Nutrivigilance: 2016 review of ANSES's national scheme

Implementation of the national nutrivigilance scheme was entrusted to ANSES in July 2009 under the French Act on Regional Health Governance (HPST). The purpose of this scheme is to improve consumer safety by rapidly identifying any possible adverse effects related to the consumption of:

- food supplements;
- foods or beverages fortified with substances for nutritional or physiological purposes (vitamins, minerals, amino acids, plant extracts, etc.) such as so-called energy drinks;
- novel foods and novel ingredients such as phytosterols, guar gum and noni juice;
- products intended as food for specific categories of the population (infants, athletes, patients suffering from food intolerance, etc.).

Healthcare professionals (doctors, pharmacists, dieticians, etc.) are invited to report these specific foods when they identify adverse effects in their patients that they suspect of being related to their consumption. Consumers who wish to submit an individual report should preferably contact a healthcare professional. The reports are recorded and then analysed initially by the Agency to determine the severity of the incident, the product's composition, any overlap with previous reports, etc. For each report, ANSES may contact the reporter again to obtain any missing information. Reports containing sufficient information and falling within the scope of nutrivigilance (valid cases) are then submitted to medical experts, who analyse the likelihood of a link between consumption of a product and occurrence of an adverse effect (causality).

Causality is determined according to the method defined in the ANSES opinion No. 2010-SA-0195 of 11 May 2011 [1]. Causality may be: excluded (I0), unlikely (I1), possible (I2), likely (I3) or very likely (I4). The Agency informs the authorities (in particular the Ministries of Health and the Economy) of the cases received and may be required to issue an alert (for example, for cases with strong causality and where symptoms are life-threatening). Cases are then examined by a group of specialised experts from ANSES. According to the effects observed, the number of cases received and the likelihood of them being associated with consumption of the product in question, the Agency may decide, with the help of these experts, to conduct a more thorough risk assessment of certain products. This work leads to the publication of scientific opinions and recommendations intended for healthcare professionals and consumers. These opinions are submitted to the ministries concerned to enable them to take appropriate management measures (regulations imposing a maximum limit in food supplements, withdrawal from the market, etc.).

Between the launch of ANSES's nutrivigilance scheme in 2009 and 31 December 2016, the Agency received 2,649 reports of adverse effects.

In terms of reports, 2016 saw a decrease in the number of cases compared to the previous year (340 cases in 2016; 432 cases in 2015) (see Figure 1) with, however, an increase (+26 cases) in the number of spontaneous reports i.e. cases transmitted to nutrivigilance without any request having been issued.

