MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

Information note

Agencia Española de Medicamentos y Productos Sanitarios
AEMPS

REPORTING TO EUDRAVIGILANCE (EVCTM) OF SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTIONS COMMUNICATED IN SPAIN IN A CLINICAL TRIAL AND VALIDATION RULES ABOUT REPORTER STATE

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It is necessary that reports of suspected unexpected serious adverse reactions (SUSAR) to EVCTM contain the Autonomous Community of the investigator reporter. Sponsors who need to adequate their systems to this new requirement could postpone SUSAR reporting to EVCTM until 22nd of January 2018, without being necessary a direct reporting of the SUSAR to the AEMPS in this period. This is irrespective of any urgent measure that the sponsor could need to implement in the clinical trial.

In order to make feasible that reported SUSAR be available to the Autonomous Communities when the clinical trial system allows this in the future, as it is foreseen in article 52 of Royal Decree 1090/2015, it is necessary that the Autonomous Community of the reporter be stated in every SUSAR, as indicated in the "Note for guidance – EudraVigilance Human – Processing of safety messages and individual case safety reports (ICSRs), appendix H related to local specific requirements".

The EMA has implemented this validation in EVCTM, making the indication of Autonomous Community mandatory. The list of Autonomous Communities codes to be used will be that in appendix H which is reproduced as follows:

CORREO ELECTRÓNICO
smhaem@aemps.es

www.aemps.gob.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 50 73
FAX: 91 822 51 61

CODE	AUTONOMOUS COMMUNITIES
01	ANDALUCÍA
02	ARAGÓN
03	ASTURIAS
04	ISLAS BALEARES
05	CANARIAS
06	CANTABRIA
07	CASTILLA LEÓN
08	CASTILLA-LA MANCHA
09	CATALUÑA
10	COMUNIDAD VALENCIANA
11	EXTREMADURA
12	GALICIA
13	COMUNIDAD DE MADRID
14	MURCIA
15	NAVARRA
16	PAÍS VASCO
17	LA RIOJA
18	CEUTA
19	MELILLA

The code “00-Unknown”, foreseen in the EU Individual Case Safety Report (ICSR) Implementation Guide, could **be exceptionally used** in those cases where the Autonomous Community is unknown. In these cases, a close monitoring by the sponsor is expected in order to get such information from the investigator, and it is a reason to submit a follow-up report with new relevant administrative information to EVCTM as soon as possible.

The AEMPS will closely monitor the use of “00” code by the sponsors.

The validation implemented in EVCTM is as follows:

- If [ICH E2B (R2) A.2.1.3 reportercountry] = “ES” then the autonomous community code in [(ICH E2B (R2) A.2.1.2 reporterstate] must be provided being a value among 00-19.

- If A.1.1 [ICH E2B (R2) A.1.1 primarysourcecountry] is “ES” then at least one reporter [ICH E2B (R2) A.2.1.3 reportercountry] section must have reportercountry = “ES”.

This validation will be applicable in EVWEB and transactions via Gateway. Cases which do not meet this validation will be rejected by EudraVigilance.

Sponsors who need to adequate their systems to this new requirement could postpone SUSAR reporting to EVCTM until next 22nd of January 2018, without being necessary a direct reporting of the SUSAR to the AEMPS in this period. This is irrespective of any urgent measure that the sponsor could need to implement in the clinical trial.

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