AskEMA - Acknowledgement to ASK-117041 - Adverse effects of Covid-19 vaccines

Collectif × CoronaVirus ×

AskEMA No-Reply <AskEMA.noreply@ema.europa.eu>

21 juil. 2022 19:52

À moi

Dear Sir/Madam

ASK-117041 - Adverse effects of Covid-19 vaccines received on 21/07/2022

Thank you for your message and your interest in the European Medicines Agency. Your request has been given the reference number ASK-117041.

We will reply to you as soon as we can. For complex queries, it may take longer to answer. In any case we will write back to you within 2 months from the date of receipt.

Please do not reply to this email, this is an automated response to confirm that we have received your request. If you need to contact us again about the same matter, please use the form on our website and mention the reference number.

Kind regards

European Medicines Agency

Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands
Send us a question. Go to www.ema.europa.eu/contact Telephone: +31 (0)88 781 6000

We received your question(s) on: **21/07/2022**

Subject of your enquiry: **Adverse effects of Covid-19 vaccines**

Your question(s):
Dear,

In line with my two previous referrals for 2021 (ASK-10501 and ASK-106713), I am coming back to you with four specific questions concerning the adverse effects of Covid-19 vaccines :

1) How do you explain that the generated files still include the overflow error (249,900 lines) reported in 2021 and remain resolutely unstable in their content, the same extraction criteria (with reset) for the same vaccine, the same day produce different files... This seems to happen when the files get slightly large?

2) How do you explain the volume of corrections relating to deaths, even notified by a health professional, this phenomenon represents more than 5,000 disappearances of deaths, note that some of these deceased return to their files, it is very intriguing

3) Can you correct and/or answer my questions concerning four of the columns structuring the files produced by your GUI, namely:

• EU Local Number Appears to correspond to only one patient with cumulative doses of vaccine received and points to a single ICSR form. What are precisely the uniqueness criteria of this value; a single patient for a single disease against which to protect? For example, a patient who is vaccinated against yellow fever, hepatitis and Covid will have three ICSR forms, one for each pathology and each of their booster doses will be notified there?
• EV Gateway Receipt Date From this date of receipt, is it possible to deduce others, for example, the data are systematically transmitted the day after the declaration of the adverse effect?
• Primary Source Qualification Are all health professions taken into account; general practitioners, specialist doctors, nurses, physiotherapists, dentists?
• Primary Source Country for Regulatory Purposes it remains to define what is considered as a "Non European Economic Area", the 20 countries (the 50 countries of geographical Europe less the 30 countries of the EEA (European Economic Area) or the 197 states of the planet recognized by the UN less the 30 countries of the EEA, i.e. 167 countries? If the definition of "Non European Economic Area" extends to these 167 countries, what about the figures reported by their own pharmacovigilance, for example, are there duplicates between VAERS data and Eudravigilance data and how can they be identified?

4) Can you give me the dates of injection of the vaccines, manifestation of the adverse effects, the references of the vaccine batches as well as the country of which the patient is a national?

In advance, thank you for your quick feedback, cordially. Catherine Tellhet.