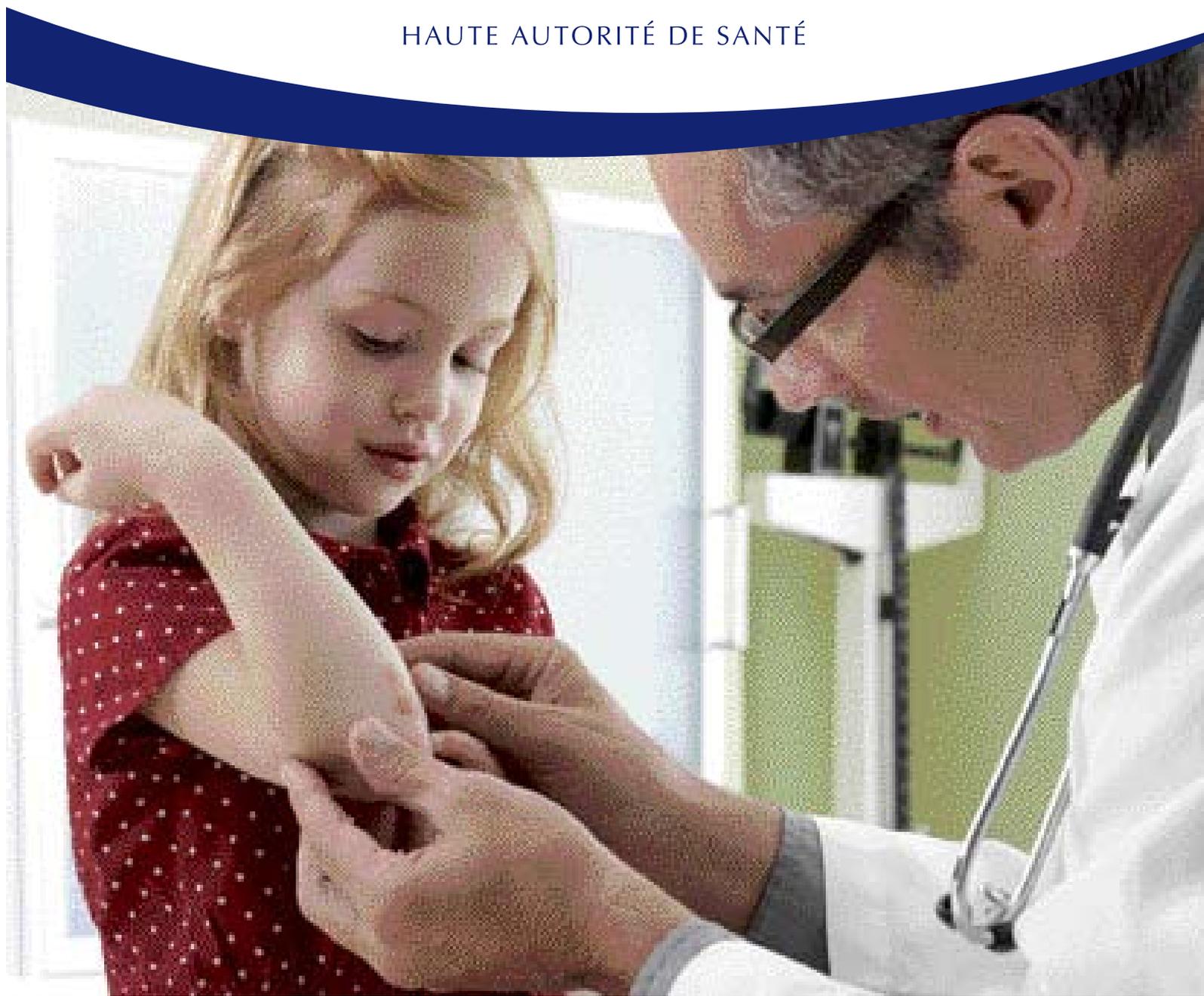


HAS

HAUTE AUTORITÉ DE SANTÉ

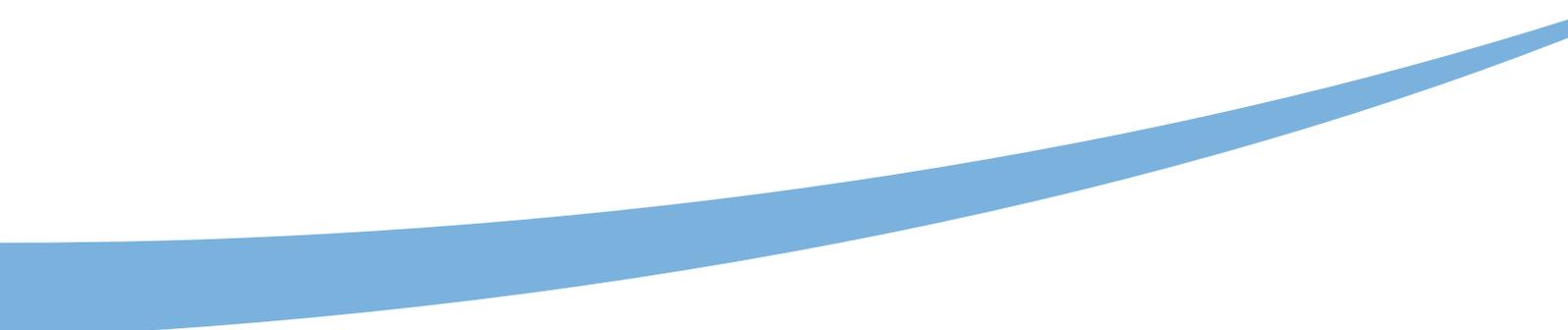


Haute Autorité de Santé

Annual report 2007

Haute Autorité de Santé

Annual report 2007





Foreword



We need concerted action in order to see improvements in the quality of the healthcare system. ”

2007 was the third year of the Haute Autorité de Santé's (HAS) operations, and a year of significant development and change.

The developments

- HAS was entrusted with a new remit, health economics assessment, in 2007. Expectations run high. This expansion of HAS' activities will require the bringing together of complementary approaches and ways of reasoning, and the convergence of actions aimed at improving the efficacy, accessibility, safety, and efficiency of healthcare, in one word, its quality. To prepare for this new remit, discussions were held throughout the year on the factors needed to assess the benefit provided to the community by health products, procedures, and strategies. Health economics assessment will be a priority in 2008.
- HAS intensified the sharing of information and experiences, and its position of repute. It promoted dialogue and consultation with healthcare professionals, partner institutions within the healthcare system, users and the public, in particular by organising its first national "HAS Meeting". HAS operates in a field fraught with expectations and tensions arising from concerns for the future of the healthcare system. In its position of an authority that is science-based and independent, it is able to encourage public debate, as well as participation in the challenge to provide quality healthcare, thus helping to reconcile divergent expectations about the healthcare system.
- HAS increased its volume of activity. The commitment of HAS staff has led to many achievements, as this report will

show. Together with the Board, we wish to commend our staff wholeheartedly for their hard work. For example, 2007 saw the publication of almost 1,000 assessments of medicinal products, for the most part delivered in less than 90 days, the publication of tools for improving professional practice (guides on chronic conditions and clinical practice guidelines), the accreditation of almost 500 healthcare organisations, the development of quality indicators, and the start of work on the new accreditation procedure known as V 2010. By the end of 2007 over 20,000 doctors had enrolled with the 112 bodies approved by HAS for the running of the HAS continuing professional development (CPD) scheme focussing on continuous quality improvement (CQI). In addition, the certification of health-related websites has started.

The changes

2007 saw the launch of many promising projects. It was, in particular, a pivotal year during which an audit led to changes being prepared in the organisation of its departments and committees in order that HAS may accomplish all that is now expected of it.

- Changes were proposed to spur further improvements in the healthcare system. Because HAS is accountable to the public, and as it has a high level of scientific expertise, HAS wants to make sure that the tools, assessments, guidelines, and standards it produces will permeate public decisions and healthcare practices for the greater benefit of the patient and community. To this end, it produced a guideline on novel forms of cooperation that calls for a new allocation



Professor Laurent Degos
Chair of the HAS Board



François Romaneix
HAS Managing Director

of tasks among health professionals. This guideline united two HAS missions: improving the quality and continuity of care delivered to the patient, on the one hand, and the efficiency of care pathways, on the other. The publication of a guideline on the future of the chronic disease management scheme reflected HAS' resolve to support public decisions that will make the healthcare system more effective and efficient.

- Changes were due in Board membership in 2007. The terms of office of Professor Lise Rochaix, Jean-Paul Guérin and Professor Gilles Bouvenot were renewed, and that of Professor Bernard Guiraud-Chaumeil, member of the Board of HAS and chairman of the Committee for the Assessment of Devices and Health Technologies, ended. We extend him our warm regards. We welcome his successor, Professor Jean-Michel Dubernard, who will now support HAS in its crucial task of serving a healthcare system that aims to provide the same, enduring quality to all citizens, as well as fair access for all.

Each step HAS takes aims to provide patients with better quality of care, whilst also providing optimal benefit to the community in line with the public resources allocated to health. 2007 was a year that helped make progress towards enduring quality, and was marked by many achievements and many promising projects. It was the year that strengthened HAS' ambition to be a cross-cutting federating body at the service of professionals, institutions, and the public, tasked with making quality a key concern in each person's choices and behaviour with respect to health.

Professor Laurent Degos
Chair of the HAS Board

François Romaneix
HAS Managing Director



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About HAS

HAS is an independent, public, scientific authority, created by the National Health Insurance Reform Act of August 13, 2004, to enhance the quality and permanence of the French healthcare system. It aims to improve the quality of healthcare as well as of the health system and to ensure enduring and fair access to care that is as effective, safe, and efficient as possible.

In 2007, it was decided to reorganise the activities of HAS departments and committees around its two main missions.

These are providing support:

- to public decision-makers so that they may optimise the management of the basket of products and medical services qualifying for reimbursement and thereby preserve cohesive and fair financing of the healthcare system;
- to healthcare practitioners in their clinical activities so that they may provide more effective, safer and more efficient care.

The actions of HAS are aimed at improving the quality of the healthcare system and concern functions all across the system. To this end, HAS cooperates with all stakeholders in a spirit of consultation and transparency. In its role of a scientific authority, it guarantees the methodological rigour and impartiality of its output, and evaluates the relevance of its actions. As an independent authority, it rejects partisan views, adopting instead the values of solidarity and fairness, in order to serve the collective interest and the public.

HAS' actions acknowledge a firm intent to make quality a key element in the choices and behaviour of health practitioners, public authorities, and users. Three ambitions will shape its actions in the years to come:

- to make quality a key element in the regulation of the healthcare system;
- to improve, together with practitioners, the quality of care and patient safety;
- to involve patients in the quality of care.

Profile of HAS

Status:

- independent, scientific, public authority with its own legal identity and with financial autonomy

Creation:

- established on January 1, 2005 (created by the National Health Insurance Reform Act of August 13, 2004)

Organisation:

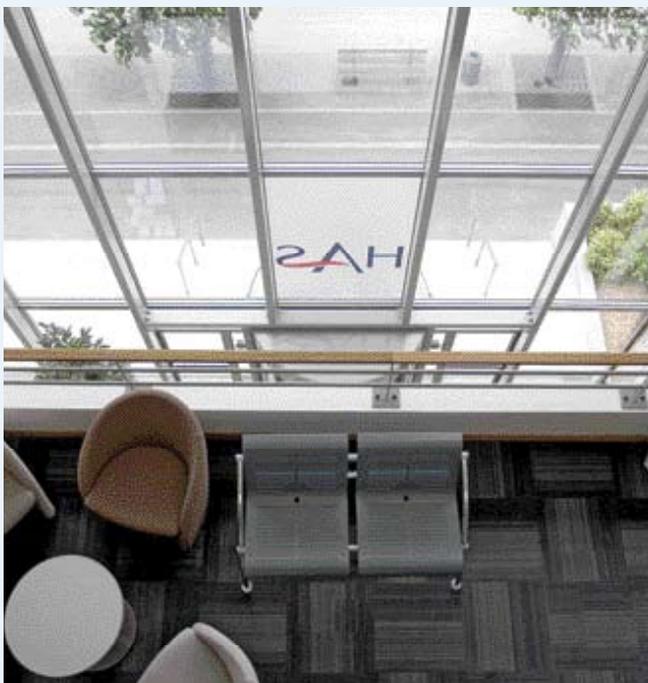
- a Board of eight members chaired by Professor Laurent Degos
- seven specialist committees
- four operational divisions headed by a Managing Director, François Romaneix

Resources:

- almost 400 full-time staff (half from the healthcare sector)
- 34 regional project leaders involved in assessment activities
- 743 surveyors for the accreditation of healthcare organisations
- more than 3,000 external consultant experts and healthcare practitioners

Budget:

- 69 million euros in 2007





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Highlights

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Diary for 2007

January

- HAS recommended subsidising a proactive personalised approach to giving up smoking
- Chronic conditions: HAS published guides for patients with diabetes and hepatitis C
- Accreditation of healthcare organisations: the first round of visits based on the first accreditation manual ended in December 2006. Between 1999 and 2006, HAS assisted almost 3,000 healthcare organisations in their quality initiatives
- Rules for certification of Continuing Professional Development (CPD) were made available to all stakeholders

February

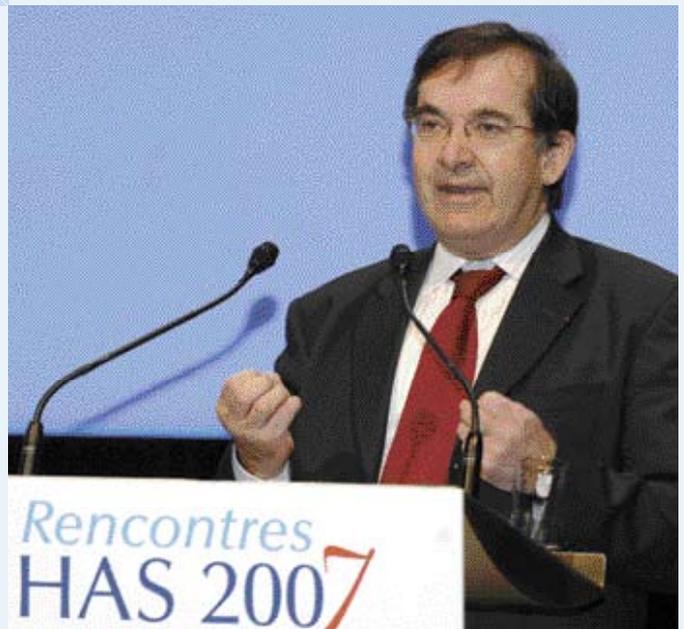
- Assessment of medicines: HAS promotes rapid patient access to therapeutic advances by reducing processing times for applications for medicines to be included on the reimbursement list
- HAS launched the 2007 Calls for Research Proposals programme on its website

March

- Publication of the 2007 work programme and preparation of the 2008 work programme
- Continuing professional development (CPD): publication of the instructions leaflet on CPD for doctors
- Publication of the interim report on cooperation between health practitioners

April

- Certification of doctors: 4 certification bodies approved by HAS
- Establishment of a workgroup to assess clinical benefit to society (SERC)



May

- Publication of three new leaflets on the proper use of medicines: Acomplia®, Caduet® and Procoralan®
- Press conference on integrated care for myocardial infarction
- Cooperation between healthcare practitioners: HAS initiated a survey of all healthcare practitioners on this topic

June

- New version of the second accreditation procedure for healthcare organisations



July/August

- Signature of an agreement on cooperation between HAS and INCa⁽¹⁾
- Preventing conflicts of interest and complying with ethical principles: creation of an independent group of external experts “Ethics and independent expert opinion”
- Presentation of the HAS 2006 annual report to the Senate
- Certification of Continuing Professional Development (CPD) for doctors: publication of the instructions leaflet on the certification scheme for doctors

November

- Participative approach to improving the prescription of psychotropic drugs to the elderly
- Therapeutic patient education: publication of a methodological guide in collaboration with INPES⁽²⁾
- Initiation of a certification procedure for health-related websites
- Decision of the HAS Board on Continuing Professional Development (CPD)

September

- Publication of the first edition of the quality charter for drug databases and of the standards for the certification of prescription software

October

- Reassessment of medicines for Alzheimer’s disease
- Assessment of medicines: online publication of Transparency Committee reports
- HAS – INCa⁽¹⁾ seminar: “Feedback on Continuous Professional Development in cancer care”

December

- The first HAS Meeting “Together, let us improve quality in healthcare”
- Chronic conditions: HAS issued an opinion on the list of medical criteria for chronic conditions
- HAS consulted patient associations: initiation of a public consultation on methods of cooperation and production of guidelines for gaining chronic condition status
- Cooperation between healthcare practitioners: initiation of consultation of all healthcare practitioners on the HAS draft guideline on ways of cooperating

(1) INCa: French National Cancer Institute

(2) INPES: French National Institute for Prevention and Health Education

Defining new horizons for health quality – a public debate

HAS has been engaged for already three years in improving the quality of care. It now wishes to introduce and encourage discussions and debate on the future of the French healthcare system. A document entitled “Defining new horizons for health quality together” was drawn up by the HAS Board and presented during the first “HAS Meeting” (December 17-18, 2007).

Improving quality: a collective initiative which is bearing fruit

HAS’ slogan – “Together, let us improve quality in healthcare” – bears witness to the fact that quality, a fundamental ethical requirement of individual medical practice, has become a collective issue which all stakeholders in healthcare have taken on board. The quality improvement initiatives spurred by HAS are making good progress. The need for quality is gaining ground, with a growing “culture of quality”. Nevertheless, questions are being raised about the furtherance and impact of these initiatives, since 15 years after their inception, problems still persist with adoption and compliance. HAS therefore proposed a framework to analyse the limitations of these initiatives and how they could be overcome.

