

Status of surveillance of the safety of vaccines against COVID-19

The Danish Medicines Agency



LINE MICHAN, DRUG MONITORING UNIT
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Vaccines against COVID-19 used in DK

- Approved for use throughout the EU
- The known side effects and frequencies appear in the vaccines' product information (updated if new knowledge is obtained after approval)
- The vaccine side effect profile is based on large amounts of data
- In the current Danish vaccination program, the mRNA vaccines Comirnaty and Spikevax

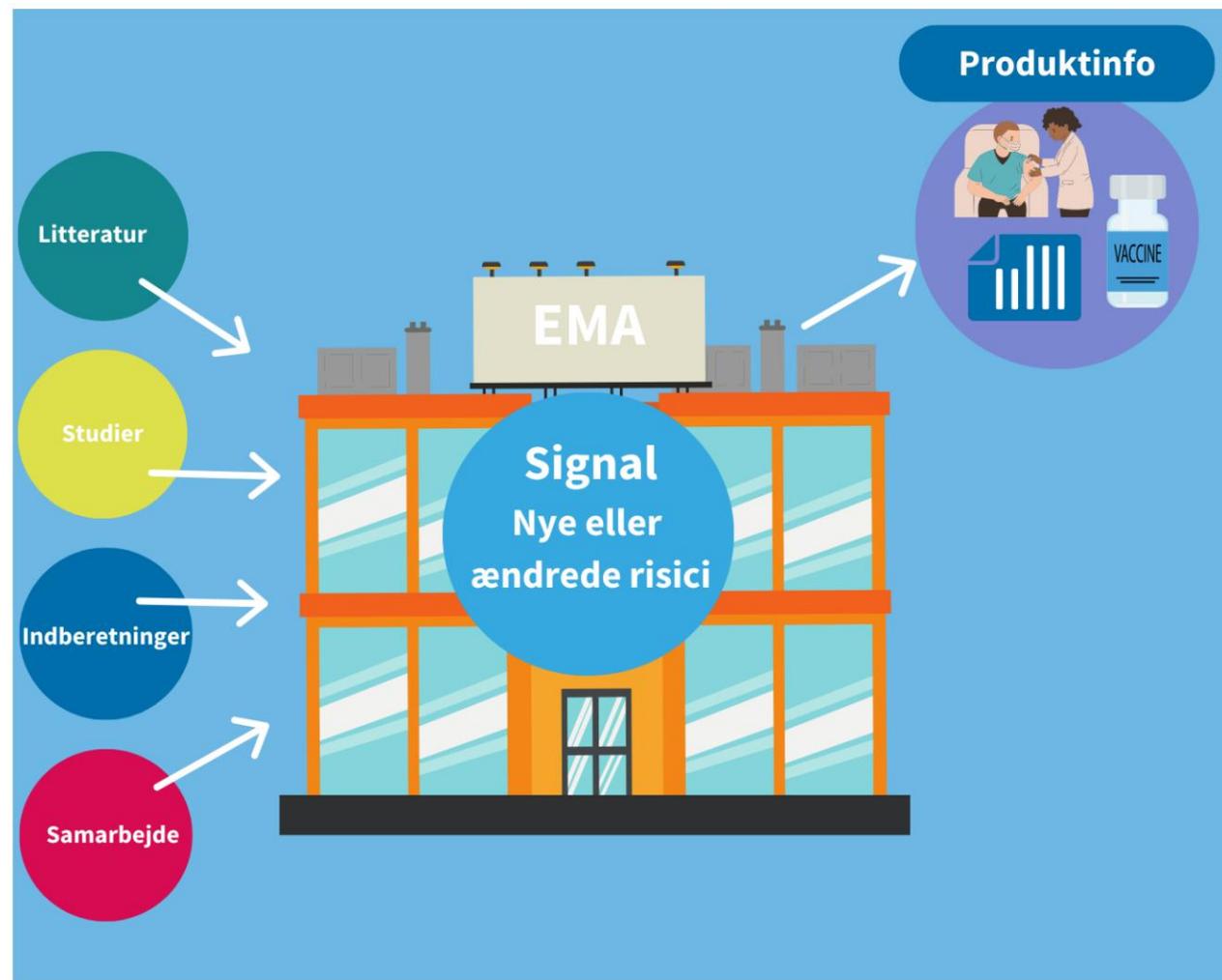


COVID-19 vaccine	Antal adm. vaccinedoser i DK (23/3-23, SSI)
Comirnaty (Pfizer/BioNTech)	13.056.864 doser
Spikevax (Moderna)	1.779.747 doser
Vaxzevria (AstraZeneca)	155.895 doser
Jcovden (Janssen)	46.090 doser

Source: Data from the Danish Vaccination Register (DDV) via Statens Serum Institut (SSI.dk)

