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Quarterly Medical Review - Health technology assessment in France Taking ethics into account: the HAS perspective



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ABSTRACT

The HAS is unique in France due to its status as an independent public authority. Its closest equivalent is the National Institute for Health and Care Excellence (NICE) in England and Wales. It stands out from other French health agencies by its independence and wide scope, covering health and the social and medico-social sectors. Its independence, guaranteed by law, is combined with regular dialogue with public authorities and external partners. Independence does not come without accountability; it must report its actions to the state and its control bodies (Parliament and Justice in particular) and more broadly to society and health actors. Scientific rigor, independence, and transparency are at the heart of its values. The 2011 health law, adopted following the French Mediator scandal, established a common legal framework for preventing conflicts of interest in health. The HAS has also developed its own complementary prevention tools. It ensures that the composition of its expert committees balances different schools of thought. In terms of transparency, the HAS publishes all its opinions and decisions, as well as methodological and practical guides. In a demanding context where scientific expertise is particularly scrutinized and the risk of a health crisis, such as Covid-19, is imminent, the HAS must maintain the highest standards of conflict of interest prevention and transparency. This is essential for the quality of expertise and public trust.

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The *Haute Autorité de santé* (HAS), France's National Authority for Health, celebrates its 20th anniversary this year [1]. It is a young institution that is unique in at least two ways. In a crowded landscape of French health agencies, it is the only body to have independent public authority status ("API" in French) and, as such, to be free from ministerial control. Its very name - "*Haute Autorité de santé*" - is set by law, giving it an important symbolic role in the eyes of the public and professionals alike. Its closest equivalent is the English's National Institute for Health and Care Excellence (NICE).

In France, it is also the only API with "independent scientific public authority" status, with missions focusing on the health field and, since 2018, the social care field [2]. Its particularly broad scope of action and wide-ranging remit enable it to take action to promote health in the broadest sense of the term, defined by the World Health Organization as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" [3].

The HAS received guarantees of independence from the legislator. Hence, the law of 2017 relative to independent public authorities [4] indicates that "In exercising their powers, the members of

independent administrative authorities and independent public authorities shall neither receive nor seek instruction from any authority". The independence of the HAS and, consequently, the refusal to be instructed or to seek instruction, relates to the content of its work. But this independence is nonetheless compatible with the exercise of regular dialogue with public authorities and external partners. Its independence also derives from the irrevocability of the mandate of the members of its Board, [4] which is the HAS' natural deliberative body.

Although the HAS is an independent legal entity governed by public law, like any other public entity, it is obliged to account for its activities; its independence does not come without control, and this control takes various forms.

In a state, such as France, governed by the rule of law, this control is first and foremost institutional. In France, Parliament votes on the legislative measures that create, modify or abolish the missions of the HAS. Over the last 20 years, the missions assigned to the HAS by the legislator have increased steadily. It is striking to note that since 2004, with the passing of major health laws [5] and annual social security financing acts (LFSS), article L.161-37 of the French Social Security Code [6], which is the article underpinning the HAS, has been amended some 30 times, i.e. 1.5 times per year. For the most part, these changes have resulted

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in the addition of new missions. In addition to the legislators' close interest in the HAS, this intensive legislative activity to which the Agency is subject demonstrates that health policies are constantly being reviewed and reformed by successive governments.

Parliament also adopts the HAS' budget, which depends on social security financing acts (LFSS). Ultimately, the HAS' budget is set by ministerial order. Like that of other independent public authorities with a legal personality, the HAS' employment ceiling is included in the annual financing act [7]. HAS board members are appointed by the highest state authorities [8]. The National Assembly and the Senate hold a public hearing of the Chairperson and Director before they are appointed [9]. The judge monitors the legality of the work and actions carried out by the HAS. Since it has a legal personality, the HAS may be subject to legal - and, consequently, financial - liability. The French *Cour des comptes* [national audit office] implements financial control, etc.

Over and above these state safeguards, the HAS must be able to report to the public on its actions at any time. Article 15 of the French Declaration of Human and Civic Rights of 26 August 1789, which has constitutional status, states that "*Society has the right to call to account any public agent of its administration*".