This framework is outlined in the document entitled “Defining new horizons for health quality together”, presented by the HAS Board during the 2007 “HAS Meeting”.

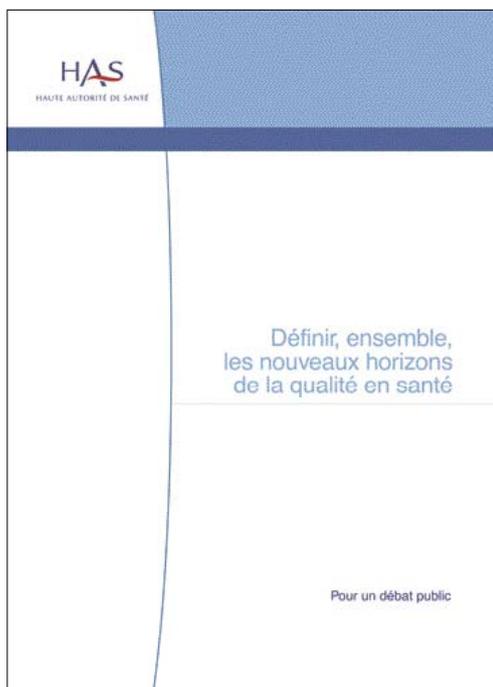
Towards a broad definition of quality

The document provides a broad definition of quality in healthcare: “The quality of a healthcare system increases when the care delivered is as effective, safe and accessible as possible, and when the conditions of delivery are as fair, sustainable, and efficient as possible.” This definition thus covers the three main quality objectives pursued by HAS: (i) to enhance the therapeutic and humane quality of care, (ii) to promote organisation of care that is consistent, (iii) to see that resources are allocated so that healthcare financing remains efficient in the long-term.

The framework for analysing quality improvement initiatives

The promotion of quality in healthcare thus combines many – sometimes competing – expectations. HAS identified four major areas of tension in its fields of intervention:

1. The levers chosen to improve professional practice are based on values that are not entirely consistent. Some levers rely on the practitioners’ own concern for the quality of their practice. Measures to induce voluntary participation in mandatory assessment initiatives are thus ways of improving average clinical practice. However, levers such as Pay-for-Performance or other financial inducements, rewards for efforts made to improve quality, and penalties for the most deviant behaviour are also legitimate measures as they can promote excellence and discourage bad practices. For its actions to be effective, HAS must strike the right balance between the different levers used to induce changes in behaviour.
2. Improvement initiatives must provide standards for good, consistent practice but must also take into account variability in clinical situations and independence of clinical judgement. HAS’ actions must therefore strike a balance between standardisation and professional autonomy.
3. The inclusion of health products on the reimbursement list has to meet double social standards. We all expect advances in treatment; but these advances may be challenged in the name of the precautionary principle. HAS must strike a balance between the freedom of stakeholders to promote the emergence and dissemination of innovations and the need to impose constraints on innovations by requesting exacting assessment procedures.



Opening the public debate

HAS is inviting all stakeholders in the French healthcare system to contribute to the debate on the major issues raised by its document “Defining new horizons for health quality together”:

- Importance of quality in public decision-making on health: The debate should be about: (i) the future with regard to the accreditation of healthcare organisations (the next round is in preparation), (ii) authorisation schemes, (iii) the inclusion of economic, social, ethical, and organisational issues in the assessment of health strategies and products. The use of economic analysis as a decision-aid requires a debate on the assessment of the collective benefit of health strategies, goods, and products.
- Further actions for improving professional practice. In 2008, HAS wishes to debate with practitioners on the simplification of procedures, the development of professional associations, and the promotion of new forms of cooperation and of rewarding commitment to quality. A debate has already been launched on the legal issues of continuing professional development (*see box*).
- Increasing user involvement. HAS wishes to take greater account of the needs and expertise of patients in the production and use of its tools and standards, and to promote user access to high-quality information.

4. Improvement initiatives have to enhance the quality of individual care, yet guarantee an efficient, fair, and enduring health system providing collective benefit. HAS’ actions must show that individual interests and the common good can be in harmony instead of fruitless competition. Quality in healthcare means effective and safe care but also fair and enduring access to efficient care.

These tensions between individual and collective interest need to be understood in order to resolve competing expectations with regard to quality.

First milestones in the public debate

The 2007 “HAS Meeting” saw the kick-off of a collective debate on the issues identified in the document “Defining new horizons for health quality together”. The debate will be pursued in 2008:

- A seminar will be organised in partnership with CNAMTS⁽¹⁾ and DHOS⁽²⁾ on the promises and limitations

of Pay-for-Performance systems

- A colloquium will be held in March 2008 on the legal aspects of practice appraisal in partnership with the Health Law Institute (*Institut Droit et Santé*) in order to develop a common view among practitioners, lawyers and patients. Practice appraisal measures are

needed to promote the safest possible care. However, practitioners are afraid that potential errors or malfunctions could serve as grounds in actions for damages. It is therefore necessary to promote research into root causes as well as into the rights of patients to transparent information.

(1) CNAMTS: National Health Insurance Fund for Salaried Workers

(2) DHOS: Directorate for Hospitals and Organisation of Care

The first “HAS Meeting”: Together, let us improve quality in healthcare

The first “HAS Meeting” brought together more than a thousand stakeholders in healthcare – health practitioners, representatives of associations or of official bodies, manufacturers... – under a single banner: “Together, let us improve quality in healthcare”. It was an opportunity to share experience and initiate a real debate on the future of the French healthcare system.

The first “HAS Meeting” was attended by over 1000 participants from the world of healthcare, and led to a genuine exchange of views between HAS and its main stakeholders (health practitioners, patients, representatives of official bodies, manufacturers, and policy makers). Lively debate enabled a true consultation to get under way about the future of quality within the French healthcare system.

The debate was opened by Professor Laurent Degos, Chairman of HAS, and by Marc Danzon, Regional Director for Europe of the World Health Organisation (WHO). The French Minister of Health, Youth Affairs, Sports and Community Life, Roselyne Bachelot-Narquin, also spoke during the morning of December 17. More than 160 invited speakers and 25 experts from HAS enlivened these two days.

An account was given of the diverse, yet coherent, actions undertaken by HAS and stakeholders, in their endeavour to improve the quality of care. *“HAS proposes a broad view of quality in healthcare, one which covers both the expectations of patients, who, like practitioners, want a healthcare system that is as safe, innovative and effective as possible, and the expectations of the public and the authorities, who want a system that is close-knit, efficient, fair, and enduring. I do not believe that these expectations are contradictory. We must find ways of reconciling them better,”* said Laurent Degos.

Plenary sessions on hot topics

The four plenary sessions addressed major hot topics as part of a global discussion on quality.

Financing quality. The system for financing healthcare organisations and practitioners does not explicitly remunerate quality. However, lack of quality engenders a cost to society. Should quality improvement be taken into account in financing? If yes, how?

Delegating and new professions: towards new forms of cooperation between health practitioners. The objective was to initiate debate on the delegation of tasks or competencies between healthcare practitioners. This topic aroused much interest throughout the meeting. HAS has decided to initiate an online public consultation on its draft guideline on new forms of cooperation between health practitioners.

How can health economics contribute to healthcare assessments. It is necessary to assess not only the therapeutic efficacy of health technologies and strategies but also their economic impact. The law on the financing of social security for 2008 has entrusted HAS with a new mission – health economics assessment – in order to relate quality and solvency better.

Quality: a factor for change in hospital organisation. This session focused on quality criteria as factors in inducing changes in hospital organisation. Should they be given more importance in the multi-year contracts established between healthcare organisations and the Regional Hospital Agencies? How best to link them with other actions conducted by HAS, such as the accreditation of healthcare organisations?

Lively round tables

There were 31 round table sessions, each attended by 100 to 150 participants, which furthered the debate on the four major topics (quality as a means of regulation, practice improvement, cooperation between healthcare practitioners, and research) by presenting real-life experiences.

Practice improvement. The discussion underscored the diversity of actions undertaken by HAS, together with healthcare professionals, notably in the areas of continuing professional development (CPD) and accreditation of healthcare organisations (e.g. early management of stroke, accreditation in 2010).



To involve patients and their associations in the debate on practice improvement, a round table session was devoted to relationships between institutions and patient associations (“How to work together”) under the aegis of the Chairman of CISS⁽¹⁾, INSERM⁽²⁾, and AP-HP⁽³⁾. Participants were able to share their experiences and propose new methods of work in order to further relationships between these institutions and patient associations.

The following topics were also covered: How to develop therapeutic education for patients; Improving medical practices: the role of patients; What medical information should be given in the case of an adverse event?

Research. An in-depth discussion took place on health indicators and on national and international feedback on their use. Discussions also took place on the 14 research projects supported by HAS in 2007.

Looking ahead. A discussion was initiated on the future of certain quality initiatives (e.g. What have we learnt from fifteen years of guideline development; How can we improve the quality of health information; Taking account of non-medical dimensions in the assessment of benefit to society (SERC)).

The programme of this first “HAS Meeting” and all the presentations are available on the HAS website.

Significant media coverage

The “HAS Meeting” received strong media coverage, especially in the health-related professional press (announcements and editorial publicity to inform practitioners about the programme before the event; numerous articles illustrating the richness of the debates and the diversity of HAS’ missions after the event).

2008 under the banner of dialogue

The first “HAS Meeting” illustrated HAS’ determination to enter into a dialogue with all stakeholders in order to share a common language and common expectations about quality in healthcare. It was a starting point for further exchanges of views. Some of these have already been scheduled by stakeholders, e.g. a colloquium at the Economic and Social Council in March 2008 on the legal aspects of Continuing Professional Development (CPD) and regional meetings on CPD and the accreditation of healthcare organisations. The dialogue will continue in 2008 and can use as a foundation the document entitled “Defining new horizons for health quality together”. This document was drawn up by the HAS Board and sent to all participants (see pages 12 and 13). The second “HAS Meeting” will be held on December 18-19, 2008, and continue to mark out the future of quality in healthcare.

(1) CISS: Inter-association Collective for Health

(2) INSERM: French National Institute for Health and Medical Research

(3) AP-HP: Association of public hospitals in Paris and surrounding areas (Paris hospital authority)

First HAS – INCA colloquium on Continuing Professional Development (CPD)

Many care teams in oncology are engaged in CPD along the lines developed by HAS (i.e. CPD focusing on continuous quality improvement and involving multidisciplinary dialogue, compliance with good practice guidelines, practice appraisal...). During the first joint HAS - INCa colloquium^{(1) (2)}, (“Feedback on CPD in oncology”), health practitioners were able to explain how CPD can help improve the quality of care using examples taken from grassroots experience.

Many professionals working in oncology have already been engaged for some time in practice appraisal and quality improvement initiatives. These initiatives are totally consistent with the principles of CPD as set out by HAS, i.e. providing benefit to the patient by improving practice through analysis.

The first HAS-INCa colloquium was opened by Professor Laurent Degos, Chairman of HAS, and Professor Dominique Maraninchi, Chairman of INCa. Its aim was to present concrete CPD initiatives in order to encourage experience sharing and new initiatives.

A total of 16 initiatives were presented by practitioners. The morning was devoted to the role of CPD in the organisation of care (e.g. multidisciplinary team meetings, oncology networks), and the afternoon to the analysis of initiatives such as clinical audits on how to break the news (a key measure of the 2003 cancer plan), mortality-morbidity meetings, or the involvement of general practitioners in population-based cancer screening.

These presentations showed that CPD, by analysing and monitoring clinical data, brings about a continuous improvement in the quality of care. The speakers emphasized that these initiatives can be part of the daily practice of healthcare practitioners working in the field of oncology and that they converge towards a better management of cancer patients.

This colloquium was one of the first upshots of the agreement, signed in July 2007, between HAS and INCa. The idea is to combine forces and know-how in a joint action programme, that includes CPD, in order to improve information for health practitioners and for the public, and guarantee patients better access to care.

(1) InCa: French National Cancer Institute

(2) La Défense (Paris), October 19, 2007



Public consultation lies at the heart of HAS' approach

In 2007 HAS initiated public online consultations about its guidelines and work in order to respond better to expectations. This new initiative completes the regular consultation work undertaken by the expert panels and working groups of HAS, and will be extended in 2008.

HAS is developing public consultations about its work and guidelines on its website in order to remain close to the concerns and needs of the general public and of health practitioners. It is inviting its audience to share their experience or express their opinion on various projects so that it can be more attentive to grassroots reactions from stakeholders and even pre-empt these reactions. The aim is also to discover new needs or new possible uses. These public consultations add to the tests and/or methods of consultation that HAS expert groups use to produce scientific documents. They reflect a desire to combine assessment and public debate in order to facilitate decision-making and acceptance of HAS productions by stakeholders.

Sharing experiences and ideas

The two public consultations conducted by HAS in 2007 on the draft guideline "Delegating and new professions... Conditions for new forms of cooperation between health practitioners" are good examples of sharing.

1. A first consultation launched between May and August 2007 invited health practitioners to share their experiences. Overall, 334 practitioners responded to this appeal on the HAS website. The "informal" activities they described covered a broad range of professions and types of cooperation (from diversifying activity to acting as locum) and of care (patient follow-up, prescribing, prevention...).

2. A second consultation between December 17, 2007, and January 31, 2008, encouraged health practitioners, patients and institutional stakeholders to respond to the draft guideline published at the beginning of December by HAS. Of the 218 responses received, 75% were in favour of the guideline. Many comments were added to the final version of the guideline after this consultation.

3. After this first success, HAS launched new public consultations on several of its activities at the turn of the year, for instance on the framework for cooperation between patient associations and HAS.



Medical and public health assessment

Providing more and better information on the proper use of health technologies and promoting their use

Open access to Transparency Committee documents

The agendas and minutes of Transparency Committee meetings, and not only their opinions, are now available on the HAS website.

The Transparency Committee is the HAS specialist committee responsible for assessing medicinal products that have obtained marketing authorisation. It gives an opinion on the inclusion of these products on the list of medicines that are reimbursed by French National Health Insurance (in community and/or hospital pharmacies). The Committee consists of doctors (specialists and general practitioners), pharmacists, and specialists in methodology and epidemiology. The opinions issued by the Committee, and more recently the agenda and minutes of meetings which include details and explanations on voting, are made public on the HAS website⁽¹⁾.



First Good Use Leaflets for medical devices and procedures

HAS published the first Good Use Leaflets for:

- medical devices: Indications and prescription for self-monitoring of blood glucose in diabetic patients (based on the opinions of the CEPP*);

- procedures: Carotid stenoses: the role of surgery and angioplasty; Which antibody tests should be prescribed in coeliac disease? (based on health technology assessment reports and the opinions of the CEAP**).

The Good Use Leaflet on Cochlear or brainstem implants in the treatment of hearing loss was produced on the basis of the joint work of the CEPP* and CEAP**.

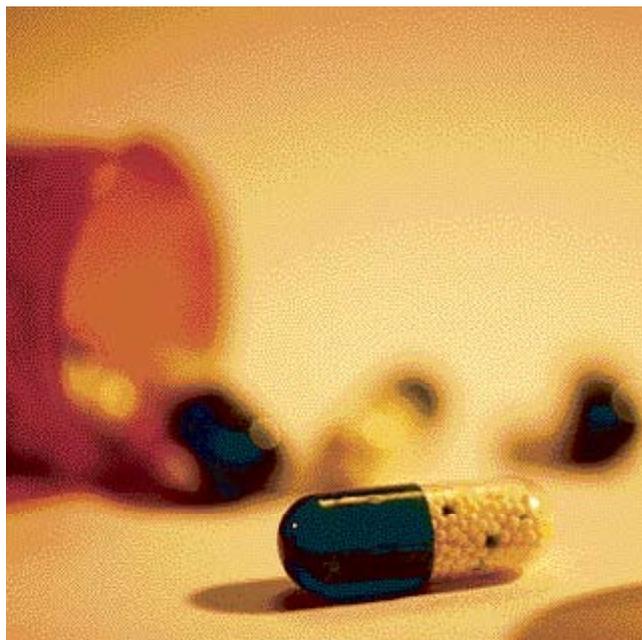
* CEPP: HAS Committee for the Assessment of Devices and Health Technologies

** CEAP: HAS Committee for the Assessment of Medical and Surgical Procedures

Further Good Use Leaflets for medicines

In 2007, HAS produced 9 new Good Use Leaflets for medicines.

HAS regularly publishes Good Use Leaflets for medicines. They are based on the opinions of the Transparency Committee. In 2007, nine leaflets on new medicinal products or new indications were produced; ten are planned for 2008. Their aim is to provide practitioners with key information on the proper use of medicinal products that have been assessed by the Committee. Each leaflet has three sections: (i) Key points, (ii) Therapeutic use, (iii) Helpful reminders. All the leaflets may be downloaded from the HAS website. The main criteria for deciding to draft a leaflet on a product are its originality, the size of the target population, and the risk of misuse.



Good use leaflets for medicines (2007)	
Product	Indication
Amlodipine-atorvastatin (Caduet®)	Hypertension
Candesartan (Atacand®, Kenzen®)	Heart failure
Ezetimibe (Ezetrol®, Inegy®)	Hypercholesterolaemia
Ivabradine (Procoralan®)	Stable chronic angina
Papillomavirus vaccine (Gardasil®)	Vaccine against certain papillomaviruses
Pramipexole (Sifrol®)	Restless leg syndrome
Pregabalin (Lyrica®)	Neuropathic pain
Rimonabant (Acomplia®)	Obesity
Ropinirole (Adartrel®)	Restless leg syndrome

First standards for use of high-cost healthcare products outside of GHS cover⁽²⁾

HAS is in charge of producing standards on the use of high-cost medical devices financed outside GHS⁽³⁾. Three standards were produced in 2007. For the first time, a decree officially recognises that hospital practitioners can use these medical devices outside of the listed indications⁽⁴⁾, provided they are used in a treatment protocol. The aim of these standards is to enable patients to access the best possible care as promptly as possible.