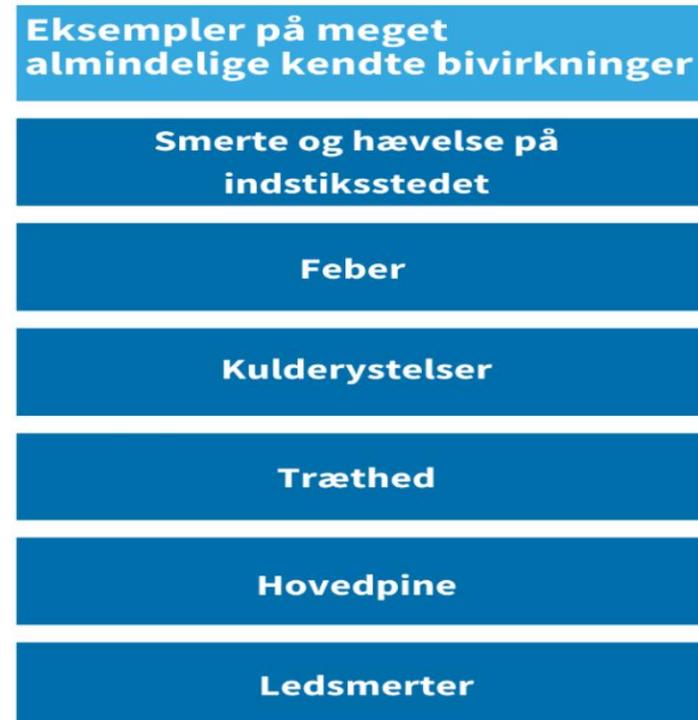
Monitoring the safety of the COVID-19 vaccines

European Medicines Agency (EMA) monitors the safety of The COVID-19 vaccines in collaboration with the pharmaceutical authorities in the EU /EEA countries



What is the status of the safety of the mRNA vaccines

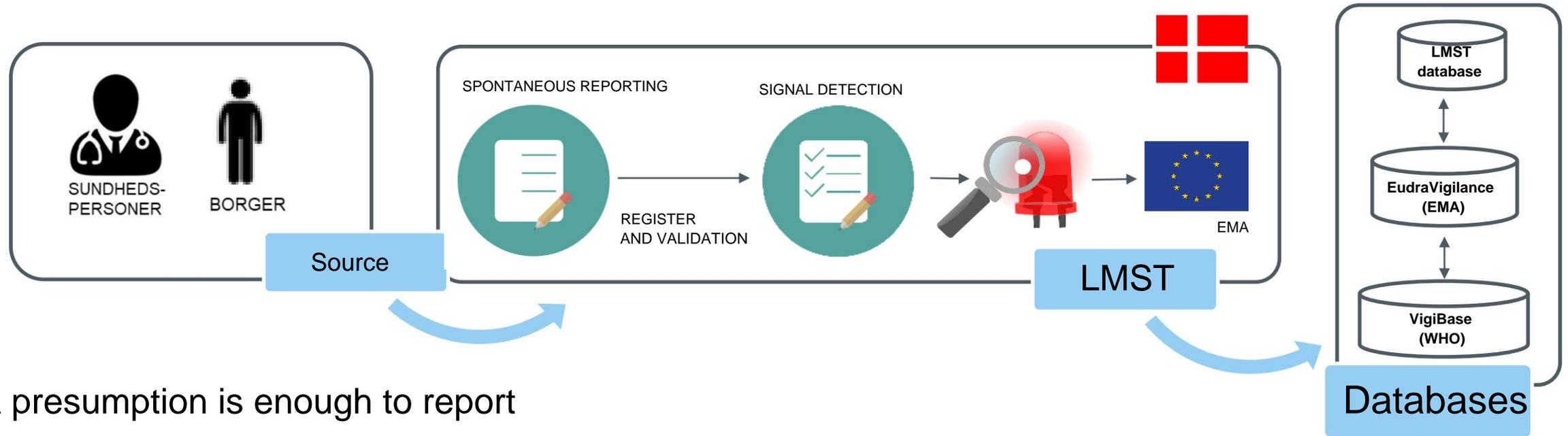
- Most known side effects of Comirnaty and Spikevax are mild or moderate, and they usually stop shortly after vaccination
- Comirnaty and Spikevax can in very rare cases cause serious side effects in the form of anaphylaxis (severe allergic reactions), inflammation of the heart muscle (myocarditis) and inflammation of the pericardium (pericarditis).
- Other known side effects are usually not serious, but in specific cases they can be serious because they have, for example, led to short-term hospitalization or incapacity for work for a period
- EMA (PRAC) reviewed it at its meeting in July 2023 latest periodic safety update (PSUR) with latest data on the safety of the mRNA vaccines: The conclusion was that Comirnaty and Spikevax are still safe and effective vaccines



What is the status of the safety of the mRNA vaccines

- The known side effects can in some cases have long-term consequences
- No signal has been raised about long-term flu-like symptoms (such as fever, headache, fatigue, muscle pain) after vaccination
- No signal has been raised about possible late consequences in the form of side effects that occur long after vaccination