Like any institution that influences public decision-makers through the positions it adopts, the HAS is scrutinised by civil society. Among the most attentive observers are the persons concerned by the results of its work. These include healthcare professionals, patients, health system users and their representative associations, learned societies, health, social and medico-social facilities and, of course, health sector industries (pharmaceutical companies, medical device manufacturers, software developers, teleconsultation companies, health tech start-ups, etc., as well as service providers and equipment suppliers). The HAS is also regularly consulted by journalists, unions and, more broadly, members of the public seeking information.

The Covid-19 pandemic and the resulting crisis showed just how fragile public confidence in public health expertise really is. This health crisis, along with recent public health scandals, such as the French Mediator (benfluorex) (2010) scandal, or the international Implant files affair (2018), to name just a few, or older cases such as the contaminated blood scandal, all bring to light a deeper crisis of confidence in health experts.

In France, it was precisely in response to the Mediator scandal that the law of 29 December 2011 [10] relative to reinforcement of the safety of medicines and health products, known as the Bertrand Law after the Health Minister who introduced it, laid the foundations for a common system for preventing conflicts of interest in the health sector.

Beyond the health field, in the political arena, the "Cahuzac affair" prompted the law [11] creating the *Haute Autorité pour la transparence de la vie publique* (HATVP), France's authority for transparency in public life, which is the independent public authority responsible for implementing a comprehensive system for preventing conflicts of interest. This law lays down the first legal definition of a conflict of interest: "a conflict of interest is any situation of interference between a public interest and public or private interests that is likely to influence or appear to influence the independent, impartial and objective exercise of a role" [11].

Immediately, two lessons can be drawn from this definition.

The first relates to the nature of the interests in question. Public interests may not coincide and may conflict with one another, even though these public interests ultimately pursue the same goal: the general interest.

The second is essential in order to fully understand the importance of preventing conflicts of interest in the health sector. It concerns the characteristics of the conflict of interest. The letter of the law indicates that a conflict arises when a *situation* appears to

influence the independent exercise of a role. In other words, when applied to health expertise, a conflict of interest may arise when it appears likely that an interest has influenced the direction taken by an expert assessment. This particularly broad definition is a manifestation of the doctrine of appearances. It can be supposed that this approach to the notion of conflict of interest is intended to restore the trust of the public, which is inclined to readily assume the existence of a conflict of interest. The side effect of this maximalist approach is to make it difficult, if not impossible, to recruit qualified experts. It is important that, by seeking at all costs to ensure the absence of interests or links in order to guarantee pure, perfect, *vacuum-sealed* independence, we do not cause public expertise to lose its attractiveness and the remarkable pool of French and foreign experts to dry up. There is a fine line to be drawn between the risk of a conflict of interest and the risk of a loss of quality of expertise.

In this demanding context, how can the HAS, an independent public authority with a "scientific" mandate, ensure its independence and that of the people who contribute to its work, while simultaneously maintaining the quality of its expertise?

Scientific rigour, independence and transparency are values that are part of the HAS' identity and contribute to the bond of trust with the public. Independence, if it is to be more than just words and fully tangible, implies a high level of ethical standards (I.) and compliance with rules of transparency (II.). Only in this way can the HAS effectively guard against conflicts of interest and create the conditions for the necessary public confidence. As the IGAS [French general inspectorate of social affairs] indicated at the start of its 2011 public report published in the midst of the Mediator scandal, "*The independence of expertise is a guarantee of its quality and legitimacy*" [12].

1. No independence without ethics

Until the early 2000s, conflict of interest law in France appeared to be dominated by criminal law. The issue of interests and conflicts of interest was initially approached from a primarily repressive angle, in particular through the offence of having unlawful interests [13] during or after leaving a post. This offence has very few equivalents in OECD countries. The United States has an almost identical criminal offence, but limited to financial interests only, whereas the French offence applies to "any interest". In France, the interest may be financial or moral, direct or indirect [14].

The preventive aspect, particularly in terms of the information and awareness-raising dimension, was underdeveloped. The impact of high-profile court cases in both the health field and the political arena (see above) has led to an increasing prominence of ethical issues.

In fact, ethical standards are a preventive tool. According to Christian Vigouroux, member of the French Council of State, ethics means "*the art of asking the right questions before it's too late [and] the art of creating public trust*" [15].