(1) In accordance with article 28 of law n°2007-248 of February 26, 2007, on miscellaneous provisions for adjustment to community law in the area of medicines

(2) GHS: equivalent to diagnosis-related groups

(3) In accordance with Decree N°2004-546 on good practice contracts concerning categories of medicines, the prescription and sales of which are restricted to certain healthcare organisations

(4) LPP: List of medical devices and technologies

Information sheets: “Removal from hospital-only listing”

These new information sheets inform healthcare practitioners about medicines that up to now have been prescribed and dispensed exclusively in hospitals and which are now available in community pharmacies following the decree of June 15, 2004*.

They provide helpful information on the proper use of these medicines and are intended mainly for retail pharmacists. Retail pharmacists can now dispense products

covering new treatments and diseases, and have an enhanced role in patient management and follow-up. HAS produced 36 guides in 2007 (10 are on the website). They will be distributed in the form of a booklet in 2008.

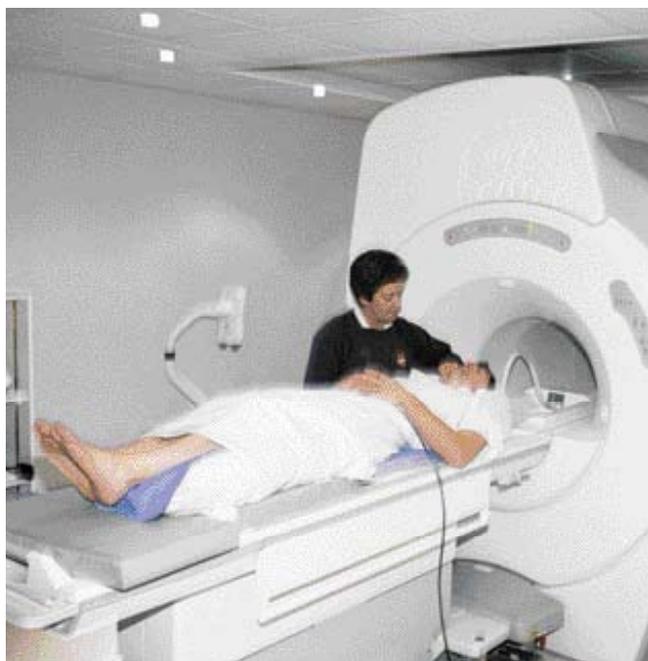
* Decree of August 24, 2005, relating to the Good practice contract for the use of medicines, medical devices and technologies, mentioned in article L.162-22-7 of the Social Security Code

Assessing innovations promptly

For a prompt assessment of technological innovations likely to provide genuine benefit to patients, HAS set up a gateway to identify these innovations in 2007.

The purpose of this gateway set up by HAS in 2007 is to make innovative medical technologies – medicines, procedures, devices or medical equipment – available to patients as soon as possible, whenever these innovations can substantially improve treatment or diagnosis. A dedicated e-mail address (innovation@has-sante.fr) now facilitates exchanges with manufacturers, scientists, and other persons dealing with innovative products. The gateway has four objectives.

1. To identify potentially major innovations. New and emerging technologies can be identified by regular review of selected information sources (scientific and medical journals...) and by establishing direct contact with manufacturers, practitioners, and researchers. HAS participates in the Euroscan international monitoring network which promotes the exchange of information between institutions through a shared database on emerging technologies. By using all these information sources, HAS can identify potentially innovative technologies likely to provide real benefit to patients.



2. To invite scientific consultation through early contacts with healthcare practitioners and manufacturers working on the development of innovative technologies. The idea is to allow practitioners to submit their planned clinical studies for review by HAS (methodology, endpoints...). A specific workgroup consisting of HAS members and experts in the field will carry out the review. The aim is to promote the early collection of relevant clinical data.

3. To promote advance review of innovative products likely to lead to progress. The aim is a prompt assessment, i.e. as soon as the necessary scientific data are available. The innovations are reviewed using the two criteria HAS employs to assess all health technologies: the “expected benefit”, which measures clinical utility, and the “improvement in expected benefit”, which measures the added value provided by a technology in comparison with another, on a scale from I to V (level V is for no improvement).

4. To accompany the introduction of these innovative technologies into the healthcare system. Early availability implies that the amount of information on inclusion of the technology on the list for reimbursement is still limited. The HAS committees may propose provisional reimbursement whilst awaiting further studies. Initial use of the technology may also be limited to certain medical teams. There are plans for international collaboration on sharing information on the monitoring of innovative technologies (follow-up studies and other activities) between European countries. HAS is a lead partner in the European EUNetHTA⁽¹⁾ project on the monitoring of new and emerging technologies.

(1) EUNetHTA: European Network for Health Technology Assessment

Assessing medical devices by category

Reassessment of hip prostheses (review of generic lines)

140,000 hip arthroplasties are performed each year in France. The number of different hip prostheses on the French market is large; HAS has assessed them all. The assessment was rigorous, and based on a critical review of the literature and on the formal consensus opinion of a panel of experts. For the first time, guidelines could be issued on the choice of prosthesis for each clinical situation. This is the first step, based on the current state-of-the-art, towards the drafting of guidelines on precise indications for each type of prosthesis.

Assessment of cochlear implants

The MIGAC⁽¹⁾ fund used to finance cochlear implants and brain stem implants, their adjustment, and post-implantation rehabilitation whereas the hospital stay for device placement came under a specific GHS⁽²⁾. The Ministry of Health decided to discontinue this method of financing. The devices now have to be included on the LPPR⁽³⁾.

In addition, implant placement, adjustment and removal were listed under four different codes in the previous version of the CCAM⁽⁴⁾. These codes are not included in the current CCAM⁽⁴⁾ tariff schedule, and the procedures are thus no longer covered by French National Health Insurance.

Devices and procedures have to be assessed by HAS before they can be included on the lists (LPPR and CCAM⁽⁴⁾). HAS received applications for the inclusion of cochlear and brain stem implants from four device manufacturers, and decided to assess the device placement procedures on its own initiative. It assessed their expected benefit, providing concomitant opinions on the devices and procedures. This meant that decision-makers could synchronise their decisions for optimum patient management.

(1) MIGAC: Missions of General Interest and Assistance with Contractualisation

(2) GHS: equivalent to a diagnosis-related group

(3) LPPR: List of Products and Services qualifying for Reimbursement

(4) CCAM: Common Classification of Medical Procedures



Reassessment of anti-Alzheimer's drugs

The HAS Transparency Committee reassessed drugs used to treat Alzheimer's disease. Their opinion, published in October 2007, was eagerly awaited on account of the burden of Alzheimer's disease, which affects about 860,000 people in France.

The Transparency Committee, whose members are all health practitioners, reassessed the four drugs indicated in Alzheimer's disease (donepezil (Aricept®), galantamine (Reminyl® and Reminyl® PR), rivastigmine (Exelon®) and memantine (Ebixa®)) against two criteria: the Actual Benefit (AB) and the added value (or Improvement in Actual Benefit (IAB)). The IAB is scored from I (major improvement) to V (no improvement).

Substantial Actual Benefit

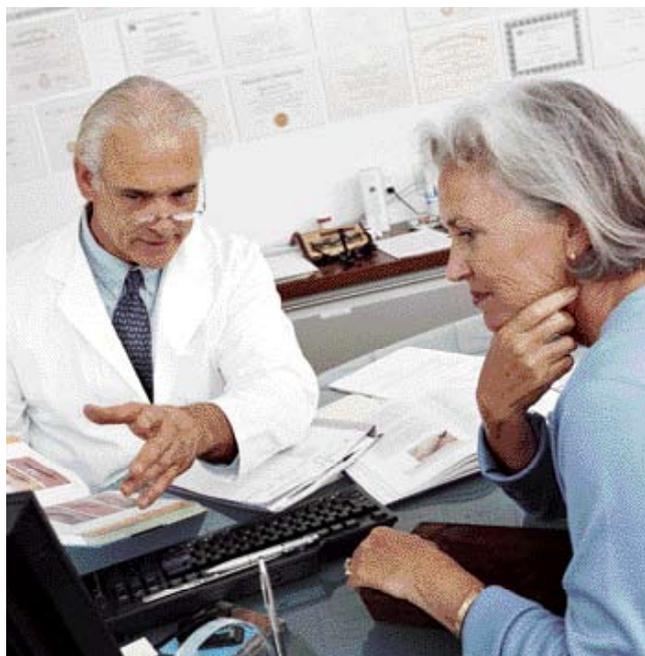
The Actual Benefit of a drug depends on the burden of the disease, the clinical performance of the drug, the drug's therapeutic use, and its potential impact in terms of public health. The HAS Transparency Committee confirmed that the Actual Benefit of the four anti-Alzheimer drugs is significant, in view of:

- their proven efficacy (albeit slight) against certain symptoms;
- the absence of an alternative treatment;
- the seriousness and frequency of Alzheimer's disease. It is estimated that about 860,000 persons are affected by Alzheimer's or related diseases in France. The incidence of the disease is estimated at 225,000 new cases each year;
- their "constructive" role in clinical management. Prescription of these drugs is often an opportunity to introduce clinical, and also psychological and social management, for the patient and his/her family.

Minor added value

In the light of the available clinical data and real-life experience, the Transparency Committee considered that the added value of these drugs was not as great as expected. It estimated the Improvement in Actual Benefit to be minor (IAB IV).

These drugs have some efficacy against certain symptoms. They are able to reduce some cognitive and behavioural problems and may impact favourably on patients' daily activities. However, they do not halt disease progression to a more advanced stage, nor delay placement of patients into a specialised institution. In addition, even though they are often prescribed for several years, their long-term efficacy is uncertain. Their effects have only been clearly established over short follow-ups, often limited to six months.



Two educational documents, a summary of HAS' opinion on the drugs and a FAQ about the disease, have been produced by HAS to assist practitioners in their daily practice. A guideline on good practice in the overall management of Alzheimer's disease will be produced in 2008.

Health economics assessment: a new mission for HAS

Since the promulgation of the law on how to finance Social Security services (LFSS) for 2008⁽¹⁾, health economics assessment has been added to the list of HAS' missions. The aim is to develop the economic aspects of healthcare studies in order to facilitate decision-making by public authorities.

Since its creation in 2004, HAS has performed health economics assessments as part of its work on public health guidelines, clinical practice guidelines, health technology assessments, and a few specifically health economics orientated reports. However, assessments of medicines and medical devices with a view to their inclusion on the reimbursement lists have included no economic assessment. This gap has now been filled by Article 41 of the LFSS which states that "within the context of its missions, the *Haute Autorité de Santé* issues medical and economic guidelines and opinions on the most efficient care, prescription, and management strategies".

Now that HAS' new mission of health economics assessment has been framed in legal terms, two avenues are opened:

- Taking account of economic factors can help make decisions not only on the development of public health programmes (screening, prevention, organisation of care) but also on the inclusion of health products on reimbursement lists.
- Economic data can also help practitioners make decisions and rank diagnostic or therapeutic interventions.

International comparison

Historically, there are two long-standing yet contrasting views. One view clearly states that economic data are part of the decision process; this is the case in the United Kingdom and in Scandinavian countries. The other view does not officially recognise the economic dimension in decision-making. Decision-making is based solely on treatment efficacy. This view prevails in France and Germany. However, over the last few years, all European healthcare systems are converging towards the more or less explicit recognition that one of the criteria for deciding to include an intervention on a reimbursement list is its efficiency.

Assessment of the benefit to society (Service Rendu à la Collectivité: SERC): a French perspective

The experience of other countries shows how difficult it is to integrate the economic dimension into the assessment of healthcare. The assessments all too often overlook ethical and sociological issues. To assist public decisions and contribute to their acceptability, HAS has chosen to include economic assessment within a global and multidimensional assessment of health technologies. It has adopted the idea of assessing the "benefit to society" (SERC), thus embracing welfare issues in addition to the existing medical issues. A SERC assessment covers economic, organisational, social, ethical, and legal issues. The approach will also be applied to the development of opinions and guidelines on good practice and use for healthcare practitioners. The objective is to make best use of the basket of products and services qualifying for reimbursement.

The SERC Working Group of HAS, set up in April 2007, produced a draft document in December 2007 containing proposals on how HAS could set about assessing the benefits of health technologies to society. How to perform such assessments needs to be explored further and HAS will initiate consultation and exchange of ideas with all stakeholders within the healthcare system on the subject.

National consultation

Experience from other countries shows the limitations of systems which emphasize economic indicators at the expense of other dimensions (e.g. ethics) and of systems that consider medical factors only. To know where to place the cursor, HAS organised a consultation with all stakeholders in the healthcare system in order to specify their needs, concerns, and expectations, and to define the most important topics. Additionally, during the first semester of 2008, HAS will launch a call for tenders to select teams for outsourcing and partnerships.

(1) Promulgated in December 2007

Improving practices, quality, and the safety of care

A new scheme for chronic conditions?

In December 2007, HAS sent the Ministry of Health an opinion on the current list of chronic conditions and on the medical criteria for including conditions on the list, in which it recommended redesigning the chronic condition management scheme.

The law has charged HAS with three missions concerning chronic conditions: (i) to give an opinion on the chronic conditions currently included on the list; (ii) to propose medical criteria for including chronic conditions on the list; (iii) to recommend the procedures and services necessary for the management of each chronic condition on the list.

Since issuing its first opinion (May 2006), HAS has produced lists of procedures and services for about 20 chronic conditions, together with guides for doctors and patients on each condition. A new opinion, dated December 2007, sets forth HAS' views on the efficacy of the scheme which is currently a matter of debate. The scheme was introduced in the 1940s when the French national health insurance system was established in order that costly chronic conditions should benefit from 100% coverage.

Financial coverage or medical management: what are the aims of the chronic condition management scheme?

The new opinion recaps the main observations made by HAS in its first opinion issued in May 2006. It underscores the shortcomings of a system that tries to achieve two quite separate objectives with a single tool: a social objective (exemption of co-payment

to limit the impact of costly care) and a medical objective (ensure quality medical management).

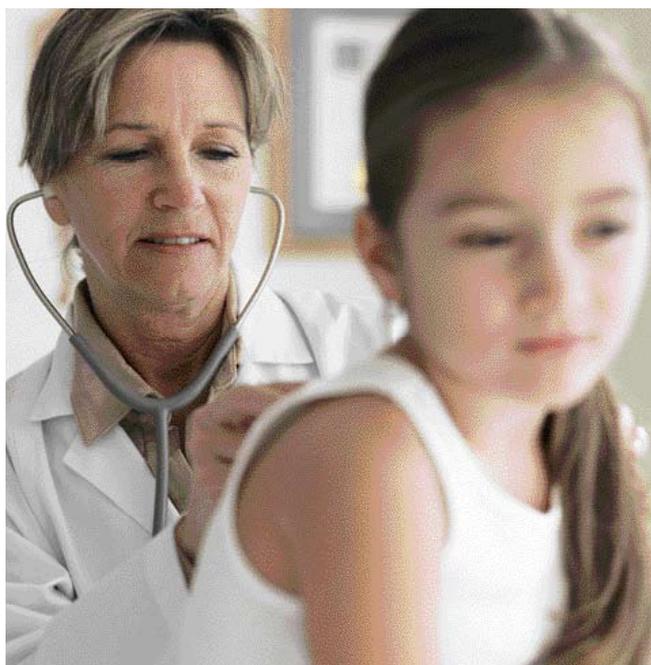
The inconsistency of the current list of chronic conditions is well illustrated by the management of cardiovascular disease. Of the major cardiovascular risk factors that can be controlled by medical treatment, some are covered by the scheme (non-complicated diabetes), some are sometimes covered but not always (arterial hypertension), and some are never covered (isolated dyslipidaemias). Moreover, the scheme does not cover the care of certain patients with hypertension and high lipid levels and of patients with well-controlled hypertension even though their care may be more costly than the care of non-insulin dependent diabetics or patients with coronary conditions whose conditions are covered by the scheme.

The three scenarios proposed by HAS

1. Merely updating current criteria

Two updating mechanisms are proposed for 19 of the currently listed chronic conditions:

- Defining the duration of exemption from the co-payment requirement as precisely as possible by taking into account the anticipated duration of treatment or the expected phases of stabilisation.



- Increasing the clinical relevance of the disease descriptions. The new criteria should take account of scientific progress and of changes in practice or management.

The main drawback of this scenario, which does not bring about any significant change in the scope for inclusion into the scheme, is that it does not eliminate current inconsistencies. In addition, by recognising the current criteria *de facto*, it perpetuates an unsatisfactory situation.

2. Making some changes to the list and revising the criteria for certain conditions

The first step in this scenario would be delisting certain curable diseases such as leprosy, complicated schistosomiasis, and tuberculosis. Arterial hypertension could also be delisted, on the condition however that provisions are taken not to compromise the quality of the medical follow-up of the patients concerned. Hypertension is a risk factor but not a disease as such, and the management of severe hypertension is not particularly costly. Only chronic conditions should be included on the list.

Furthermore, for certain cardiovascular and other conditions (stroke, coronary disease, diabetes or chronic kidney disease), this scenario only covers situations of proven clinical severity (“option 2” situations). Only situations where costs to the patient (co-payment charges) remain high would qualify for total exemption of charges. Less costly forms or phases of disease would no longer receive 100% coverage.

The adoption of this scenario would lead to more consistent management of cardiovascular risk, since the withdrawal of hypertension from the list would mean that only established disease would be eligible under the scheme.

However, the basis of this scenario is rather weak: There is no clear definition of what is understood by “particularly costly care”, the costs required to manage a given disease may vary considerably among individuals, and restricting the scheme to situations of proven clinical severity is at variance with the public health objective of preventing complications by early management. The scenario cannot therefore be accepted until new tools for high-quality patient surveillance have been put into place.