Reporting of suspected side effects in DK



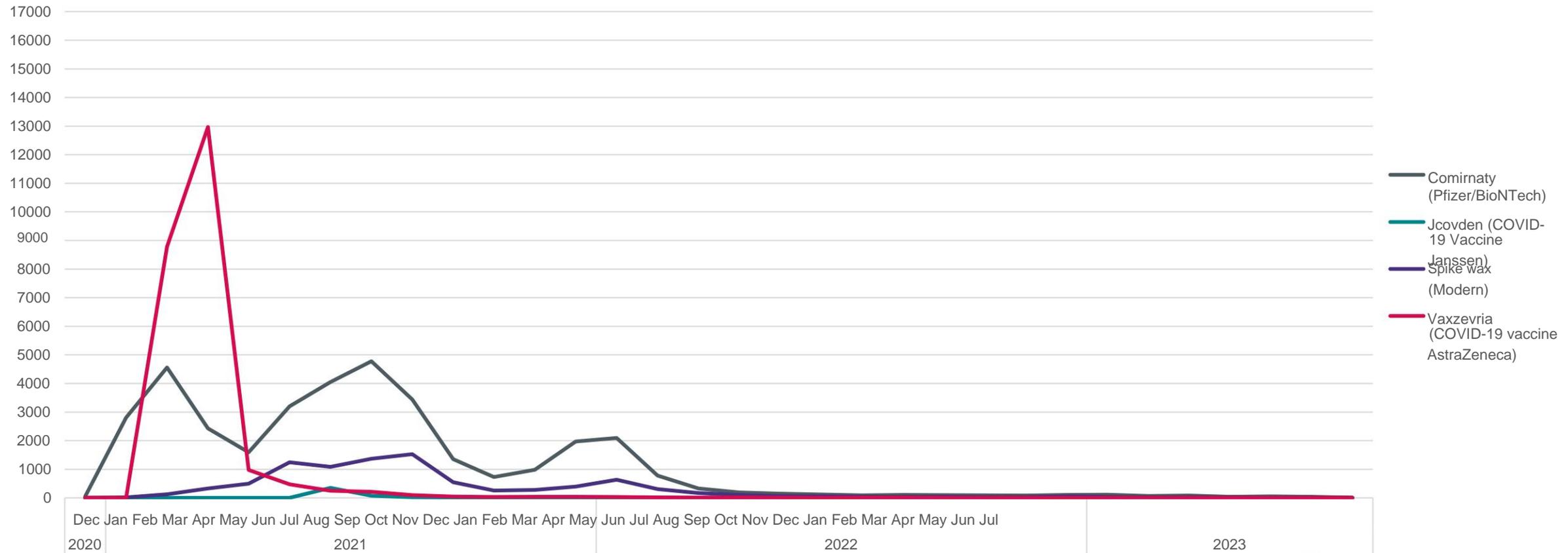
- A presumption is enough to report
- Doctors, dentists, treating pharmacists, midwives and veterinarians have reporting obligations (increased reporting obligations for COVID-19 vaccines)
- Other healthcare professionals, patients/citizens and relatives can report

Distribution by number of reports of suspected serious and non-serious side effects

Vaccine	Serious	Non-serious	Total
Comirnaty, monovalent and variant updated bivalent vaccine (Pfizer/BioNTech)	5,217	32,158	37,375
Spikevax, monovalent and variant updated bivalent vaccine (Moderna)	1,043	8,339	9,382
Vaxzevria (AstraZeneca)	1,206	22,830	24,036
Jcovden (Janssen)	60	455	515
Reports where the reporter is missing the name of the vaccine	8	16	24
Total	7,534	63,798	71,332

Figures calculated per August 8, 2023

Received reports on suspected side effects from the COVID-19 vaccines per month year



What is the status of reports in DK

The vast majority of reported suspected side effects after COVID-19 vaccination are known and transient side effects that are mild or moderate

Most frequently reported suspected side effects for Comirnaty (Pfizer/BioNTech) per 11 August 2023

- Headache
- Fever
- Fatigue
- Muscle pain
- Dizziness
- Pain at the injection site
- Nausea
- Joint pain
- Discomfort
- Chills

Most frequently reported suspected side effects for Spikevax (Moderna) per 11 August 2023

- Fever
- Headache
- Fatigue
- Pain at the injection site
- Muscle pain
- Swelling at the injection site
- Dizziness
- Nausea
- Joint pain
- Redness at the injection site

Security status

- We currently have an extensive international database to use assessment of the safety of vaccines
- The benefits of the vaccines still outweigh the known risks (side effects) of the vaccines
- The Danish Medicines Agency continues monitoring the safety of the COVID-19 vaccines in collaboration with the EMA and the other pharmaceutical authorities in the EU/EEA

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