The literature includes a multitude of reports and public enquiries on ethical issues and the prevention of conflicts of interest [16]. The has also embraced this ethos of ethics.

In 2006, HAS put in place its own system [17] with an "Expertise ethics and independence" group, to deal with deontological issues.

Ethical safeguards are present at every phase in the HAS' work, from the recruitment of experts and employees collaborating in the work through to the adoption of HAS opinions and decisions (at either board or committee level), even after HAS members have ceased their role. The institution thus has access to a set of legal and practical tools enabling it to effectively protect itself against conflicts of interest. Some of these tools come from outside (from the legislator and the regulatory authorities). The has also developed complementary tools.

Legislative and regulatory tools - The legislator and the regulatory authorities have given the HAS and health agencies very specific legal tools to safeguard against the risk of conflicts of interest.

The 2011 Health Act introduced a common set of ethical rules applicable to health agencies, to the HAS and also to the central administrative departments of the Ministry of Health [10]. Previously, each institution had its own specific mechanisms. The law proceeded “by more or less felicitous reference to existing provisions or by more or less felicitous rewriting of existing provisions”. Ethical rules were therefore dispersed throughout the Public Health Code and the Social Security Code, as regards the HAS.

The 2011 Health Act made the legal framework clearer and therefore more effective.

It also reinforced the mechanisms for monitoring, taking into account and preventing conflicts of interest, which concern not only the members and staff of the institutions responsible for public health issues, including the HAS, but also all those who, in whatever capacity, on an ad hoc or regular basis, collaborate with them.

On the basis of the provisions of the French Public Health Code [18], a double-check process is therefore implemented.

First of all, anyone working at or for the HAS must complete a declaration of interests, made public according to the missions performed or positions held, and updated for each new activity and at least annually.

One of the cardinal rules that the HAS drawn from this is that no employee of the HAS, whether on a permanent, regular or ad hoc basis, may take part in the HAS’ work unless they have provided an up-to-date declaration of interests (less than one year old) and this has been the subject of a validation by the ethic officer.

The 2011 Health Act supplemented this system by providing for the publication of declarations of interest on a single website: DPL.sante. Previously, each institution published the declarations of interest it collected on its own website, and practices varied. The texts implementing the law also provide for a single, common template for the declaration of interest form [19].

Secondly, companies producing or marketing healthcare products or medical devices are required to publish, on a website managed by the Ministry of Health, “*Transparence Santé*”, the precise purpose, date, beneficiary and amount of any agreements they conclude with, in particular, healthcare professionals, healthcare system user associations, academies, foundations, learned societies and consultancy bodies working in the healthcare sector. The same obligation applies, beyond a legally set threshold, to all benefits in kind or in cash as well as any remuneration that the same companies provide, directly or indirectly, to these persons, associations, establishments, foundations, companies, organisations and bodies.

As the work for the 2011 law shows, this tool is directly inspired by the American model. In 2010, the USA adopted the Physician Payments Sunshine Act, commonly known as the “Sunshine Act” This federal law requires pharma companies and device manufacturers to declare any transaction in kind or in the form of monetary payment made to physicians or teaching hospitals.

The prevention of conflicts of interest at the HAS is therefore based on a comparative analysis of the interests revealed by the declarations of interest in relation to the specific work the experts are involved in and the information accessible on the “*Transparence santé*” website.

The HAS ethics officer required by the 2016 Health Act [5], is responsible for ensuring compliance with obligations with respect to declaration of interests and prevention of conflicts of interest. It is specified that, to this end, the ethics officer must check with HAS departments, at least annually, “that declarations (of interest)... have been submitted and are up to date”. Each year, the ethics officer submits an activity report, which is published on the HAS website [20]. The individuals concerned by the obligation to declare their interests are required to respond to requests for information sent to them by

the ethics officer. The conditions under which these powers are exercised were set out in provisions [21] that have been incorporated into the regulatory section of the French Public Health Code. Ethics officers must therefore have access to the necessary resources to enable them to carry out their mission successfully. They have direct access to the “DPI-santé” website. The ethics officer ensures that the HAS takes appropriate measures to ensure that declarations of interest are collected and that interests are analysed. To this end, the officer proposes the organisational measures required to comply with the obligations to declare interests and prevent conflicts of interest [22] and verifies that the HAS implements appropriate measures to prevent or put an end to any conflict of interest situation [22].