3. Maintaining the status quo whilst waiting for a rapid reform of the scheme

This reform should take separate account of the social and medical aspects of the scheme, and establish appropriate tools for each:

- a social scheme that is fair and based on an objective measure of the costs supported by the insured. The French so-called “*bouclier sanitaire*” (ceiling of out-of-pocket payment) would be a solution; its scope is also broader than that of the chronic conditions scheme;
- a medical scheme that is effective and improves the quality of the surveillance of patients with chronic diseases.

This scenario is the one that corresponds best to the general orientation fixed by HAS in 2006. HAS will continue, within the framework of its remit, to work on improving medical surveillance of patients with chronic diseases and to propose amendments to the public authorities.

A methodological framework for developing therapeutic patient education (TPE)

In November 2007, HAS and the Institut National de la Prévention et de l'Education pour la Santé (INPES)⁽¹⁾ published a methodological guide entitled "Structuring a therapeutic education programme for patients with chronic disease", which aims to improve the quality of life of these patients.

Therapeutic patient education (TPE) "aims to assist patients to acquire or maintain the competence to manage their life with a chronic disease in the best way possible. It is a permanently integrated part of patient management. It consists of organised activities and includes psychological support, designed to keep the patients aware and informed about their disease, about their care, of the organisation of hospitalisation and hospital procedures, and behaviour associated with health and with the disease. The aim is to assist the patients (as well as their families) to understand their disease and treatment, to collaborate together and to take responsibility for their own management, with the objective of helping them to maintain and improve their quality of life"⁽²⁾.

HAS and INPES have published a methodological guide to help practitioners and their organisations (e.g. specialty societies, scientific bodies), patients and their associations, and institutional stakeholders set up, implement, and assess a structured TPE programme. The general framework given in this guide can be adapted to any chronic disease or any setting (healthcare organisations, networks, community care, etc.) and tailored to a patient's specific needs.

The goal of TPE is to improve the patient's health and quality of life. It is a continuous process of learning and psychological support intended to help patients deal with their disease and treatment in daily life (e.g. how to relieve symptoms, understand self-monitoring results, carry out technical procedures such as injecting insulin, adapting drug dosages). Patients get to know themselves better, regain self-confidence, set themselves targets, and make choices.

Few studies are available on TPE but its efficacy has already been established in type 1 diabetes and asthma as shown, for example, by the reduction in the number of hospital admissions, visits to the emergency department, and unscheduled visits to the doctor. However, any new TPE programme should include an assessment of its long-term efficacy.

Guidance on TPE for practitioners

The guide is based on a critical review of the available literature, discussions within working groups among practitioners involved in TPE, interviews of patients with chronic disease, and data from studies conducted by HAS in the primary care sector.

It consists of three parts: (i) the definition of TPE, its aims, targets, and steps; (ii) the contents of each step and the implementation of a tailored TPE programme, (iii) the development of a structured TPE programme for a given chronic disease and its assessment in order to make improvements.

The guide has three companion documents – three Quick Reference Guides – to help practitioners adopt TPE. An additional report analyses the available health economics data and makes proposals on funding TPE programmes. HAS also gives guidance on the factors for a successful TPE programme. A key factor for success according to HAS is the involvement of a multidisciplinary team working in close collaboration with patients, either individually or through their associations.

The collaboration between HAS and INPES will be pursued throughout 2008 to increase our knowledge base and the availability of studies in this promising area of development for the chronic disease sector.

(1) INPES: French National Institute for Prevention and Health Education

(2) Definition as given by the WHO-Europe report: Therapeutic Patient Education – Continuing Education Programmes for Health Care Providers in the field of Chronic Disease, 1996

Together, let us improve patient management

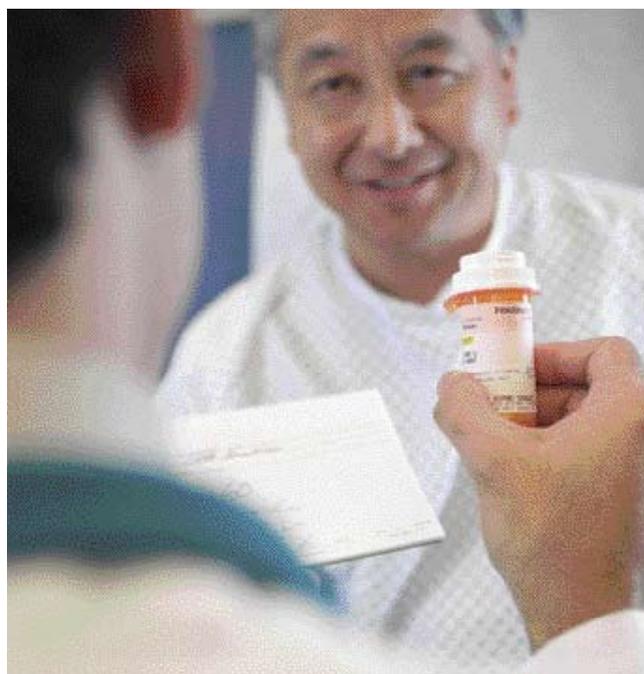
Improving the prescription of psychotropic drugs to the elderly

In 2007, HAS initiated discussions among health practitioners and public authorities on improving the prescribing of psychotropic drugs to the elderly. This is a complex issue that concerns a variety of clinical settings. Collaborative actions have already begun, thanks to an innovative participatory initiative by HAS, and will be pursued over the next two years.

The consumption of psychotropic drugs (anxiolytics, hypnotics, neuroleptics, antidepressants...) is far higher in France than in other European countries, even though the treatment of depression is not optimal. Many reports, including that of the Parliamentary Office for Health Policy Evaluation, highlight the risks associated with the widespread use of these drugs. The elderly are particularly vulnerable because of their lower physical resistance and slower metabolism. In 2006, HAS offered to collaborate with stakeholders and institutions on the prescribing of psychotropic drugs to the elderly in order to find practicable ways of improving prescribing and of raising the awareness of the elderly on the proper use of these drugs.

A national consultation

A national consultation was organised jointly with the Ministry of Health, Youth Affairs, Sport and Community Life. Many representatives of health practitioners were invited (*Ordre des Médecins*, *Ordre des Pharmaciens*), general practitioners, geriatricians, psy-



chiatrists, pharmacologists, neurologists, specialty societies...), as well as institutional stakeholders (ministerial bodies, health insurance organisations, *Mutualité Française*, healthcare agencies...). This rather novel participatory approach sought to pool knowledge, competencies, and feedback from experience and field work.

Key action programmes

- **Better drug prescribing in the elderly** – intended for all prescribers (general practitioners, pharmacists, specialists, and healthcare organisations);
- **Depression in the elderly** – better screening and treatment of dependent

- elderly persons in care homes and of elderly patients receiving outpatient care;
- **Behavioural disorders in Alzheimer's disease** – guidelines to be drafted in 2008 and implemented in 2009 within the "good

- welfare" programme for dependent elderly persons in care homes;
- **Discussions on ratification of the pharmacotherapeutic classes concerned** – improving drug prescription software (starting with psychotropic drugs in 2008).

Key activities

The consultation first identified the four areas where most problems arise: sleep disturbances, depression, anxiety, and behavioural disorders. The lead partners drew up an inventory of existing provisions for each of these situations in order to identify needs, draw up strategic objectives, and establish actions to be taken. Some of the actions are very specific, e.g. making available tools for a better diagnosis of anxiety in the elderly; others are more general and cross-disciplinary, e.g. programmes for assessing and improving prescription practices for the elderly.

Some actions were initiated in 2007 such as the drafting of practice guidelines on the withdrawal of benzodiazepines in the elderly. This topic was considered to be a priority by all concerned. The guidelines are available on the HAS website.

HAS and its partners will draw up a balanced scorecard for monitoring prescription practices in the elderly, particularly of psychotropic drugs, and post it on its website.

Myocardial infarction: concerted action for integrated care

The management of myocardial infarction involves a whole chain of professionals from ambulance staff and specialists in emergency medicine during the acute phase, to cardiologists and general practitioners for long-term management. Coordination among all these professionals within an organised network is required for best management.

Each year in France, 120,000 people are victims of myocardial infarction or acute coronary syndrome. This is a major public health issue as 10% of patients die during the acute phase and 18,000

within the first year. HAS seeks to improve the management of myocardial infarction by making available documents on good practice for professionals throughout the entire care chain. Assisted by health practitioners, it produced consensus conference guidelines, specific CPD programmes, new indicators, guides for practitioners, and brochures for the general public. The final objective is to assess and standardise practices across France.

Concerted action

HAS organised a press conference on myocardial infarction on May 22, 2007. Two experts took part: Dr Jean-Louis Ducassé, head of the emergency department at Purpan University Hospital in Toulouse and chairman of the working group of the consensus conference, and Professor Jean-Pierre Bassand, head of the cardiology department at Besançon University Hospital and chairman of the working group on CPD programmes. They described the “ideal” management of myocardial infarction from the initial crisis to long-term treatment, and reminded the general public of the need to call the emergency service (SAMU 15) at the first sign of symptoms (chest pain lasting more than twenty minutes, sometimes radiating into the left arm, neck and lower jaw).

Two new information brochures were presented at this press conference:

- one for health practitioners, which summarises the main stages of the care chain and lists the reference documents that are available;
- one for the general public, reminding them to call the emergency centre and providing answers to FAQs.

HAS arranged to meet with the press and the general public in a year's time for an update on practice improvements in the management of myocardial infarction in France.

Publications after two years work with health practitioners on myocardial infarction and acute coronary syndrome (ACS)

- 6 CPD programmes – management of ACS in primary care, in casualty departments, by the emergency service and in cardiology, with particular attention given to diabetic patients and smokers;
- a **chronic conditions guide** on coronary disease published in 2007;

- **clinical practice indicators for myocardial infarction after discharge from hospital** – produced by the COMPAQH* project (HAS/Ministry of Health/INSERM) and made available as part of a methodological guide on data collection in April 2007;

- a **clinical practice guideline** - “Management of myocardial infarction during the acute phase outside of cardiology departments” (Consensus conference (Nov. 2006) organised by the emergency services (SAMU) in France, the French-speaking Society for Emergency

Medicine, and the French Society of Cardiology, with methodological and financial support from HAS).

** COMPAQH: French national coordination project for measuring performance and ensuring quality in hospitals*

A decision amending the procedures for implementing CPD

On November 7, 2007, the HAS Board published a decision on the implementation of Continuing Professional Development (CPD) for doctors, that reflects its desire to develop this activity within a professional, scientific and independent framework⁽¹⁾.

All doctors in France must take part in CPD whatever their type of practice. HAS was entrusted with setting up the CPD scheme⁽²⁾. Its conditions of application were defined in 2005 and revised in November 2007 by the HAS Board, following the work performed between January and September 2007 by the CPD contact group⁽³⁾.

HAS simplifies the CPD scheme

The scheme was amended as follows:

- certification criteria were clarified. Appraisal should be all-embracing. The initiative undertaken must be one of continuous quality improvement and the impact of participation in the scheme on changes in practice and on improving quality of care should be monitored;
- industry funding of the approved CPD bodies was forbidden;
- support should be given to the creation of independent professional corporate bodies overseeing practice improvement in their specialty (their creation is taken into account when approval is up for renewal).

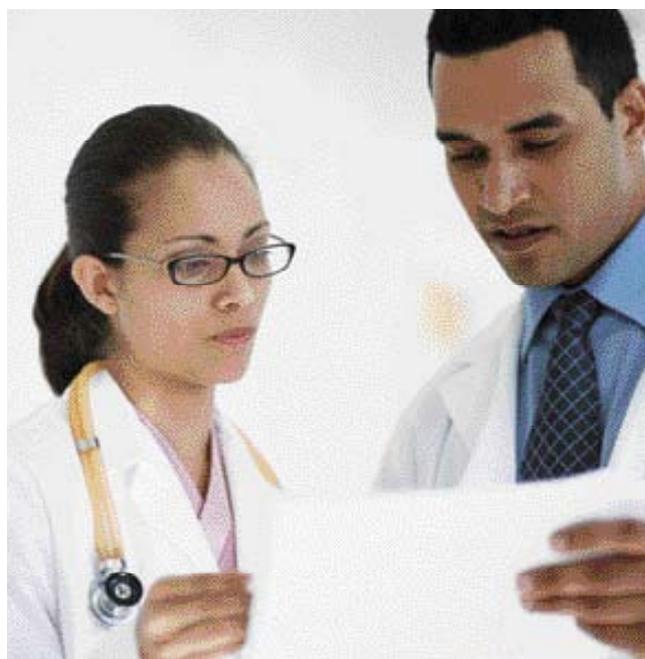
The bodies requesting approval for CPD must satisfy the conditions listed in the specifications given in the appendix to the document that was presented.

The amendments also included charters concerning medical appraisers (commissioned by the Regional Association of Doctors in Independent Practice), external medical experts (chosen by the medical committee of the healthcare organisation from a list of persons with the skills required to participate in the appraisal of the CPD of hospital doctors, as established by HAS) as well as the framework defining the relationships between partners in the scheme.

(1) *Journal Officiel*, January 3, 2008

(2) *Law of August 13, 2004, on French National Health Insurance*

(3) *Members of the CPD contact group: HAS, representatives of the National Councils for Continuing Education, Regional Associations of Doctors in Independent Practice, medical committees and conferences, public and private healthcare organisations, as well as representatives of approved CPD bodies, of the federation of medical appraisers, and of medical faculties*



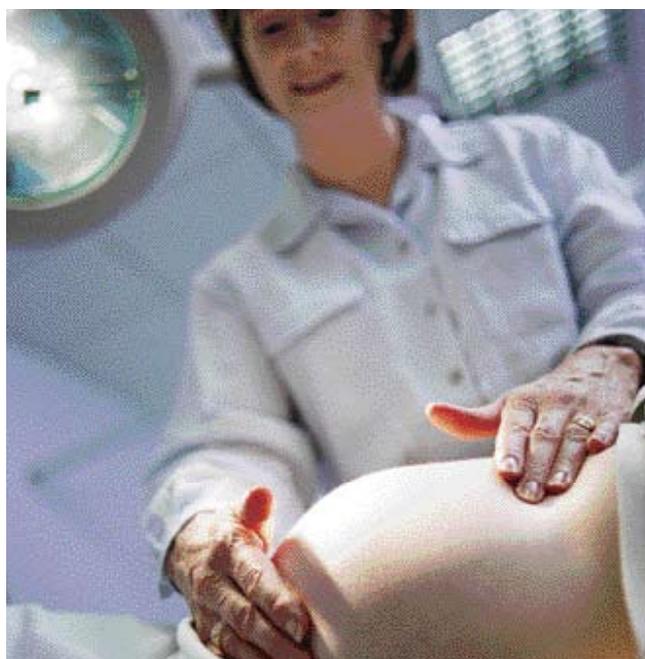
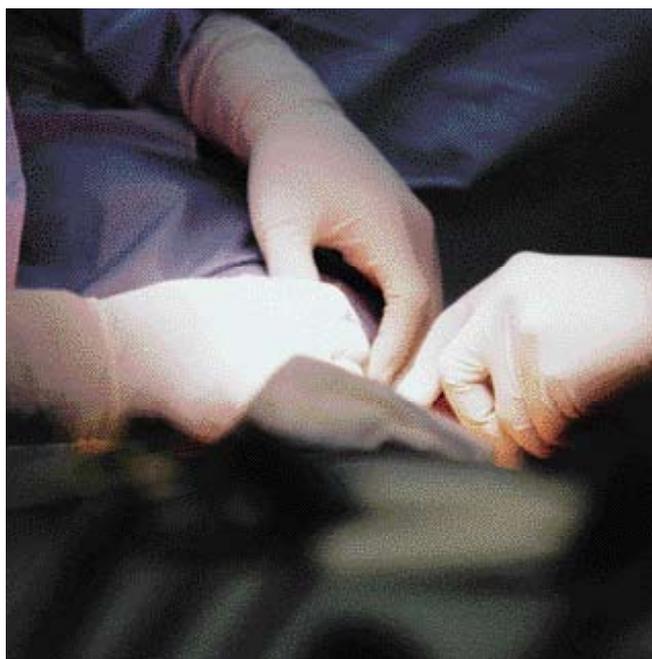
Certification scheme for doctors in high-risk specialties: first approved bodies

HAS has been entrusted with setting up a voluntary certification scheme for doctors practising in high-risk specialties in public and private healthcare organisations. The scheme is run by national bodies approved by HAS. Twelve bodies have been approved since the beginning of 2007 and eight applications are being examined.

The foundation of the certification scheme is the RESIRISQ project (2003-2004) developed by anaesthetists, intensivists, gynaecologists-obstetricians, and surgeons in the independent sector to limit the rise in premiums for medical professional indemnity insurance. French law has extended its scope to all so-called high risk medical specialties, whether in public or private healthcare organisations, and regardless of type of practice: ultrasound, obstetrics, gynaecology-obstetrics, surgery, anaesthesia-intensive care, interventional specialties...⁽¹⁾

Approval and certification

The scheme aims to reduce the number and severity of care-related adverse events, and is run by "approved bodies" (e.g. specialty societies) that have met the criteria set by HAS. In 2007, 12 bodies obtained approval from HAS; 9 others should do so in 2008. All the 21 targeted specialties will then be covered⁽²⁾.



The approved bodies examine and assess requests for certification submitted by doctors, analyse and consolidate their data on near-misses, and draw up clinical practice guidelines with the assistance of HAS. Participation in the scheme is voluntary. However, by participating, doctors fulfil their obligation to take part in CPD (the scheme is based on continuous quality improvement) and are awarded continuing medical education (CME) credits. Certification is valid for four years. By February 11, 2008, almost 2,500 practitioners had already engaged in the scheme.

