Ref: COVID-19 MRNA VACCINE PFIZER-BIONTECH (TOZINAMERAN) – Number of fatal cases

Dear Sir,

Your request has been handled in accordance with the European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use (EMA/759287/2009 Revision 4). EudraVigilance was set up in December 2001 to facilitate the electronic reporting of suspected adverse reactions in the European Economic Area (EEA). According to Directive 2001/83/EC and Regulation (EC) No 726/2004, since July 2012 all suspected adverse reactions for all medicinal products authorised in the EEA from within and outside the EEA (only serious reactions) are reportable to EudraVigilance.

To protect personal data as explained below, the information about *suspected* Adverse Drug Reactions (ADRs) that is provided to you originates from spontaneous case reports. Spontaneous case reports can be defined as follows: 'an unsolicited communication by a healthcare professional, or consumer to a competent authority, marketing authorisation holder or other organisation (e.g. Regional Pharmacovigilance Centre, Poison Control Centre) that describes one or more suspected adverse reactions in a patient who was given one or more medicinal products and that does not derive from a study or any organised data collection systems where adverse events reporting is actively sought' (please also refer to the Guideline on good pharmacovigilance practices, Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2), https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-collection-management-submission-reports_en.pdf). Healthcare professionals or consumers may be stimulated to report a suspected adverse reaction in several situations including a Direct Healthcare Professional Communication, a report in the press, direct questioning of healthcare professionals by company representatives.

Spontaneous case reports of *suspected* ADRs alone are rarely sufficient to prove that a certain *suspected* reaction has indeed been caused by a specific medicine. This could be a symptom of another illness, or it could be associated with another medicinal product taken by the patient at the same time.

Any case report should be seen as a piece of a jigsaw puzzle, with consideration given to all available data to complete the picture. These data include spontaneous case reports world-wide, clinical trials, epidemiological studies and toxicological investigations. Only the assessment of all available data allows for robust conclusions.

The number of case reports for a particular medicinal product or ADR depends *inter alia* on its availability on the market and its extent of use, the nature of the reaction as well as the public awareness of a safety concern. This means that comparing reporting rates of the number of case reports per time unit for different reactions in relation to the same product or for the same reaction in relation to different products may be misleading.

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Spontaneous reports reflect the information as provided to EudraVigilance by the reporter. Due to the nature of spontaneous reports, not all data fields are provided for all reports.

Based on the current reporting rules in the EEA, report duplications may occur e.g. where a healthcare professional reported the same *suspected* ADR to the national medicines regulatory authority and the marketing authorisation holder (MAH) and they both reported subsequently to EudraVigilance. The data provided to you may have not been screened by the EMA for potential duplicates, i.e. the same case might appear more than once. This is taking into account that duplicate management is a continuous process taking into account new information received in EudraVigilance on a daily basis.

With regard to the identification of the medicinal product, please note that the data in the EudraVigilance are coded against the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD).

The EMA has to comply with the EU Data Protection Regulation (EU DPR) 2018/1725[1] and to ensure that, *in applying Regulation (EC) No 1049/2001*, the protection of privacy and integrity of individuals is guaranteed. In accordance with Article 3(1) of the EU DPR, personal data means '*any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person*'. To comply with this legislation, certain data elements (e.g. country specific information, name of nationally authorised products that can disclose country information) are not disclosed to safeguard the identity of individuals in relation to spontaneous reports.

We would clarify that vaccination against COVID-19 will not reduce deaths from other causes. During vaccination campaigns, deaths from other causes will continue to occur, and these may also happen soon after a vaccination.

As you might know, for COVID-19 vaccines, priority is currently being given to older people as they are at higher risk of developing a severe form of COVID-19 and dying from it.

Just to give you some background information in case this helps: about 12,000 people die every day in the EU from various causes, of whom 83% are aged over 65 years. No cases of death in elderly have been associated with a COVID-19 vaccine to date.

The fact that someone has died after being vaccinated does not mean that the death has been caused by the vaccine. EU regulatory authorities carefully review all reports to determine if there is any possible link to the vaccine.

The number of spontaneous cases reported as fatal submitted to EudraVigilance for COVID-19 MRNA VACCINE PFIZER-BIONTECH (TOZINAMERAN) up to 21 January 2021 is 245. Of those, 179 were in the European Economic Area (EEA).

Please note that these numbers refer to cases where the outcome of any of the reactions in the case has been reported as 'fatal' or when the serious criteria for any of the reactions in the case has been reported to 'result in death'. These figures do not necessarily mean that the events reported were caused by the vaccine.

[1] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC

With regard to your questions about the search criteria in the ADR website (http://www.adrreports.eu/), to retrieve the fatal cases, the website provides with the number of cases for which any reaction outcome has been reported as fatal. You can find this information by 'reaction group' or by 'reported suspected reaction' in the 'Number of Individual Cases for a selected Reaction' tab. Please be aware that looking for reported reactions and terms related to death (e.g. death, sudden death) will not provide you with an accurate number of the fatal reports submitted to the database due to the particularities of the case and data management intrinsic to the spontaneous reporting systems.

We would point out to you that whenever a death or serious event occurs soon after vaccination, authorities investigate to see if the vaccine may have played a role.

We hope this information will be of help.