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Recommendations to MA holders to improve the quality of data in adverse event reports

This document targets all individuals who file adverse event reports with ANSES-ANMV through the Eudravigilance network.

When filing reports via Eudravigilance, it is important to precisely fill in as many of the fields as possible.

While the goal of this document is not to provide a detailed description of each of the fields to be filled out in Eudravigilance, it will emphasise certain fields or sections which are particularly important for the administrative and scientific processing of these reports, and/or for which experience has revealed divergent interpretations in the way to fill them out.

These recommendations apply to both administrative data,

- which are the result of Eudravigilance constraints or constraints which facilitate reports management
- and scientific data, used for the scientific processing of the reports.

ADMINISTRATIVE DATA

Data	Recommendations
"Worldwide number"	When filing an initial case report, please construct the wwnumber in compliance with the following EMA format: "Country code–EMA-assigned organisation code–internal case reference code".
	In order to avoid creating duplicates, please provide the original worldwide number when filing case follow-ups.
"Sender report identification number"	Please follow the same construction format as for the wwnumber.
	Must be the number of the organisation filing the case (as opposed to the wwnumber, which never changes).
"Original received date"	To be filled in and remain unchanged when sending in additional information. This date is used to determine the cases to include in the analysis of a PSUR as well as when verifying compliance with filing deadlines.
"Most recent information"	To be filled in systematically and updated when sending in additional information. These dates enable rapid identification of case follow-ups and are also used to verify compliance with filing deadlines.
"Primary source"	Provide at least the first letter of the last name, the first letter of the first name and the first two digits of the postal code.

SCIENTIFIC DATA

Classification serious / minor	Classification made according to the definitions in Volume 9B
Affected animal or human	Fill in the number of individuals treated and affected. If the number of exposed individuals is not known, the number of affected individuals should be provided by default. If both are unknown, provide an approximation.
	File one form per species.
	Fill in the age, sex and weight data, which may affect case assessment and can be used for determining whether use was compliant with the MA.
	For groups of animals: provide an age and weight range and fill in "mixed" for the sex if both males and females are involved. This data may affect case assessment and can be used for determining whether use was compliant with the MA.
	Effects on offspring: fill in offspring information (age, weight, sex, number of exposed and affected individuals and outcome) and specify in the text whether the mother or father received treatment.
	When an adverse reaction occurs in the mother and its offspring, two separate forms must be filed.
Product(s) involved	Full name of the medicinal product in French (including dosage and dosage form) and authorisation number, as well as those for the medicinal products of the other marketing authorisation holders involved.
	Precise dates of the beginning and end of treatment, consistent with the date of onset of the reaction (beginning of treatment must occur before onset of the reaction). The treatment and reaction dates make it possible to determine the period before symptom onset, which are essential assessment data.
	Route of administration, dose, treatment duration. These data also make it possible to determine whether or not use was compliant with the MA.
	For vaccines: the date treatment began must be the date of the last time the product was administrated before onset of the reaction. Ex: if the animal reacted after a booster vaccination, and the vaccine was administered for the first time a year prior to this, you should indicate the date of the booster, not the date of the initial vaccination, as the date that treatment began. Similarly, do not indicate "12 months" as the treatment duration. In this case, you do not need to provide a treatment duration. Previous or later treatment dates should only be mentioned in the case "Description" section.
	Batch number, expiration date. These data may be used to identify a possible quality flaw.
Description of the adverse reaction	Provide the precise date of the onset of the reaction, which must be consistent with the date that treatment began (the start of treatment must precede the onset of the reaction). The period preceding the onset of symptoms is essential assessment data.

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	In the "Description" tab, provide a thorough description of the adverse reaction: types of symptoms, site of reaction, severity, duration, changes (in particular after administration of product has ceased, or on the contrary following administration of another dose of the product), case outcome (recovered, died, alive with sequelae, under treatment, unknown). This field can also be used to provide any relevant information for which there is no specific field.
	In the "Description" section, please include all additional tests and treatments begun after the onset of the adverse reaction.
	The time between exposure and the onset of the adverse reaction should be provided to the best of your knowledge, especially if specific treatment and reaction dates are not known.
Clinical signs	The choice of Veddra terms should be consistent with the text field (with regard to the reporter's description, as complete and precise as possible).
	Do not forget to fill in "death" in fatal cases and to use "unrelated death" if the death is not due to the product(s) used (for example a dog that is hit by a car leaving the clinic).
	Do not forget "lack of efficacy" for SLEEs, "residues, etc." for problems with waiting times.
	When there is a strong enough suspicion of anaphylaxis (assessed A or B), remember to provide the corresponding Veddra terms. In cases of anaphylaxis, fill in "Anaphylactic shock", not "shock" or "circulatory shock", since these two terms are not part of the "Immune system" SOC and will skew statistical analysis results.
	Remember to add the corresponding Veddra terms to additional test results (blood tests, autopsy, etc.).
Assessment	Must be systematically filled in at least for the medicinal products of which you are the holder. If the final case assessment is on hold while waiting for the results of additional tests, fill in "O" under the assessment section (do not file the case without an assessment).
Conclusion	An explanation of the assessment can be provided here.