(1) Article 16 of law of August 13, 2004, on French National Health Insurance

(2) Decree of July 21, 2006

Quality indicators: their extension within healthcare organisations

The collection of data on quality indicators by healthcare organisations (HCOs) will be generalised across France in the second half of 2008. In 2007, more than 100 volunteer HCOs participated in tests launched by HAS.

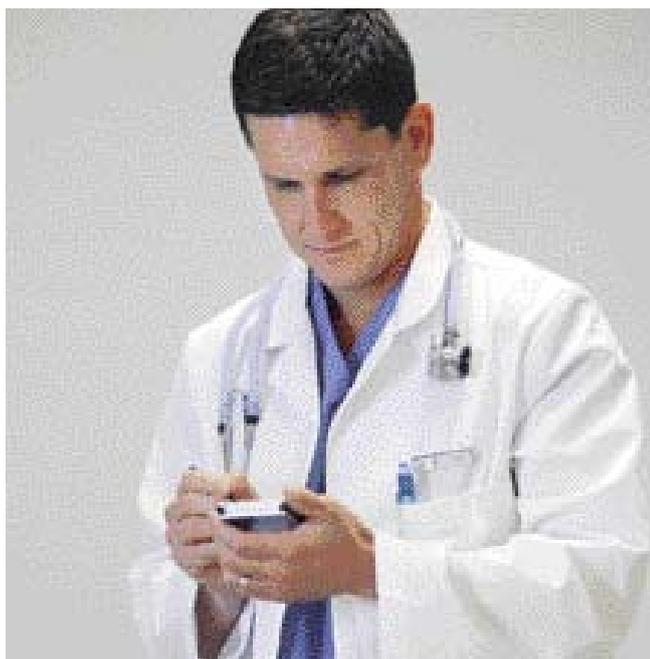
Between now and the end of 2008, HAS will extend data collection on quality indicators (QIs) to all HCOs across France. The QIs will be included in the HCO accreditation procedure, to increase its efficiency. HCOs will be provided with new quality management tools, public authorities with further data to account for quality of care in the hospital sector, and users and their representatives with a response to their requests for transparency.

Test phase

In the first half of 2007, HAS tested QIs for 3 activities in 26 university hospitals and 20 cancer centres: keeping patient records (4 QIs), keeping anaesthesia files (1 QI), and compliance with clinical practice guidelines for post-acute management of myocardial infarction (6 QIs). This pilot phase was then extended to a panel of about 60 volunteer general hospitals, private, not-for-profit HCOs, and private clinics. By the end of 2008, HAS should be able to extend data collection on the QIs tested in 2007 to all HCOs.

HAS is running the project in line with the Ministry of Health's objectives. The Ministry has developed a score card for hospital-acquired infections and made available, in January 2007, an online information platform (*Platines*) on HCOs. All the QIs are taken from the COMPAQH⁽¹⁾ research project.

(1) COMPAQH: French national coordination project for measuring performance and ensuring quality in hospitals

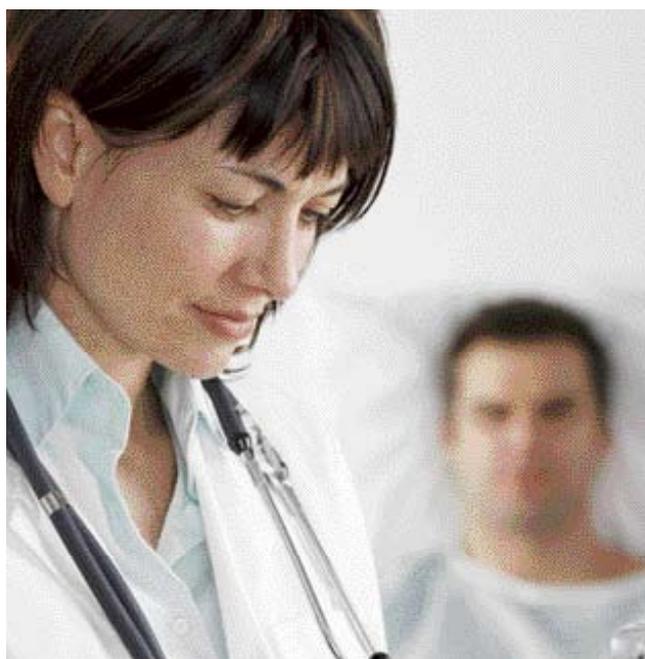


Accreditation of HCOs: work has begun on the 2010 version of the procedure

HAS is preparing a new version (“version 2010”) of the healthcare organisation (HCO) accreditation procedure that will enhance efficacy and reduce constraints.

There is little doubt that the first versions of the accreditation procedure (V1 and V2) have had an impact on the development of quality and safety initiatives in HCOs over the last 10 years. Since 2006, all 3,000 or so French HCOs have received V1 accreditation. The improvements requested by HAS from HCOs receiving “accreditation with follow-up” have been implemented in 98% of cases. However, the procedure has also attracted criticism⁽¹⁾. According to health practitioners, it is laborious and lacks adaptability. Its usefulness and objectives clearly need to be explained better.

On December 31, 2007, 826 HCOs were V2 accredited. HAS is currently working on a third version of the procedure (V 2010) which will reduce constraints (in particular workload) and enhance efficacy (greater impact on quality of care and patient safety). Priorities will be defined more clearly than in the V1 and V2 versions, in consultation with all stakeholders, so that HCOs can direct their efforts – and surveyors their scrutiny – on these priorities. Version 2010 should be launched at the beginning of 2010.



(1) IPSOS survey on behalf of HAS: in-depth individual discussions in March 2007 with 40 health practitioners, 15 opinion leaders, and 10 patients, and 6 meetings with a project group bringing together quality managers and surveyors

A new network to promote patient safety in Europe

At the end of 2007, the European Commission agreed to fund a new network to improve patient safety in Europe. This network, called EUNetPaS⁽¹⁾, is coordinated by HAS.

EUNetPaS will be launched officially in Utrecht (The Netherlands) in February 2008 in the presence of Professor Laurent Degos, chair of the HAS Board. Its aim is to improve the quality of care in the 27 Member States of the European Union.

EUNetPaS brings together representatives of the European medical community (doctors, nurses, pharmacists, hospital managers, patients' associations, etc) and institutional partners (members of competent national bodies and health ministries). The idea is to get practitioners and institutional representatives of the 27 Member States to work together on patient safety, thus enabling them to share information and pool their national experiences on quality of care. Sharing good practice guidelines and developing effective tools should lead to a reduction in the number of medical, diagnostic and treatment errors and, ultimately, to fewer resources being wasted.

A project spurred by HAS

HAS devised the project in February 2006 and submitted it to the European Commission in May 2007. It was accepted in December 2007. HAS is responsible for its coordination and must ensure that it runs smoothly (work programme, method to achieve objectives, meeting the Commission's deadlines...). HAS receives the funds, distributes them amongst its partners, and is accountable for their use.

The first step will be to produce a framework for the network and identify a national contact point (NCP) in each Member State.

These NCPs will be then asked to identify likely participants in their country and to involve them in the project through the organisation of national platforms on patient safety.

A common patient safety culture

The network will enable the development and testing of tools for disseminating a common patient safety culture in Europe, especially among healthcare practitioners:

- Core European curricula for patient safety will be produced for higher education and as part of continuing education. They will be tested in medical faculties and nursing schools in several Member States.
- A database providing information on reporting and learning systems in Member States will be set up, and should help devise a rapid response mechanism.
- Identifying best practices with regard to medication safety in hospitals will lead to the drafting of a guideline on how to tackle drug iatrogenicity. It will be tested in 15 Member States.

The first tools should be available between now and February 2009. The project is planned to run for 30 months. It has a budget of 3 million euros, half coming from the Member States and the other half from the European Commission. Communication of the project's results will take place in partnership with INSERM⁽²⁾.

(1) EUNetPaS: European Network for Patient Safety

(2) INSERM: French National Institute for Health and Medical Research

European alliances to improve healthcare assessment

HAS is pursuing cooperation on methods of healthcare assessment with other national institutions, particularly NICE⁽¹⁾ (UK) and IQWiG⁽²⁾ (Germany), which have missions in common with HAS.

This initiative is being extended to other European institutions (in Denmark, Ireland and Poland) in order to maintain close ties, benefit from successful experiences, and enrich activities at home.

HAS participates in the EUNetHTA⁽³⁾ project which seeks to establish a permanent European network for health technology assessment. HAS is a lead partner for the work package on monitoring of the diffusion of new technologies within the

healthcare system, which involves 30 partners.

(1) NICE: National Institute for Health and Clinical Excellence (UK)

(2) IQWiG: Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Germany)

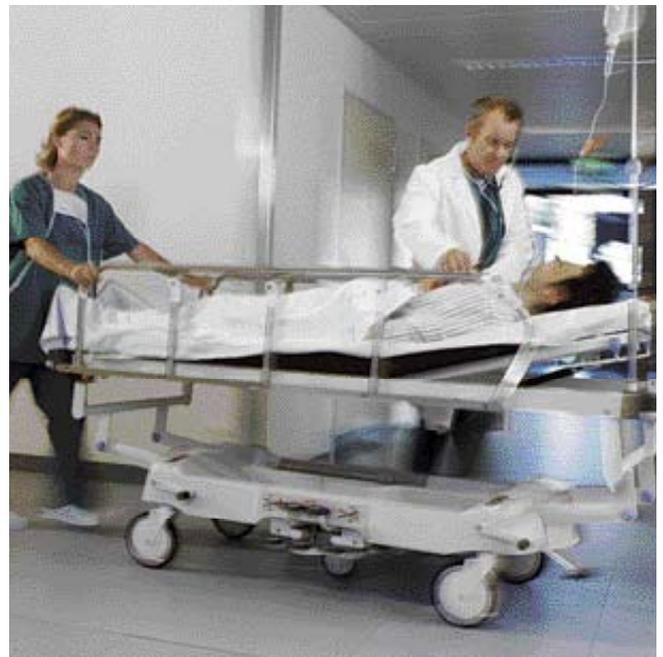
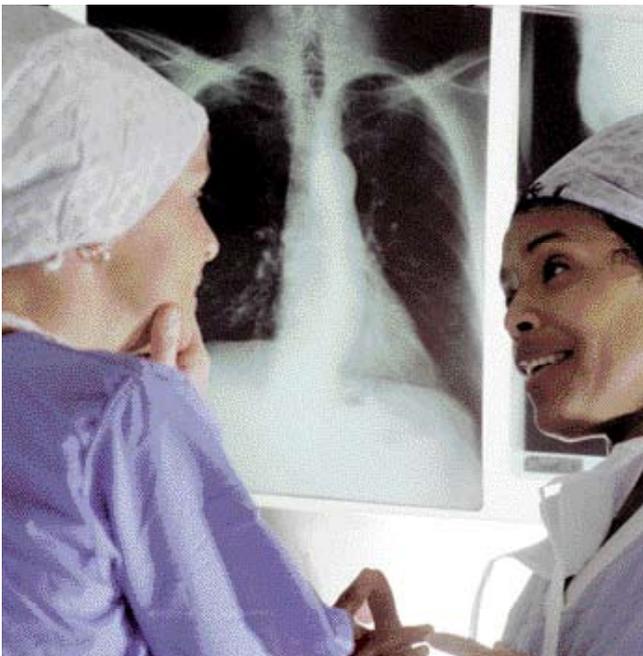
(3) EUNetHTA: European Network for Health Technology Assessment

Guideline on cooperation

HAS issued a draft guideline on new forms of cooperation among health practitioners in 2007. The draft guideline was posted on the HAS website for one month to garner comments from practitioners.

The draft guideline concerns the division of labour among doctors and other healthcare practitioners. By improving cooperation, it should be possible to improve the quality of care.

In 2006, Xavier Bertrand, then Minister of Health, commissioned HAS to work on the conditions for establishing new forms of cooperation among healthcare practitioners. The work was carried out in partnership with ONDPS⁽¹⁾ and led to the draft guideline. Its aim was to identify the changes required to facilitate cooperation among healthcare practitioners and thereby possibly improve the quality of patient care.



Choosing a suitable work method

In view of the complexity of the issue, HAS combined several approaches:

- Quantitative and qualitative assessment of test results;
- Three working groups, one on each of three strategic topics;
- Internet survey of current practices;
- Meetings (information and consultation) with professional and institutional representatives;
- Public consultation via the HAS website on the draft guideline.

Three working groups

When drafting the contents of the guideline, HAS took into account the experience of other countries (United Kingdom, Canada, United States) and the results of tests on cooperation conducted in France between December 2003 and October 2007. It also took into account the discussions of three working groups on key issues to be considered when making changes to the roles of healthcare practitioners:

- the legal framework for professional practice in healthcare
- the training undergone by practitioners
- the economics and organisational background to professional practice

Healthcare practitioners were also encouraged to share their experiences through a public survey launched on the HAS website between May and August 2007

Draft guideline

The draft guideline (“Delegating and new professions... Conditions for new forms of cooperation between health practitioners”) distinguishes between two types of cooperation:

- “technical” cooperation which can be carried out on a day-to-day basis;
- cooperation due to changes in patient management.

It underscores that these new forms of cooperation imply radical changes to the overall organisation of the health system, in particular as regards training, fees for independent health professionals, and legal provisos for conditions of practice of the various professions.



A public consultation

The draft guideline was presented to stakeholders during the first “HAS Meeting” (December 17-18, 2007). It was also the subject of a broad public consultation on the HAS website – an online questionnaire – which was much welcomed by practitioners. Account was taken of their opinions in the final version of the guideline, which was accepted by the HAS Board and published on April 16, 2008.

(1) ONDPS: National Observatory on the Demography of Health Professions

Tests of cooperation among health practitioners in France

• Tests on “technical procedures” in which the non-physician takes no diagnostic or therapeutic decision, e.g. collaboration between a physician radiologist and a radiology technician, or between a doctor and nurse conducting

functional gastrointestinal investigations.
• Tests on an activity-segment in the management of a patient which may involve taking a diagnostic or therapeutic decision: analysis of the patient’s health status, identifying a problem,

and finding a solution (ordering tests or deciding treatment). An example is the collaboration between doctors and nurses during the follow-up of patients with chronic disease (renal impairment, type 2 diabetes, and hepatitis C) or during management of

oncology patients.
• Nurse intervention during the interview set up by EFS* prior to blood donation.

*EFS: French Blood Transfusion Institution

The certification of health-related websites is underway

HAS has established a certification procedure for health-related websites in order to improve the quality of such sites and to assist patients in identifying trustworthy and high-quality websites.

The Internet is playing an increasing role in medical information. A literature review performed by HAS in 2007 revealed that about one in every five patients searches for medical information on the Internet. According to a survey by Mediametrie/Net Ratings, two websites – health-related or with a health-related section – were among the 25 most visited sites in France in September 2007.

HAS has been entrusted with the task of developing a certification procedure for health-related websites⁽¹⁾. It presented the procedure it had selected to the press at the end of November 2007. The procedure has two main aims: (i) to contribute to the general improvement of the quality of health-related websites, (ii) to assist users in identifying trustworthy and high-quality websites.

The choice of the Health on the Net (HON) foundation

HAS first performed a literature review and listed the principal tools used to assess the quality of health-related websites. An analysis of experience in other countries identified the three key factors needed for a certification procedure to succeed. It has to be

free of charge to publishers, simple, and have an internationally visible logo.

The Health on the Net (HON) foundation met all these criteria. HON is a Swiss Non Governmental Organisation, created in 1995, and provides an internationally renowned scientific standard for certifying health-related websites. It has already certified more than 5,500 sites in 72 countries, which also meet the European Commission's quality criteria (see "e-Europe2002"). HAS has accredited HON as a certifying body and set up a 3-year partnership contract with HON.

Certification criteria

Certification applies to websites – or site pages - providing information about health and includes discussion forums on health issues. The health-related pages of a general information website can be certified if the quality criteria are met.

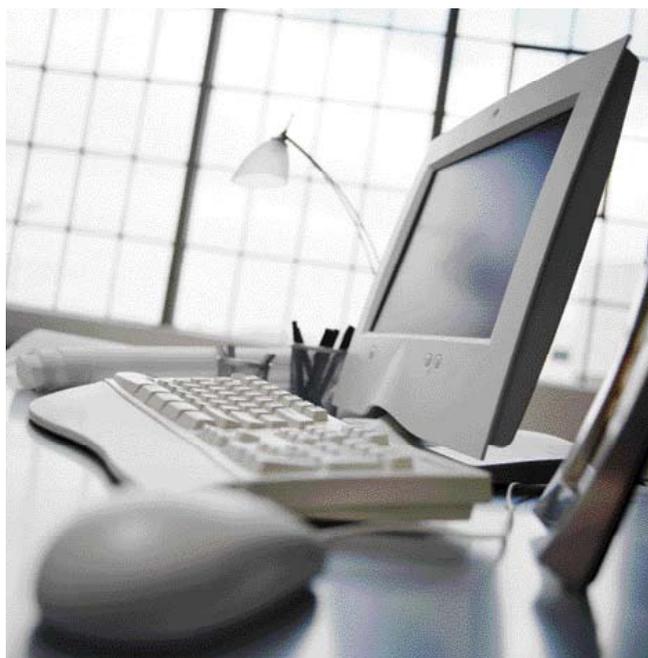
Certification requires compliance with the following 8 principles:

- authority (editors' qualifications given);
- complementarity (information an addition to, but not a substitute for the doctor-patient relationship);
- confidentiality (site visitors' personal details kept confidential);
- crediting information provenance (sources cited, pages dated);
- justification (statements on the pros and cons of products or treatments substantiated);
- professionalism (ease of access to information, webmaster named, and contact details given);
- transparency of funding;
- separation between advertising and editorial policy in management of the site.