The current ethics officer, is a former Attorney General.

In practice, it is the HAS ethics officer who, based on a preliminary analysis by the department concerned, examines the links and interests of prospective experts and future employees at the HAS. Depending on the dossiers submitted, the officer may return an unfavourable opinion on recruitment, a favourable opinion, a favourable opinion with reservations, or a deferral on certain matters. To fulfil this remit, the ethics officer is assisted by the HAS Legal Department.

To prevent conflicts of interest, the HAS and its ethics officer rely on the health expertise charter. This pivotal methodological tool with a regulatory value results from a decree implementing [23] the 2011 Health Act.

The charter specifies the notion of conflict of interest in the health field in the following terms: “A conflict of interest arises from a situation in which an expert’s interests are likely, by their nature or intensity, to call into question their impartiality or independence in the exercise of their expert assessment mission with regard to the case to be dealt with”.

It lays down procedural rules on the recruitment of experts and provides informative definitions, in particular a definition of stakeholders or interested parties. Its durability (it has not been modified since it was first adopted in May 2013) shows that it is appropriate to current health expertise challenges. It should be noted here that the charter sets out the exceptional cases in which the body responsible for the expert assessment may call on an expert with a conflict of interest. This exception makes it possible to guarantee a high level of expertise in therapeutic areas in which experts with no links or interests are scarce, for example in the treatment of rare diseases. Like all exceptions, it is strictly applied and must meet certain conditions of form and substance, which are reiterated below:

“Exceptionally, one or more experts with a conflict of interest may contribute their expertise:

- if this expertise is of essential scientific or technical interest; and

- if the body commissioned to carry out the expert assessment has been unable to find an expert with equivalent competence in the field concerned with no conflict of interest.

In these exceptional and justified circumstances, such experts may provide their expertise in accordance with the terms and conditions laid down by the body responsible for carrying out the expert assessment and brought to the attention of the commissioning party.

”.

Complementary tools developed by the HAS - In addition to the tools provided by the legislator and the regulatory authorities, the HAS has its own ethics charter, adopted in 2008, as well as its own ethics guide, initially adopted in 2013 and amended several times since then [20].

The HAS also opted to construct a dedicated IT tool to analyse interests.

The HAS developed an IT tool to analyze interests and present data from the “*Transparence santé*” database in a clear and flexible way.

These everyday tools used by the HAS are widely distributed. The charter and guide are published on the HAS website [20]. The charter is also appended to all the internal rules of the HAS' specialized committees, whether provided for by law or created by the HAS.

All the tools and information required to protect against conflicts of interest are freely available. They are public. Ethics and transparency go hand in hand. The 2011 law approaches them together, in an integrated manner.

2. No independence without transparency

The independence granted to the HAS presupposes the transparency of its actions. This transparency is first and foremost aimed at the outside world, the public. But it also retains an internal dimension; within the HAS, ethics is everyone's business.

Externally - Firstly, the HAS reports on its work by publishing all its opinions and decisions. Numerous methodological and practical guides are available on its website, providing information on its working methods and assessment policies to anyone wishing to consult these documents.

In addition to the ethical tools already discussed, the 2011 law also provides for numerous transparency measures. It requires meetings of the HAS' expert bodies to be publicized. This involves the dissemination of their agendas and detailed meeting minutes, as well as details of the votes cast by the body's members and, where applicable, the dissemination of minority opinions expressed by members [24].

Committee sessions are also recorded. Over and above these legal obligations, in the interests of transparency, the HAS opted to publish written transcripts of the sessions of some of its committees on its website for information purposes.

The HAS and its committees are also required by law to publish an annual activity report. The most exposed HAS committees - respectively the appropriately named Transparency Committee (CT), the National Committee for the Assessment of Healthcare Devices and Technologies (CNEDiMTS) and the Commission for Economic and Public Health Evaluation (CEESP), responsible for issuing medico-technical or medico-economic opinions on medicinal products and other health products with a view to their reimbursement by the French national health insurance system - must publish their assessment policy, i.e. "the methods and principles according to which the criteria for assessing health products with a view to their funding by the national health insurance system are implemented" [6].

