safety signals had been identified nationwide and submitted to the EMA.

In parallel, the ANSM analyses all international signals (databases, information from other authorities, scientific publications, etc.).

At the European level

- The European Medicines Agency (EMA) coordinates the European Union (EU) pharmacovigilance system and produces a monthly safety report (MSR) assessing all signals and AEs of specific interest (SAEs) pertaining to each COVID-19 vaccine. Every 6 months in the Periodic Safety Update Report (PSUR), the EMA monitors their safety profiles. A tracking tool (EPITT) is available for urgent signals.

- ANSM’s action at the European level: MSR, PSUR and EPITT analysis in France taking into account the French data along with the international PV data, the scientific literature, and results from pharmaco-epidemiological studies.

- Monthly collegial discussion of the Pharmacovigilance Risk Assessment Committee (PRAC) with all member states on the safety profile and new signals pertaining to COVID-19 vaccines. If at the end of the European assessment, a safety
signal is validated, the EMA issues recommendations that may lead to:

- updated summary of product characteristics (SmPC)
- additional risk reduction measures adapted to the characteristics of the risk

Examples of confirmed signals

- Myocarditis (Fig. 2)
- Multisystem inflammatory syndrome in children (MIS-C) and adults (MIS-A) (Fig. 3)
**Conclusion**

Initial conditional Marketing Authorizations for COVID-19 vaccines were renewed for one additional year. That said, enhanced pharmacovigilance surveillance of COVID-19 vaccines is still ongoing, based on:

- Enhanced pharmacovigilance
- French and international pharmaco-epidemiology
- Permanent dynamic exchange at the international level
- Adaptive reporting system

Furthermore, reinforced surveillance has been set up for treatments against COVID-19 (antivirals, monoclonal antibodies, etc.).

**Authors’ contributions**

All authors contributed equally to this work.

**Declaration of Competing Interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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**Fig. 3.** Multisystem inflammatory syndrome in children (MIS-C) and adults (MIS-A).