Site contents are not certified as this would require real-time monitoring by a considerable number of qualified experts, and would in any case be misleading as information on the Net can be modified at any time.

A freely chosen procedure, free-of-charge

The site publisher chooses whether to apply for certification or not. All publishers residing on French territory providing information on medicine and healthcare are concerned, e.g. institutional sites, sites providing general and/or specialised healthcare information, scientific information sites, sites of pharmaceutical laboratories, patient association sites, etc. The application is made via the Inter-



net on the HON website. The procedure is free of charge. The costs are met by HAS and the HON foundation as part of their partnership.

Once certified, the site may place the HON logo on its homepage or in the space allocated to certification, and can be accessed via the search engine on the HON site (www.hon.ch). A joint HAS-HON certification monitoring committee has been set up, and deals in particular with complaints from users.

Supporting documents

To publicize the certification scheme, HAS posted supporting documents on its website:

- for site publishers, to explain the benefits of applying for certification: ethical recognition, increased number of hits;
- for healthcare practitioners, to encourage them to discuss the Internet with their patients: "Internet health and your patients";



- for the general public, to help them judge sites and search for information on the Internet: "Searching for medical information on the Internet" and "Internet health: making the right choices".

(1) Law of August 13, 2004, on French National Health insurance

What users look for in health-related websites

Patients will search for information on the Internet to gain a better understanding of their disease and treatment, and to enter into contact with other sufferers. Searches mostly concern:

- a disease or clinical situation;
- a treatment;
- diet and physical fitness;
- alternative treatments.

It is difficult to evaluate precisely how ease of access to information via

the Internet affects the doctor-patient relationship. Most doctors report that the Internet does not change the relationship of trust they have with their patients. Only 20% of patients consider

that doctors might feel competition from the Internet.



02

HAS: facts and figures

- 40 Assessing medical, economic and public health benefits
- 47 Improving the quality and safety of healthcare
- 54 Communicating with healthcare practitioners and the general public
- 60 Sharing scientific expertise
- 65 Resources activated

Assessing medical, economic and public health benefits

Key figures for 2007

940 assessments by the Transparency Committee

236 assessments by the Committee for the Assessment of Devices and Health Technologies

83 assessments by the Committee for the Assessment of Medical and Surgical Procedures

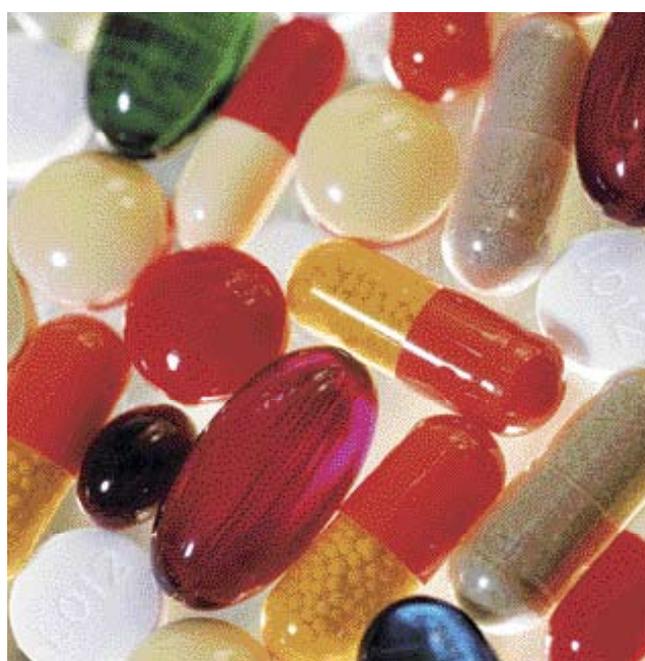
4 health technology assessments

17 health economics assessments

Assessing medicines

The year 2007 was one of considerable activity in terms of the number of opinions issued by the Transparency Committee on medicinal products. Activity increasingly includes the global re-assessment of pharmaco-therapeutic classes of drugs or drugs with the same therapeutic use.

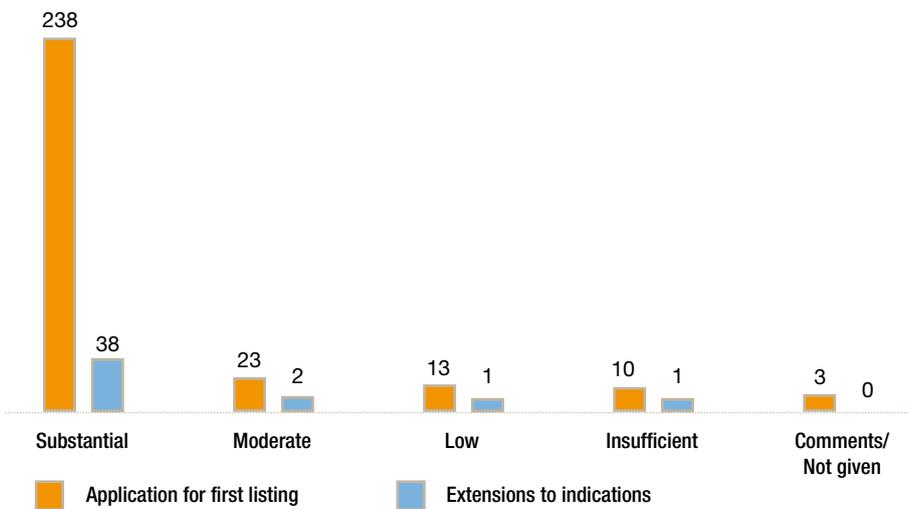
The time required to examine applications for inclusion onto the list of medicines reimbursed by French National Health Insurance was shorter in 2007 than in 2006: 76% of applications were processed in under 90 days.



Applications lodged and opinions issued in 2007, by application type

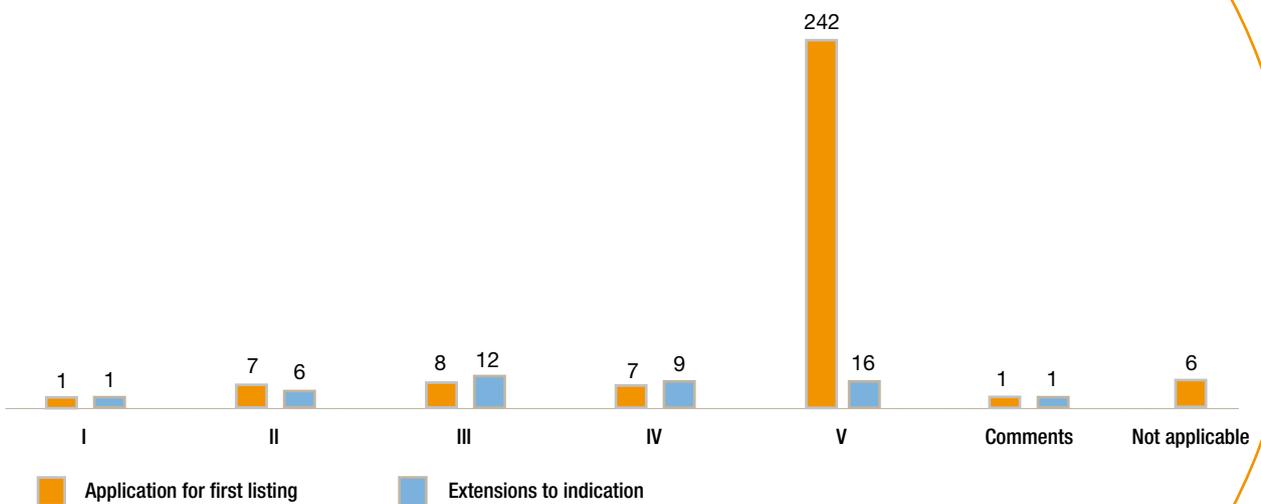
Activity 2007	Total	2006 versus 2007	First listings	%	Extensions to indications	%	Listing renewals	%	Other applications	%
Applications lodged (N)	838	- 23%	259	31	45	5	297	35	237	28
Opinions issued	940	- 21%	267	28	41	4	403	43	229	24

Actual Benefit (AB) of medicines (2007)



A single opinion can include more than one AB.

Improvement in Actual Benefit (IAB) of medicines (2007)



A single opinion can include more than one IAB.

Assessing medical devices

The year 2007 saw the publication of the first good practice standards for medical devices and the first good use leaflets. The number of opinions issued in response to manufacturers' applications was 74% higher in 2007 than in 2006.

A total of 30 assessments of product clusters, in particular reassessments of generic descriptions, have been scheduled, of which 14 were completed in 2007. Overall, 13 opinions and 7 assessment reports (some produced in collaboration with the Departments for the Assessment of Medical and Surgical Procedures and for Health Economics) were published in 2007 and 3 reports are in the process of being published.

Applications lodged and opinions issued in 2007, by application type

Activity 2007	Total	Versus 2006 %	First listings	%	Listing amendments	%	Listing renewals	%	Reminders and administrative amendments	%
Applications lodged (N)	237	+ 13.4	98	41.35	39	16.46	84	35.44	16	6.75
Opinions issued	223	+ 74.2	114	51.12	38	17.04	61	27.35	10	4.49

Assessment of product clusters

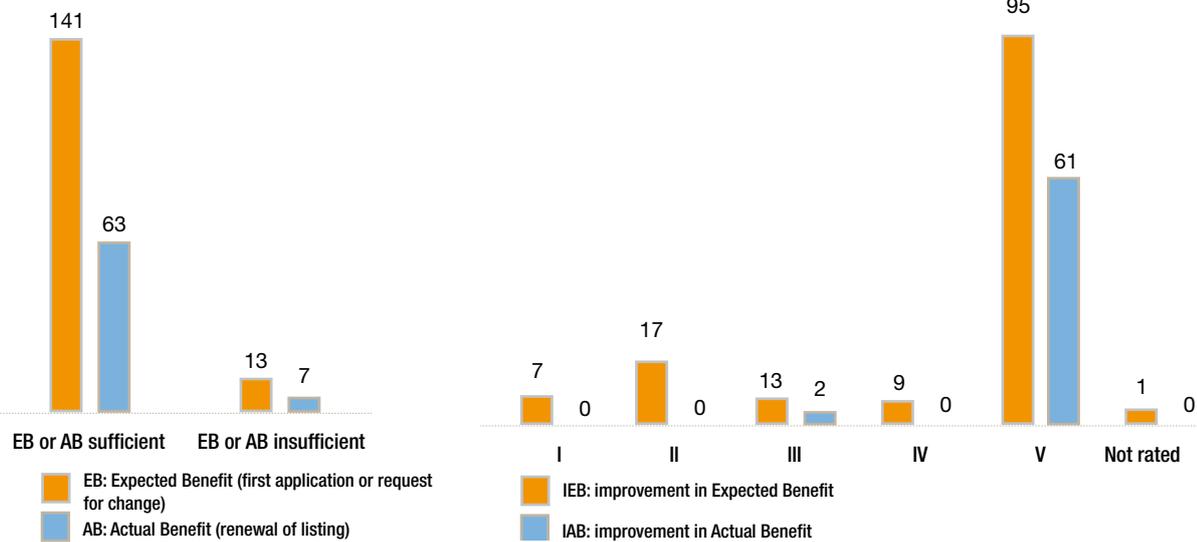
Topic	Request	Assessments (N)
Wound dressings	Reassessment (2005 work programme)	25 generic descriptions
Medical devices for self-treatment and self-monitoring		10 generic descriptions
Total hip prostheses		33 generic descriptions
Implants of animal and synthetic origin for wall repair (urology/gynaecology)		2 generic descriptions
Medical beds and accessories	Reassessment (2007 work programme)	9 generic descriptions
Walking sticks and crutches	Reassessment (2008 work programme)	Generic descriptions carried over
Lumbar disk prostheses ⁽¹⁾	Own initiative	4 listings by brand name (EB sufficient, IEB V)
Cochlear implants		7 listings by brand name (EB sufficient, IEB II)
Ventricular assistance ^{(1),(2)}		4 brand name devices (3 EB sufficient, IEB I; 1 EB insufficient)
Valves for transcatheter implantation ⁽¹⁾		2 products (EB sufficient, IEB I)
Dedicated moderate-field MRI	French Society of Radiology	Health technology assessment
Nebuliser system for aerosol therapy	French Ministry of Health	8 generic descriptions of implants + descriptions of accessories
Dynamic response feet (assessment criteria)	Own initiative	4 generic descriptions based on 28 products
Reassessment of cardiac defibrillators		Revision of indications and technical specifications

(1) Procedures also assessed for these product clusters

(2) Health economics assessment also performed

Distribution of EBs & ABs attributed in 2007

Distribution of IEBs & IABs attributed in 2007



In one case, attribution of 2 IEB for 1 EB in two indications

Assessing diagnostic and therapeutic procedures and health technologies

The year 2007 was characterised by a move from assessments of single procedures, which became less frequent, to assessments of series of procedures or of the conditions under which they are performed.

Health technology assessments (HTA) can include opinions on several procedures or, on the other hand, impinge on procedures without a formal opinion being given. The 4 HTA reports produced in 2007 (see table next page) covered several hundred procedures. These procedures have been omitted from the histograms.

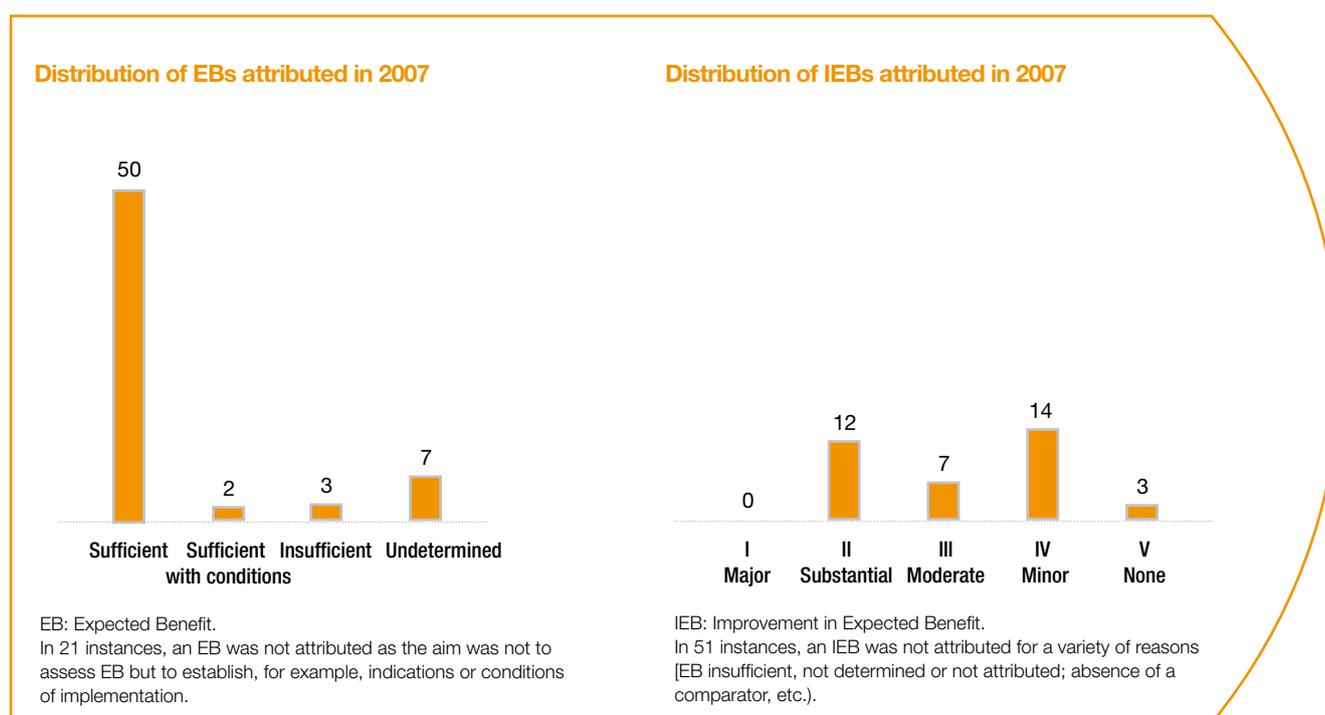
For some procedures, Improvements in Expected Benefit (IEB) were estimated for several indications. This explains the difference between the number of IEBs and the number of procedures

Several assessments were performed with the Department for the Assessment of Medical Devices in order to produce a joint opinion on devices and procedures (see table on previous page).



Health Technology Assessment Reports
Strategy for the management of stenoses of the carotid bifurcation: indications for revascularisation techniques ⁽¹⁾
Cardiac surgery with or without extra-corporeal circulation (ECC): role of the second surgeon ⁽¹⁾
Suburethral synthetic tapes in the treatment of female stress urinary incontinence – retropubic and transobturator approaches ⁽¹⁾
Dental prostheses with a ceramic structure

(1) Includes health economics assessment



Post-listing studies

The Transparency Committee and CEPP⁽¹⁾ may request post-listing studies (within the framework of periodic reassessments) in order to document all or some of the following, under real-life conditions: conditions for institution of treatment, populations actually treated, duration of treatment, compliance, benefits of treatment, impact of treatment on therapeutic strategies, organisation of care, etc. These requests are part of the committees' opinions and are included in the contract signed between CEPS⁽²⁾ and the manufacturer. The conditions applying to post-listing studies on medicinal products are covered by a framework agreement between CEPS⁽²⁾ and the drug companies (LEEM)⁽³⁾.

The manufacturers submit the names of the scientific committee members and the study protocols to HAS. For CEPP⁽¹⁾ requests, these protocols are analysed by a special unit at HAS on post-listing study methodology – together with the CEPP⁽¹⁾ and external experts – in order to ascertain whether the methods described in the protocols are in fact able to provide an answer to the request.

For Transparency Committee requests, a working group on the public health benefit of medicines (ISPM) performs the analysis.