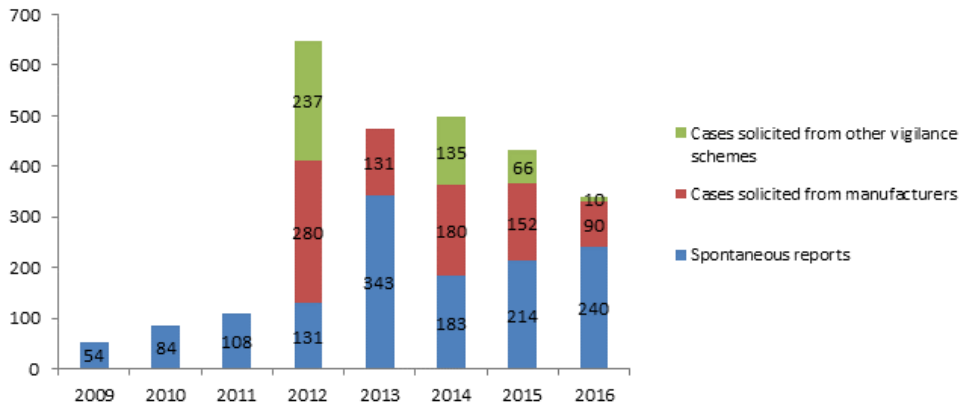

Figure 1: Change in the number of reports received since 2009

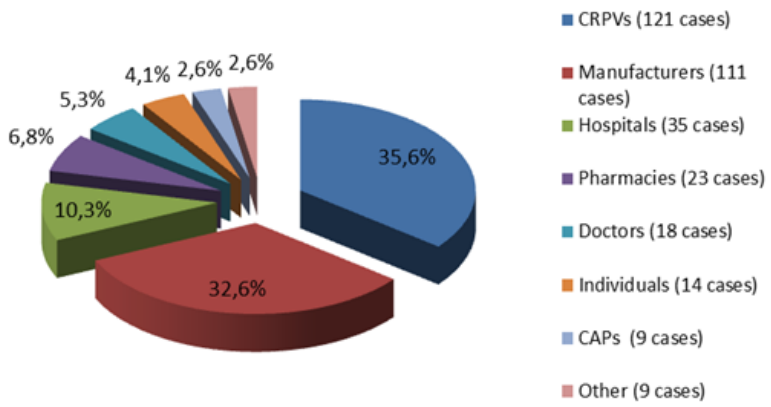

Figure 2: Identity of the reporters.

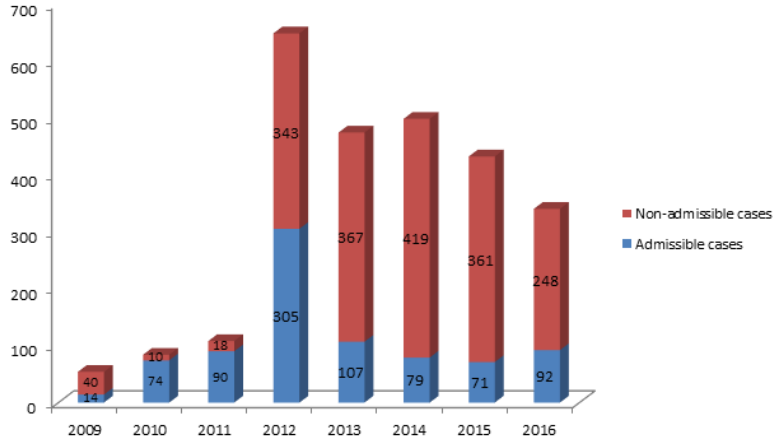

Figure 3: Change in the proportion of valid cases since 2009.

Accounting for more than 35% of the reports transmitted, the regional pharmacovigilance centres (CRPVs) were the main reporters, followed by manufacturers (32.6%). Healthcare professionals in hospitals accounted for around 10% of reporters, pharmacists 7% and non-hospital doctors 5%. Members of the public, who are not meant to notify ANSES's nutrivigilance scheme directly, reported 4% of cases. Lastly, the Poison Control Centres (PCCs) and other professionals (nurses, medical testing laboratory staff, the General Agency for Health Equipment and Products (AGEPS) etc.) each submitted less than 3% of reports (see Figure 2).

In 2016, the proportion of valid cases rose sharply (26% compared to 16% in 2015) with large variations depending on the reporter (50% for pharmacies; 18% for manufacturers) (see Figure 3). Unfortunately, the main reason preventing exploitation of cases was a lack of data on, for example, the dates the product was taken or the progression of the adverse effect.

As in previous years, the vast majority of the cases received involved food supplements (89.9% of the valid cases received in 2016). These are mainly intended for people seeking "joint comfort", or improved "vitality" or "vision".

Most of the reported adverse effects were of a general nature (impaired general state of health, fever, etc.) or concerned the digestive system (intestinal or hepatic). In 2016, causality of the products was found to be likely in 35% of cases and very likely in 3% of cases.

In terms of publications, ANSES issued an opinion on food supplements for athletes in 2016 [2] and an opinion on food supplements for pregnant women in June 2017 [3].

ANSES is also continuing its work to produce opinions on the risks associated with consumption of:

- food supplements containing spirulina;
- food supplements containing melatonin;
- food supplements for joint comfort containing glucosamine and/or chondroitin.

Gwenn VO VAN REGNAULT (Anses)

The Agency reminds healthcare professionals of the importance of their participation as reporters to notify ANSES of cases of adverse effects that they suspect of being associated with the consumption of food supplements. ANSES asks them to continue questioning their patients during medical consultations about their use of food supplements and other special dietary foods such as fortified foods, and to notify the nutrivigilance scheme of any adverse effects they are made aware of.

References

[1] Method for determining causality in nutrivigilance https://www.anses.fr/fr/system/files/NUT2010sa0195.pdf

[2] Opinion on food supplements for athletes https://www.anses.fr/fr/system/files/NUT2014SA0008Ra.pdf

[3] Opinion on food supplements for pregnant women https://www.anses.fr/fr/system/files/NUT2013SA0240Ra.pdf