

Our ethical requirements

Consultez la version française

<u>French Law No. 2011-2012 of 29 December 2011</u> enhancing the safety of medicines and health products, supplemented by the Decree of 9 March 2012, includes important provisions relating to ethics.

It introduces enhanced transparency measures relating to conflicts of interest, particularly by systematically requiring all public actors in the healthcare system to make public declarations of interests. All experts involved in this area were already obliged to make a public declaration of interests (PDI). The law lays down the general principle whereby health expertise must comply with the principles of impartiality, transparency, plurality, and joint undertaking.

Our staff are required to stay abreast of the Ethics Charter.

A charter has been drafted, setting out all the ethical principles applicable to ANSM and the rules of behaviour to adopt, rounding out the various tools already in place in the Agency within the framework of the policy promoting staff awareness of ethics requirements. This charter provides a concrete overview of impartiality, integrity and probity requirements, in keeping with confidentiality and discretion obligations.

The Ethics Charter also plays an educational role for all ANSM staff: it provides them with the recommended course of action in various scenarios liable to constitute breaches of probity that they might encounter in the course of their day-to-day duties.

This charter is part of the set of tools and procedures implemented by ANSM to prevent risks of unlawful acquisition of interests, corruption, influence peddling, and other breaches of probity.

After reiterating the content of each ethical principle, reference is made to the information documents and detailed procedures prepared by the Ethics of Expertise Department, the Human Resources Division, the Communication and Information Division, or the Legal and Regulatory Affairs Division.

Download ANSM's Ethics Charter (09/01/2025)

Download the expert booklet (15/04/2025)

Staff are provided with information sheets on impartiality and probity obligations: these information sheets are intended to encourage them, regardless of their role, to ask the right questions and use their sense of responsibility, in order to fulfil their impartiality and integrity obligations which should guide their action. Using concrete examples, these information sheets define and illustrate cases that potentially constitute breaches of probity. They repeat mandatory proscriptions and describe the recommended course of action when faced with at-risk scenarios. They repeat the rules for preventing conflicts of interest, and the approach for dealing with external parties.

Consult the fact sheets relating to the duties of impartiality and probity and their breaches (in french)

- isdictife fact sheets relating to the duties of impartiality and probity and their breaches (in hence
- Fiche 0 : Sommaire
- Fiche 1 : Le conflit d'intérêts
- Fiche 1bis : Identification et prévention des conflits d'intérêts
- Fiche 1ter: L'attitude à observer face aux sollicitations d'interlocuteurs extérieurs

- Fiche 1quater : Le cumul de fonctions avec d'autres activités
- Fiche 2 : La prise illégale d'intérêts pendant les fonctions
- Fiche 3 : La prise illégale d'intérêts après les fonctions ou délit de pantouflage
- Fiche 3bis : Procédure Projet de départ des agents vers le secteur privé
- Fiche 4 : La corruption
- Fiche 5 : Le trafic d'influence
- Fiche 6 : Le favoritisme
- Fiche 7 : Le détournement de fonds publics
- Fiche 8 : La concussion
- Fiche 9 : Le délit d'initié
- Annexe : références textuelles

Conflict of interest prevention

Within the framework of our staff recruitment and expert appointment processes, applicants' interests are systematically reviewed.

What is a conflict of interest?

• A conflict of interest refers to "any circumstances of interference between a public interest and public or private interests which are likely to influence or appear to influence the independent, impartial, and objective fulfilment of a duty".

The requirement to produce a public declaration of interests (DPI) made within the previous year applies to members of collective bodies and to experts consulted on a one-off basis.

The same rules in respect of impartiality apply to expert assessments conducted by ANSM's internal assessors, management and executive staff, as well as staff whose duties justify it (staff involved in preparing decisions, guidelines, references and opinions on public health or health safety topics, staff fulfilling inspection, assessment, surveillance and inspection duties, etc.) (decision of ANSM's Director General of 06/07/2012*).

These declarations can be viewed on the DPI Santé website

The scope of the DPI is extended to connections of any kind, whether direct or indirect, with the introduction of time-related factors, namely current interests and those arising in the last five years.

As a result of these measures, it is prohibited to:

- take part in expert assessment without having previously completed or updated a declaration of interests;
- handle a question in the event of a direct or indirect connection with the dossier in question, under penalty of committing an offence of unlawful acquisition of interests.

Opinions obtained in disregard of the impartiality principle are unlawful, and may result in the revocation of the decisions made on that basis. Deliberately omitting to prepare or update a declaration of interests or providing false information is punishable by a $\leq 30,000$ fine.

Obligations of transparency of interests

The public declarations of interests of all external experts and over 600 Agency employees can be accessed on the Agency's website Fidweb and on the DPI Santé unified website for declarations made after 2018.

Disqualification procedure

A member of ANSM staff or an external expert cannot work on a dossier within their remit if they have any connections liable to call their impartiality into question.

Expert incompatibility plan

An incompatibility plan sets out connections that are not compatible with the duties of a member of one of ANSM's consultative bodies. It applies to current connections at the time of the declaration of interests and for the duration of the term.

This system requires members of bodies to sign a confidentiality and independence agreement whereby they undertake to unwind or terminate the activities in question when they are appointed, and according to the specific terms for each circumstances. In addition, they must not engage in new activities which might result in a change to their initial level of risk of conflict of interest.

Download the table detailing the scope of incompatibilities applicable to members of ANSM bodies (15/03/2021)

Besides these incompatibilities, the general conflict of interest prevention and management rules must apply with regard to authorised connections and prior activities. These must be reviewed on a case-by-case basis in accordance with the dossiers to be examined, and, should they give rise to a conflict of interest, may lead to the participation of the member in question being limited or excluded.

Tools assisting with the review of conflicts of interest represent the common scenarios and their outcomes in terms of participation in the Agency's work.

Conflict of interest prevention and management scheme (version as at 25/09/2018) (07/06/2022)

Conflict of interest review assistance tool: Members of consultative bodies (version as at 04/01/2019) (01/02/2022)

Conflict of interest review assistance tool: External experts (version as at 04/01/2019) (18/12/2024)

Further reading

- Decision of 06/07/2012 setting out the list of roles occupied by staff of the French National Agency for Medicine and Health Product Safety (for whom the declarations of interests under Section II of Article L. 1451-1 of the French Public Health Code are published)
- Decision of 06/07/2012 setting out the collective bodies of the French National Agency for Medicine and Health Product
 Safety for which members' declarations of interests under Section II of Article L. 1451-1 of the French Public Health Code
 are published