A review of its procedures prompted the CEPP⁽¹⁾ to start drawing up proposals for improving requests for the implementation of post-listing studies.

Transparency Committee: Distribution of post-listing studies

	2006	2007
Post-listing studies requested (N)	16	24
Products involved (N)	16	23
Protocols analysed (N)	57	86
Previous requests involved (N)	36	62

Transparency Committee: Status of post-listing studies* (2004 – end 2007)

95 post-listing studies requested by the Transparency Committee	
completed	12%
ongoing or on the point of being started	32%
protocol awaited or scheduled for analysis	29%
no protocol submitted	27%

* 141 requests for studies since 1997.

CEPP: Distribution of post-listing studies

	2006	2007
Post-listing studies requested (N)	24	45
Medical devices concerned (N)	24	42**
Protocols analysed (N)	7	35
Previous requests involved (N)	7	20

**And medical devices from 3 generic lines.

CEPP: Status of post-listing studies*** (2004 – end 2007)

102 post-listing studies requested by the CEPP	
completed	9%
ongoing or on the point of being started	11%
protocol awaited or scheduled for analysis	14%
no protocol submitted	66%

*** 128 requests for studies since 1997.

In 2007, the CEAP⁽⁴⁾ requested post-listing studies for 7 procedures for which their opinion was: "Expected benefit (EB) undetermined – procedure in clinical research". The implementation of these studies could come under a HAS-UNCAM contract⁽⁵⁾. A protocol selection committee was set up in March 2007 but no protocols have been submitted so far.

(1) CEPP: Committee for the Assessment of Devices and Health Technologies
(2) CEPS: Committee for Pricing and Reimbursement of Healthcare Products
(3) LEEM: Les entreprises du médicament (french institution for drug companies)
(4) CEAP: Committee for the Assessment of Medical and Surgical Procedures
(5) UNCAM: National Union of Health Insurance Funds (as per framework contract of July 12, 2006)

Health economics assessment and public health

HAS intensified its assessments of public health programmes and actions in 2007 in line with its remit to assist public decision-making. When required, it addressed the economic and organisational aspects of several of the topics under study by HAS, whether these related to

medical technologies (medicines, procedures, and medical devices) or to the drafting of guidelines.

All HAS' public health guidelines include a health economics assessment.

Health economics assessments – published online in 2007

Cardiac surgery with or without extra-corporeal circulation (ECC): role of the second surgeon
Rheumatoid arthritis: management of established cases
Rheumatoid arthritis: diagnosis and initial management
Management of progressive complications of a characteristic depressive episode in adults
Assessment of TVT (tension-free vaginal tape) in female stress urinary incontinence – update
Method of assessing hepatic fibrosis in the course of chronic liver disease
Therapeutic patient education in the management of chronic diseases: economic and organisational analysis

Public health guidelines – published online in 2007

Smoking cessation
Evaluation of screening strategies for Down's syndrome
Follow up of assessments of tests on new forms of cooperation between healthcare practitioners (1 st interim report)
Strategy for screening of neonatal deafness
A priori assessment of syphilis screening in France

Public health guidelines

– **Neonatal screening for bilateral permanent deafness** (January 2007): The report concluded that screening was probably effective in terms of developing communication. However, because of uncertainties relating to organisation of care, HAS recommended that screening in France be introduced gradually and take account of the results of ongoing tests. This report was part of a global assessment of health

policies aimed at improving the management of the deaf.

– **Screening for syphilis** (May 2007): The incidence of syphilis, a sexually transmitted infection, is rising sharply. These guidelines established which serological tests should be used, the target populations, and ways of organising monitoring and screening.

– **Prenatal screening for Down's syndrome** (June 2007): To reduce the number of amniocenteses and to improve the detection rate of Down's syndrome, HAS recommended that, during the first trimester of pregnancy, pregnant women be offered screening that combines ultrasound measurement of nuchal translucency and measurement of 1st trimester serum markers. This screening should

be conducted between weeks 11+0 and 13+6 of pregnancy and be accompanied by a quality control programme for nuchal translucency measurement.

Improving the quality and safety of healthcare

Key figures for 2007

Clinical practice guidelines

17 clinical practice guidelines (including 3 produced in partnership)

Chronic conditions

22 guides for doctors (including 6 national protocols for the diagnosis and treatment of rare diseases)

4 guides for patients

1 updated guide on diabetes for doctor

3 updates to the list of procedures and services

Continuing professional development (CPD)

49 approved bodies

4 methods for practice appraisal and improvement

6 programmes for practice appraisal and improvement in the area of acute coronary syndromes

High-profile pilot programmes

2 programmes (myocardial infarction and psychotropic drugs in the elderly)

Certification scheme for doctors working in high-risk specialties

12 approved bodies

Accreditation of healthcare organisations

490 establishments with V2 accreditations

Clinical practice guidelines

Clinical practice guidelines – published online in 2007

Quality criteria for practice appraisal and improvement

Implantation and maintenance of peripheral venous catheters

Initial management of a recent transient ischaemic attack

Rheumatoid arthritis: clinical coordination of multidisciplinary management

Rheumatoid arthritis and physiotherapy

Methodology guides

Method and process for adapting existing clinical guidelines

Drawing up quality criteria for CPD appraisal and improvement

Structuring a therapeutic patient education (TPE) programme for chronic diseases

Quantitative methods for assessing interventions aimed at improving clinical practice

Formal consensus

Use of fundal pressure during the second stage of labour

Clinical practice guidelines – published online in 2007
Public hearings
Psychiatric expertise in criminal law
Obtaining technical assistance: who is involved? what is the process?
Abuse, dependencies, and multiple drug consumption: strategies for care
Consensus conference
Management of acute myocardial infarction outside cardiology units
Guidelines for clinical practice in partnership
Management of adult patients with insomnia in general practice
Hygiene and prevention of the risk of infection in the medical or paramedical practice
Subclinical hypothyroidism in adults: diagnosis and management
Clinical Practice Guidelines
Diagnostic criteria and initial assessment for uncomplicated cirrhosis
Osteopathy-chiropractic
Rheumatoid arthritis: therapeutic aspects other than medication and surgery - community health and organisational aspects
Management of sudden infant death syndrome
Management strategy in cases of protein-energy malnutrition in the elderly
Rheumatoid arthritis: management of established cases
Management of complications in patients with cirrhosis
Surveillance of patients with uncomplicated cirrhosis and primary prevention of complications
Rheumatoid arthritis: diagnosis and initial management
Economic and organisational analysis of therapeutic patient education in the management of chronic diseases
Management and diagnosis of peripheral neuropathies (polyneuropathies and multiple mononeuropathies)
Management of progressive complications of a characteristic depressive episode in adults
Antenatal care and referral pathways according to identified risk situations
Ways of withdrawing benzodiazepines and related medicines in the elderly

Chronic conditions

By the end of 2007, guides for doctors were available for about two-thirds of the listed chronic conditions. Several patients' guides, encouraging patient involvement in their own care, were produced in partnership with patients' associations. Overall, guides have been published for 19 of the 30 listed chronic conditions.

Work was started in 2007 on the first cancer guides in collaboration with INCa⁽¹⁾; guides on colon cancer and melanoma will be

published in the 2nd quarter of 2008. 2007 also saw the publication of the first updates of guides for doctors and lists of procedures and services.

(1) INCa: French National Cancer Institute

ALD⁽¹⁾	Guides on chronic conditions – published online in 2007
1	Guide for doctors: Stroke ⁽²⁾
3	Guide for doctors: Peripheral occlusive arterial disease of the lower limbs ⁽²⁾
4	Guide for doctors: Schistosomiasis
5	Guide for doctors: Chronic symptomatic systolic heart failure ⁽²⁾
5	Guide for doctors: Chronic symptomatic heart failure with preservation of systolic function ⁽²⁾
5	Guide for doctors: Atrial fibrillation ⁽²⁾
5	Guide for doctors: Pulmonary arterial hypertension ^{(2) (3)}
6	Guide for patients: Hepatitis B2 ⁽²⁾
9	Guide for doctors: Severe epilepsy ⁽²⁾
9	Guide for doctors: Amyotrophic lateral sclerosis (PNDS) ⁽³⁾
11	Guide for doctors: Haemophilia ⁽²⁾
13	Guide for doctors: Coronary disease ⁽²⁾
14	Guide for patients: Asthma ⁽²⁾
14	Guide for patients: Chronic Obstructive Pulmonary Disease (COPD) ⁽²⁾
16	Guide for doctors: Parkinson disease ⁽²⁾
17	Guide for doctors: Haemochromatosis
17	Guide for doctors: Gaucher disease (PNDS) ⁽³⁾
17	Guide for doctors: Mucopolysaccharidosis (PNDS) ⁽³⁾
19	Guide for doctors: Severe chronic kidney disease ⁽²⁾
20	Guide for doctors: Paraplegia
21	Guide for doctors: Systemic necrotising vasculitis (PNDS) ⁽³⁾
23	Guide for doctors: Severe anxiety disorders ⁽²⁾
23	Guide for doctors: Schizophrenia ⁽²⁾
29	Guide for doctors: Active tuberculosis ⁽²⁾
29	Guide for patients: Active tuberculosis ⁽²⁾
31	Guide for doctors: Xeroderma pigmentosum (PNDS) ⁽³⁾

ALD⁽¹⁾	Updates of guides for doctors and lists of procedures and services – published online in 2007
6	Updated list of procedures and services: Hepatitis B
6	Updated list of procedures and services: Hepatitis C
8	Updated guide for doctors: Adult diabetes type 1
8	Updated guide for doctors: Paediatric diabetes type 1
8	Updated guide for doctors: Diabetes type 2
8	Updated list of procedures and services: Diabetes type 1 and 2

(1) ALD (Affection de longue durée): Official numbering of the listed chronic conditions

(2) Updated lists of procedures and services are only available on the HAS website

(3) PNDS (Protocole national de diagnostic et de soins): National diagnostic and care protocol

Continuing professional development (CPD) focussing on continuous quality improvement

In 2007, implementation of CPD was intensified, and its infrastructure was strengthened: 49 additional bodies were approved (current total: 112) and 147 external medical experts were selected and trained. According to a recent estimate, over 20,000 doctors are now engaged in CPD (excluding doctors practising in a high-risk specialty and engaged in the certification scheme).

2007 saw the completion of the practice appraisal and improvement programmes for acute coronary syndromes, including myocardial infarction. These programmes are intended for general practitioners, specialists in emergency medicine, and cardiologists. They are part of HAS' high-profile pilot programme on myocardial infarction.

Approved bodies

112 approved bodies by March 2008 (49 in 2007)

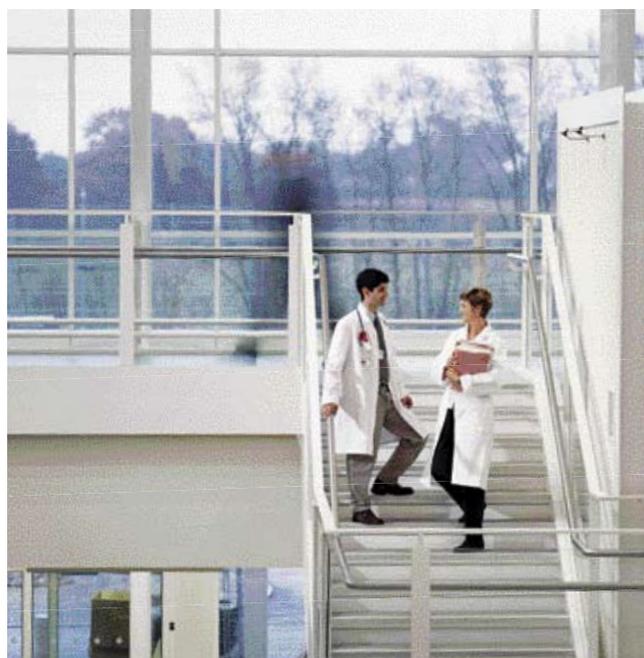
Tools and methods

Four leaflets published in 2007:

- CPD for doctors: instructions
- Criteria for practice appraisal and improvement
- CPD and staff meetings
- Practice by protocol in nursing homes, health units, health centres

6 programmes for practice appraisal and improvement concerning acute coronary syndromes (ACS)

- ACS: primary care management
- ACS: management in the casualty department
- ACS: management by ambulance services (SAMU)
- ACS: management in cardiology units
- ACS and smoking: management in cardiology units
- ACS and diabetes: management in cardiology units



High-profile pilot programmes

HAS has developed a global and participative approach to improving practice in key fields of healthcare where patient management is complex. The first step is sharing the problem with stakeholders (healthcare practitioners, patients, and institutions) in order to identify areas of practice needing improvement as well as ways of implementing and assessing actions. HAS then gears its output (e.g. guidelines, assessment programmes, indicators) to these chosen areas so that output is consistent with objectives.

HAS also promotes the chosen areas in quality improvement schemes such as the accreditation of healthcare organisations or CPD. These programmes will be pursued in 2008 and 2009 and the results will be analysed.

Pilot programmes in 2007:

- Improving the prescription of psychotropic drugs in the elderly;
- Better management of myocardial infarction.

Certification scheme for hospital doctors

The initiative to certify the quality of the professional practice of doctors and clinical teams working in healthcare organisations is a risk prevention strategy that has been developed to prevent the occurrence of avoidable adverse events.

HAS is in charge of setting up the certification scheme⁽¹⁾. Doctor participation in the scheme is voluntary. The modus operandi, the list of medical disciplines involved, and the role of stakeholders are defined in the decree of July 21, 2006.

Certification is based on the reporting and analysis of near-misses. The doctors engaged in the scheme must:

- report near-misses;
- implement the guidelines for their specialty;
- take part in the activities of their specialty's safety improvement programme.

The point of reporting near-misses is to ensure that all useful measures are taken to prevent care-related adverse events or to limit their effects.

The deployment of the scheme started in 2007. Twelve bodies have been approved by HAS, covering more than half of the disciplines and about 70% of the doctors concerned.

About 120 experts from approved certification bodies were trained by HAS in 2007. Training (two modules per expert) covered the following topics:

- understanding how the certification scheme works;
- using the IT system;
- knowing how to implement the principles of risk management and the methods of analysis used in the certification process.

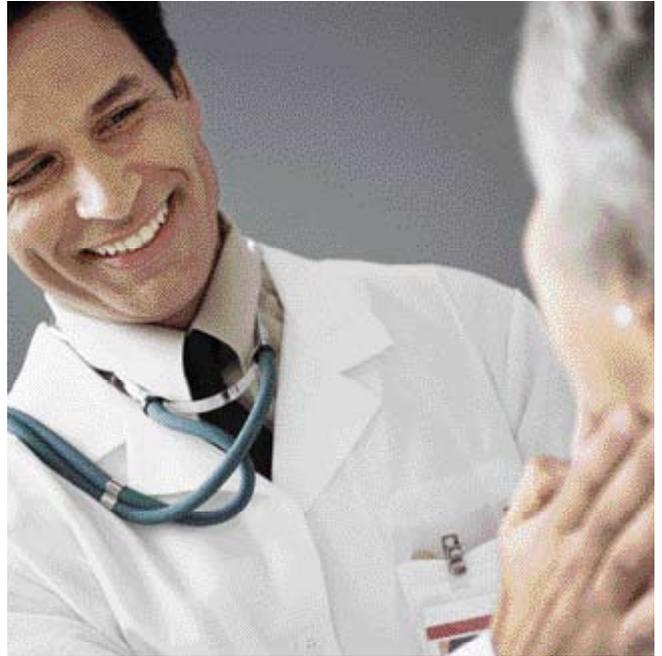
HAS set up a database for data entry and feedback which it administers. It became operational on December 26, 2007 and is used to manage the risks associated with a medical specialty as well as administrative files.

The first registrations were received via the Internet (<https://accreditation-des-medecins.fr>) at the end of 2007. The first certification certificates will be issued by HAS in a year's time.

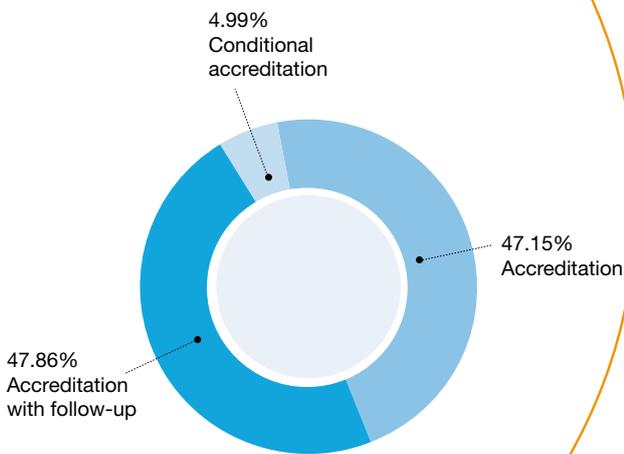
(1) Article 16 of the law of August 13, 2004 on National Health Insurance

Accreditation of healthcare organisations

Accreditation results for healthcare organisations (HCOs) in 2007 show that the procedure has become more demanding. For the V2 procedure, 52% of HCOs are accredited either “with follow-up” or conditionally, and are given a short deadline before corrective actions are reviewed (versus 33% for the V1 procedure).



