EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ilze Bude
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State Agency of Medicines of the Republic of Latvia
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LATVIA

15 December 2021
EMA/745417/2021
Human Medicines Division

Dear Mrs Bude,

Subject: On the possible conflict of interest regarding safety monitoring of vaccines

Thank you for your letter which we received on 9 December 2021. We understand that the State Agency of Medicines of Latvia (SAM) will become responsible as from January 2022 for the Latvian compensation scheme for individual patients if serious or moderately serious harm to the health or life of the patient has been inflicted due to adverse effects caused by the vaccination against Covid-19. In your letter, you ask the European Medicines Agency's (EMA or the Agency) opinion on the possible conflict of interests for the Latvian member and alternate in the Pharmacovigilance Risk Assessment Committee (PRAC) in view of these new responsibilities for SAM.

We agree with your point of view that this new responsibility for SAM can be considered as a conflict of interests for the SAM staff members who are the member and alternate for Latvia in PRAC. SAM is the national competent authority regarding pharmacovigilance of medicinal products for human use, including Covid-19 vaccines. As such, SAM is responsible for the supervision of reporting of side effects and the safety monitoring for medicines in Latvia. It is, in our view, therefore considered not appropriate that the authority holding this pharmacovigilance responsibility would also be responsible for evaluating if a side effect encountered by a patient can qualify for a compensation. The authority could be perceived as biased when it needs to take a position on a medicinal product, both in its responsibilities towards PRAC and the national pharmacovigilance system and to the individual patient claiming a compensation for a side effect. The main task of the pharmacovigilance authority is to collect and evaluate reports on side effects and to assess if these side effects have an impact on the safety and efficacy of the concerned medicinal product, and whether any updating of the product information is required. The objective of this authority could be put into question when it also needs to evaluate if a compensation is necessary for harm to a patient due to a side effect.

We have no objection against SAM referring to EMA's opinion on this matter during your discussions and further communication with the Ministry of Health in Latvia on the matter.

Sincerely yours,

Alexis Nolte (KTT)

Digitally signed by Alexis Nolte (KTT)
Date: 2021.12.16 09:51:41 +01'00'

Alexis Nolte
Head of Human Medicines