The contribution of the portal for reporting adverse health events

On 13 March 2017, the Ministry of Health launched a single portal on its website for reporting adverse health events:

https://signalement.social-sante.gouv.fr

Its purpose is to promote reporting by enabling any healthcare professional or user to declare in just a few clicks "any adverse event or unusual effect with a negative impact on health" about which they become aware.

Its tree structure helps the healthcare professional choose the relevant vigilance scheme for the event (pharmacovigilance, haemovigilance, cosmetics vigilance, nutrivigilance, toxicovigilance, etc.), while users are guided by the choice of "agent" (medicinal product, blood derivatives, cosmetics, food supplements, everyday products, etc.).

Depending on the vigilance scheme, information on the adverse event is entered on the portal and the report is then transmitted to either the Agency or the organisation in charge of the vigilance scheme concerned. The person submitting the report is informed of the organisation to which the alert has been addressed. As the portal does not replace existing tools, the reporter may be redirected to an online form on the vigilance system's website, if an electronic reporting system is already in place.

Thus, with regard to the vigilance schemes for which ANSES is responsible, reports are submitted:

- for **nutrivigilance**: on ANSES's website for healthcare professionals and via the portal for users (whose reports are then transferred to a Poison Control Centre for investigation);
- for **veterinary pharmacovigilance**: if it is an event observed in a person (and not an animal), the report is submitted through the portal for healthcare professionals and users. Reports are then transferred to a Poison Control Centre for investigation. Effects observed in animals are not covered by this portal and should be reported to the French Agency for Veterinary Medicinal Products (ANMV) or the Veterinary Pharmacovigilance Centre in Lyon (CPVL);
- for **phytopharmacovigilance**: holders of marketing authorisations or parallel trade permits for plant protection products, manufacturers, importers, distributors or professional users of these products, as well as advisers and trainers of these users subject to mandatory reporting under the Act on the future of agriculture, food and forestry (LAAAF) of 13 October 2014, do so through the portal, which will then notify ANSES. The same applies to healthcare professionals, users and other professionals. All reports are then analysed by a Poison Control Centre;
- for **toxicovigilance**, all reports, whether from healthcare professionals or users, are submitted via the portal and then transferred to the Poison Control Centres for analysis.

The ANSES website pages for each of these vigilance schemes have been updated to direct reporters to the correct reporting site.

Reporters must leave their contact details so that they can be called back if necessary, in particular to document more precisely the product(s) or agent(s) involved, the effects observed and the timeline of events.

The "usability" of the reports, the percentage of misdirected reports (e.g. a food poisoning report sent to toxicovigilance instead of the Regional Health Agency), the proportion of people who need to be called back and consequently the additional workload this will entail, are for the moment unknown. All cases reported to the Poison Control Centres will be recorded in their information system (SICAP) and an initial review may be conducted 6 to 12 months after the launch of the site, in order to specify the volume of reports, how they were dealt with (followed up or not) and, lastly, the percentage of reports providing useful information for toxicovigilance.

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