EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mrs Emer Cooke
Director Regulation and Prequalification
World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland

Dr Marie Lindquist
Director
Uppsala Monitoring Centre
Bredgränd 7
Box 1051
751 40 Uppsala
Sweden

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EMA/308793/2020

Dear Ms Cooke and Dr Lindquist,

Conditions for making available reports of suspected adverse reactions by EMA to WHO/UMC in accordance with Article 28c (1), 2nd paragraph of Regulation (EC) No 726/2004

Since November 2017, reports of suspected adverse reactions occurring in the European Union (EU) have been made available by the European Medicines Agency (EMA) to the Uppsala Monitoring Centre (UMC). This is in accordance with Article 28c (1), 2nd paragraph of Regulation (EC) No 726/2004 as amended and with the modalities and conditions agreed by means of exchange of letters between EMA (EMA/730003/2015), the World Health Organization (WHO) and the UMC completed on 1 December 2015.

As these agreements include regular reviews of the modalities and conditions, we are pleased to provide you below with an update mainly in relation to new EU data protection law, while we consider that the process is in a well-established and satisfactory operational phase.

Modalities and conditions

The following modalities and conditions apply to the process of sending EU adverse reaction reports from the EudraVigilance database (EV) held by EMA to the VigiBase database held by the UMC established in Sweden, as the UMC is the Foundation WHO Collaborating Centre for International Drug Monitoring:

- The data fields provided are those agreed with WHO and the UMC in 2015 and reflected in the applicable EudraVigilance Access Policy.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

- Data stored in EV may be considered personal data within the meaning of EU data protection law (including Regulation (EU) 2016/679 (General Data Protection Regulation)[1] and Regulation (EU) 2018/1725[2]), as individual case safety reports (ICSRs) reported to EV contain pseudonymised personal data concerning the health of data subjects. By means of accepting the modalities and conditions of this letter, the UMC provides written assurance to EMA that the UMC will be the data controller of the data made available from EV to VigiBase.
- The UMC as data controller will act in accordance with EU data protection law, in particular Regulation (EU) 2016/679 and other applicable national legislation. Accordingly, the UMC will take adequate measures for secure data storage and the protection of personal data. The data will be used for the sole purpose of carrying out the pharmacovigilance activities of the WHO Programme on International Drug Monitoring, and the UMC will make no onward transfer of the data and will not attempt or allow to re-identify data subjects from the pseudonymised data sets and/or procure third parties with the possibility to do so. The UMC will only make publicly available from VigiBase anonymised information concerning adverse reactions originating from EV.
- EMA sends the reports of suspected adverse reactions electronically in ICH-E2B(R3) format and the EV schema reference is provided in XML files.
- The files are sent via a restful API established at the level of the UMC, under the conditions that this fulfils the EMA's technical and IT data security requirements, and as long as those requirements are in compliance with EU laws and regulations.
  - Under these conditions, EMA sends the data daily, five days after data receipt by EV or at the latest the following Friday of each week (or the subsequent working day at EMA, should the Friday be an EMA holiday).
  - The message sender identifier "EVHUMAN" is provided in the E2B(R3) fields N.1.3 & N.2.r.2 and the message receiver identifier "UMCWHO" is provided in the E2B(R3) fields N.1.4 & N.2.r.3.
- All versions of the ICSRs received from European Economic Area countries as reported to EV are provided to the UMC. Therefore, the data are sent with medicinal product information as provided, rather than as recoded by EMA. The UMC may recode the data with their own drug dictionary. As some of the ICSR data may include either EV drug dictionary codes or ISO IDMP codes, EMA is making available, upon request from the UMC, the data content required to identify the medicinal product. The UMC may indicate in the future that they prefer receiving recoded medicinal product information from EV. The ICSRs are provided to the UMC before EMA has removed duplicated cases; however, EMA can include master case reports of duplicated ICSR if requested by the UMC.
- If issues with the data provided are found, the EV Helpdesk should be the first contact point for the UMC. Likewise, EMA will notify any technical difficulty or delay in sending data to the UMC as soon as possible and keep the UMC updated on the progress in addressing the difficulty until it is solved.
- The modalities and conditions set out in this letter are subject to regular review, given potential future changes and updates in health data security, policies and regulation. The next review will

[1] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1–88

[2] 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 (Text with EEA relevance) PE/31/2018/REV/1, OJ L 295, 21.11.2018, p. 39–98

- occur in two years' time, unless an earlier review will become necessary. Any review will include setting a timeframe for the following review.
- The UMC undertakes to inform EMA immediately of any event or change in its operation of the VigiBase database, which could have an effect on the UMC's capacity to meet the obligations set out in this letter, or that could have an impact on the EMA process of making data available to the UMC.

We will be grateful for your review and written acceptance of above modalities and conditions.

We look forward to our continued collaboration,

Yours sincerely,

[redacted]

Guido Rasi
Executive Director