To ensure the smooth running of its work and prevent any attempted interference, the names of the ad hoc experts called upon by the HAS are published at the end of the work. The list is appended to the opinion in its evidence report or in the final recommendation.

The rules relative to analysis of declarations of interests and the prevention of conflicts of interest of experts and HAS employees are the subject of a published guide [25]. As well as being intended to be consulted and used by the general public, this guide serves as a basis for analysis by the HAS's departments which recruit experts.

Internally - Ethics and the prevention of conflicts of interest can only be a reality if they are taken into account collectively and shared at all levels of the institution, by all employees. In order to develop this collective culture, each HAS department has its own ethics coordinator.

The independence and public service missions of the HAS require all those involved in its activities to comply with the ethical principles and obligations set out in the law and clarified by case law.

Over and above the legal texts and mechanisms implemented, the independence and credibility of an institution such as the HAS also depend on the individual behavior of those who belong to it and/or represent it.

While the HAS' missions require knowledge of healthcare players and cannot be carried out by isolated managers, the latter must be constantly vigilant not to give the appearance of maintaining collusive relationships, by accepting personal benefits, and must avoid

non-institutional relationships with healthcare industry players, or their supporters, and singular relationships with them.

Transparency also lies in publicizing the method used to analyse interests and links. For both members of the HAS and the public, the HAS' ethics guide provides information on the method used to analyse the HAS' interests and links. In politics, the interests of those involved are often direct. They are "obvious" and do not require a detailed analysis of the intensity of the interest. The specificity of preventing conflicts of interest in the field of health is that the interests of the people involved are mostly indirect. Their interests are most often *via* a stakeholder (manufacturer, for example) who has a direct interest in the results of the expert assessment.

For all cases requiring the use of experts, the HAS therefore carries out an *intensity check* to determine whether an interest is likely to place the person concerned in a conflict situation. It is essential to remember here that not every interest or link is inherently a conflict of interest.

This examination involves first of all assessing the nature of the link(s) or interest(s) in question in relation to the subject of the expert assessment. Next, an intensity check is carried out. This is based on the frequency of the interest or link, the length of time it has existed and the extent of the perceived benefit.

Interests are not only financial. Intellectual links or interests, such as belonging to a school of thought, membership of an association or involvement in unpaid work, expert assessments or publications directly related to the subject of the assessment, may also have an influence on the expert assessment in question. Public adoption of positions may lead to the expert's impartiality being called into question. In fact, this type of link or interest is not currently the subject of any legal or regulatory definition. However, it is nonetheless taken into account in the analysis carried out by the HAS. It systematically makes sure that the composition of its working groups and committees guarantees a balance between the different pluralities of opinion.

Tomorrow - The European regulation [26] of 15 December 2021 on health technology assessment (HTA) provides for the joint clinical assessment (JCA) of a health technology (medicinal product or medical device). These JCAs in which the HAS will take part shall precede assessments carried out on a national level by the HAS. The purpose of this regulation is to improve coordination between EU member states for these assessments. It will be gradually phased in from January 2025.

On the eve of this major European reform, which will have a pivotal impact on the HAS, new rules and procedures for preventing conflicts of interest are being drawn up. An implementing regulation on ethics was published in May [27]. The European Commission will be the competent authority in terms of management of interests [26]. However, within this new European framework built to last, the HAS intends to highlight the uniqueness of its model for preventing conflicts of interest

Irrespective of the requirements of French and European law which bind the HAS, it is the latter's duty to ensure that its work is carried out with the highest possible degree of independence and impartiality. In a fast-changing world, where future health, climate and environmental crises are set to increase in intensity and will therefore bring into play colossal financial interests for the world's population, French health institutions such as the HAS, as well as foreign and global institutions such as the WHO, will be particularly required and scrutinized by the public.

In this context, which will necessarily involve urgent responses, the HAS must maintain the very highest standards in terms of preventing conflicts of interest and guaranteeing transparency. The quality of our expertise and public confidence depend on it.

Conflict of interest

none.

CRedit authorship contribution statement

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