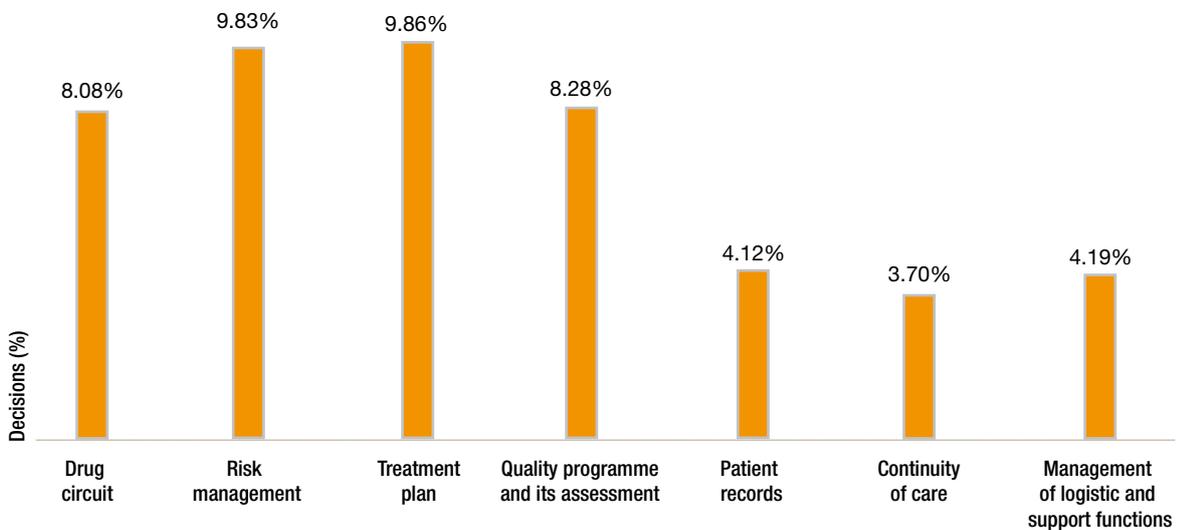
Distribution of the 490 healthcare organisations accredited in 2007 by level of accreditation (version V2)



Number of visits performed in 2007 (V2 accreditation)

666: 633 first visits
33 targeted visits

Most common areas requiring improvement (version V2)



Quality of medical information

Certification of visits by medical sales representatives, websites, and prescription software

HAS has been entrusted with three certification missions in the field of medical information⁽¹⁾. Their aim is to contribute to improving the quality of the information delivered to healthcare professionals and the general public by health-related websites, prescription software, and pharmaceutical company medical sales representatives.

Certification of visits by medical sales representatives

HAS was asked to convert the Code of Practice for medical sales representatives, signed by the drug companies and CEPS⁽²⁾, into a certification standard. In 2005 and 2006, it produced standards for quality improvement in the following areas: training of medical sales representatives, documentation given to the representatives, compliance with ethical rules, and company quality assurance procedures for medical sales visits. The system chosen, certification of a company's technical qualifications, requires the company to invest in quality training. An accreditation programme for the certifying body was established.

In 2007, COFRAC⁽³⁾ accredited four certifying bodies: SGS-ICS, AFAQ-AFNOR Certification, Bureau Veritas Certification, and AB Certification. By the end of the year, 31 companies had been certified. CEPS⁽²⁾ has requested that distributor pharmaceutical companies with which it has a contract should be certified by June 2008.

HAS has also developed certification of medical sales providers. They perform about 15% of sales visits on behalf of the drug companies. The requirements are the same as those for the medical sales representatives themselves: professional training (regulatory, ethical aspects...) and training relating to the products being promoted, in particular with regard to therapeutic use, proper use campaigns, public health programmes, and information on health insurance cover. In order that the pharmaceutical companies who commission service providers remain accountable, they must set up systems ensuring that the providers comply with the Code of Practice for medical sales representatives. Every medical sales provider company will have to become certified for its medical sales activities in the primary care sector and will have to choose a certifying body for this purpose before December 31, 2008.

Certification is a means of providing drug companies with a set of common benchmarks for appraising the practice of medical sales

representatives. However, this will not guarantee good outcomes. At the end of 2008, HAS will publish a first assessment of the certification procedure of medical sales representatives, which will include measurements of impact.

Certification of prescription software

Certification of prescription software should improve prescription quality, facilitate the work of the prescriber, and reduce the cost of treatment without sacrificing quality. The standards produced in 2005 and 2006 describe the software functions needed to achieve these aims (e.g. drug contraindications, drug interactions to ensure safety of prescription), but also include more general criteria such as the need for a statement of commercial interests, the inclusion of user documentation, a hotline, etc. A test for each criterion will show whether the software reaches the defined standard. The assessment procedure (examining methods, issuing of certificates, etc.) was also defined. HAS has chosen to implement a type of test certification, which checks whether a sample specimen complies with the standard, as this is the simplest form of product certification.

The standards and the certification procedure were reviewed, tested, and validated in 2007. An accreditation programme for the certifying body was defined. In addition, as certification of prescription software requires a guarantee that the information on the drug processed by the software is of high quality, a quality charter for drug databases (BdM) was produced in partnership with AFSSAPS⁽⁴⁾ and database publishers. It gives minimum requirements, i.e. information on the drug should be complete, well-organised, up-to-date, and independent. Anyone applying for certification of prescription software will have to work with a drug database which complies with the charter.

2008 should see compliance of drug database publishers with the quality charter, the first certifications of prescription software, and the accreditation of a certifying body. A procedure for hospital prescription software will start to be drawn up.

(1) Law of 13 August 2004

(2) CEPS: Committee for Pricing and Reimbursement of Healthcare Products

(3) COFRAC: French Certification Committee

(4) AFSSAPS: French Healthcare Product Safety Agency

Communicating with healthcare practitioners and the general public

Developing close, interactive communication

In 2007, HAS pursued its communications policy which focuses on dialogue, consultation, and proximity in order to make HAS and its missions better known to healthcare practitioners.

There were many events in 2007 but the highlight was certainly the first "HAS Meeting" ("Together, let us improve quality in healthcare"⁽¹⁾) which was attended by over a thousand practitioners and stakeholders in healthcare. It was a great opportunity for sharing ideas and experiences on how to improve the quality of the French healthcare system.

(1) Dec 17-18, 2007, Cité des sciences et de l'industrie, La Villette, Paris



The 4 national events organised by HAS in 2007

FEBRUARY

Public hearing "Substance abuse, dependencies, and multiple drug consumption"

JULY

Presentation of HAS Annual Report 2006

OCTOBER

HAS/INCa Colloquium

DECEMBER

First HAS Meeting

Other ways of consulting healthcare practitioners were also used to obtain an opinion on HAS' work. For example, the first public consultations were held on the HAS website. They concerned the

guideline "Delegating and new professions... How to promote new forms of cooperation between healthcare practitioners".

Development of consultation on the website

First consultation on the guideline on cooperation between practitioners

Second consultation on this guideline

Consultation with patient associations on methods of producing guides for chronic diseases



In 2007, HAS continued to produce newsletters and information sheets for its audiences:

- a newsletter for institutions to highlight the diversity of its actions and to raise awareness of its missions;
- an information sheet called *EPP Infos*, e-mailed to health

professionals, which provides information on CPD.

In 2008, HAS plans to produce an information sheet for general practitioners, providing concrete and useful information for daily practice.

Newsletters produced in 2007

HAS newsletter (5 issues)

EPP Infos (10 issues)

HAS Infos (9 issues)

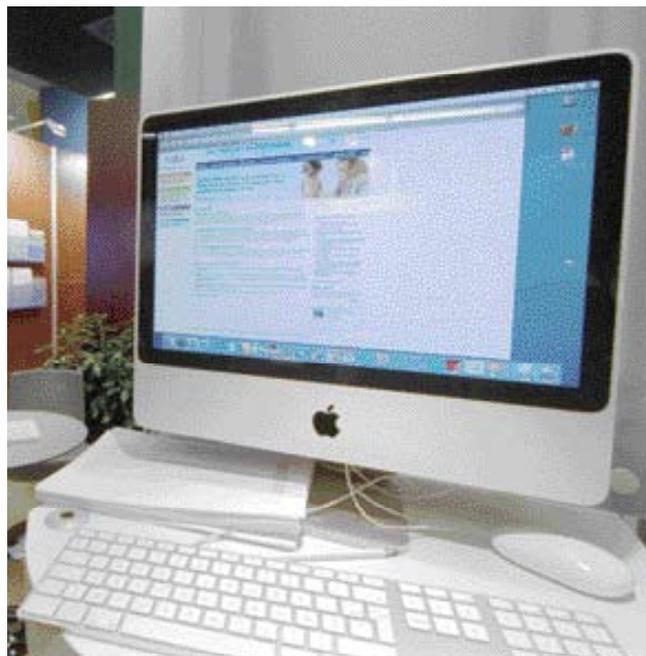
Informing healthcare practitioners and the general public

Making information available on the website (www.has-sante.fr)

4,844 visits on average per day in 2007
 ↑ an increase of **8%** from 2006

603 publications made available in 2007
 ↑ an increase of **52%** from 2006

11,764 downloads on average per day in 2007
 ↑ an increase of **198%** from 2006



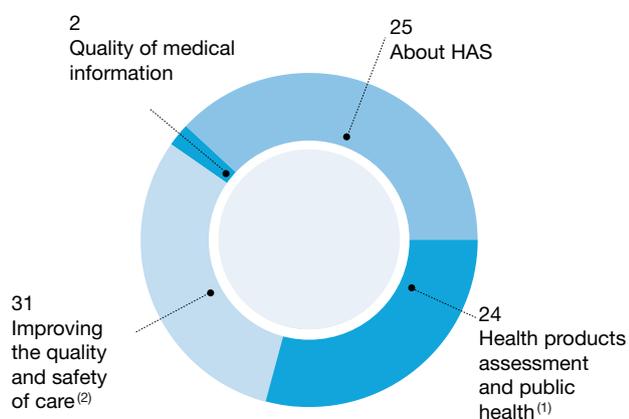
Top 5 downloads in 2007

- Accreditation of healthcare organisations: manual V2
- Accreditation of healthcare organisations: manual V2007
- Instructions on CPD for doctors
- CPD as part of the accreditation of healthcare organisations
- Accreditation of healthcare organisations: guide to scoring

Visibility

82 press releases in 2007

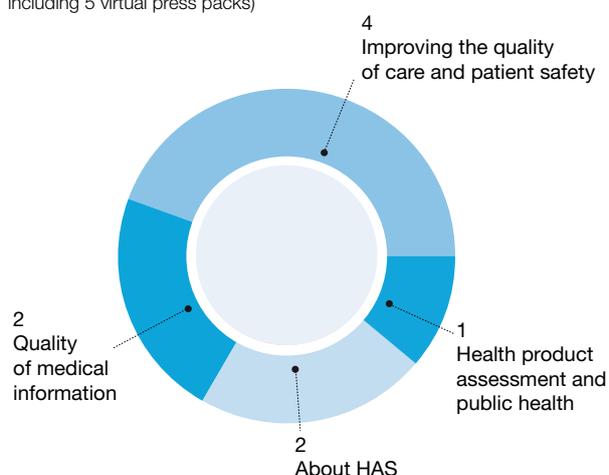
130% higher than in 2006



(1) including assessment of medicines, devices, and procedures, health economics assessments, and public health
 (2) including clinical practice guidelines, chronic conditions, CPD, accreditation of HCOs, and certification in high-risk specialties

9 press meetings in 2007

an increase of 50% from 2006
 (press conferences and breakfast or lunch meetings, including 5 virtual press packs)



Meeting topics: presentation of the annual report for 2006 to the Senate, first "HAS Meeting", good use of medicines leaflets, myocardial infarction, psychotropic drugs, guides to chronic conditions, therapeutic patient education, certification of prescription software, certification of health-related websites

HAS participated in 11 national and regional exhibitions and conferences in 2007

List of national exhibitions

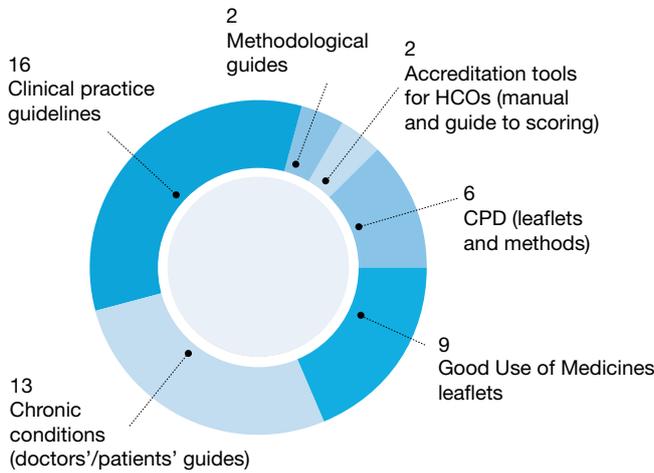
Physiotherapy Congress – Paris
MEDEC 2007 – Paris
Nursing Fair 2007 – Paris
WONCA Europe Congress (World Organization of Family Doctors) – Paris
French Radiology Days – Paris
Pharmaceutical Forum – Lyon
Public Health Congress – Montpellier

539 participations in national colloquia in 2007

↑ an increase of 42% from 2006

Targeting for greater impact

48 different types of documents...



... sent to specific targets in 2007

- institutions
- general practitioners
- specialists (private and hospital)
- pharmacists
- hospital staff (administrators, quality managers, chairpersons of CME [medical committees])
- medical distribution channels
- approved bodies

Examples



- 1 - Good Use of Medicines leaflets
- 2 - Quick Reference Guides for Clinical Practice Guidelines
- 3 - Good Use of Medical Devices and Medical Technologies leaflets

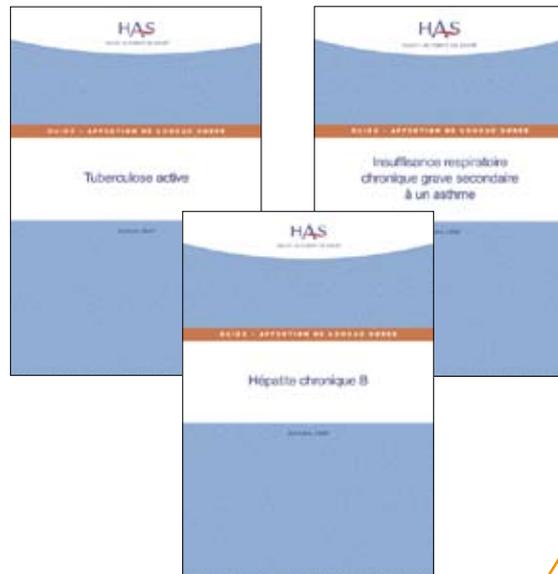
Promoting good use and good practice

In 2007 HAS increased the distribution of Good Use of Medicines leaflets and of guides on chronic conditions for doctors and patients in order to promote the good use of healthcare and good practice by practitioners and to encourage a critical attitude. During the year, this led to commentaries in the general medical press on key topics such as Acompli[®], type 2 diabetes, asthma, and hepatitis C.

In addition, surveys were performed to discover practitioners' views on these publications, the extent to which they were taken on board, and ways of improving future publications.

Chronic condition guides for patients and doctors were produced concurrently. In 2007, eight guides were distributed to patients by doctors working for the French National Health Insurance funds. These patient guides, underpinning doctor-patient dialogue, present key facts on the disease, its treatment and follow-up. Each patient who enters the chronic condition scheme, or who benefits from inclusion renewal, receives the appropriate guide from his or her doctor.

Doctors' guides to chronic conditions*



* Examples of guides published in 2007.

Patients' guides to chronic conditions*



* Examples of guides published in 2007.

Sharing scientific expertise

Research programme

In 2007, the HAS Study and Research unit diversified its partnerships in order to initiate calls for research proposals.

- It issued a call for research proposals in partnership with the CNSA⁽¹⁾;
- It was a partner to a call for research proposals on prevention from the IReSP⁽²⁾;
- It was scientific adviser to a call for research proposals on hospital quality (PREQHOS) issued by the DHOS⁽³⁾;
- It issued calls for research proposals on topics relating to specific needs identified by its own departments.

In 2007, HAS also issued four calls for tenders:

1. Study of the relationship between volume of activity and quality within healthcare organisations;
2. Critical analysis of the methods used to make indirect comparisons;
3. Producing summary notes based on a review of the health economics and public health literature;
4. Performing literature reviews and writing assessment reports on surgical and diagnostic procedures.

The unit also carried out work in its own name: participation in the project on new forms of cooperation, drafting of a report on the financial participation of patients in Europe, and modelling of the impact on equity of capping expenditure on healthcare.

Call by HAS for research proposals: 7 projects selected

Topic I	Production and assessment of novel methods for identifying or preventing clinical risks
Topic II	Impact of management and human resource management on quality of care
Topic III	Methods to assess telemedicine

Call by HAS – CNSA⁽¹⁾ for research proposals: 4 projects selected

Topic I	Improving access of persons with loss of independence to primary and preventive care No project selected
Topic II	Assessment of the quality of care of persons with loss of independence in different types of structure
Topic III	Improving the referral of persons with loss of independence for adapted management

Call by IReSP⁽²⁾ for research proposals on prevention: 19 projects selected (one funded by HAS)

Contribution of self-measurement of blood pressure to the understanding and management of hypertension in the elderly

In 2007, the unit initiated an in-depth discussion on the role of research within HAS in order to identify priority topics. This is part of a general discussion on the organisation of research on the healthcare system and services, in which other stakeholders (INSERM⁽⁴⁾, CNRS⁽⁵⁾, Ministry of Health, National Health Insurance, and IReSP⁽²⁾) are also involved. HAS organises annual seminars on patient safety. In 2007 experts from HAS and around the

world debated on the subject of “Medical autonomy vs prescriptive strategies”.

(1) CNSA: National Independent-Living support fund

(2) IReSP: Institute for Public Health Research

(3) DHOS: Directorate for Hospitals and Organisation of Care

(4) INSERM: French National Institute for Health and Medical Research

(5) CNRS: French National Centre for Scientific Research

International affairs

HAS maintains close links with its foreign counterparts not only to learn from successful experiences in other countries and to enrich its own activities, but also to extend its know-how and the French point of view in the field of healthcare assessment and quality.

HAS participates in a large number of international events and regularly welcomes official delegations from abroad. In 2007, it participated in 82 international events (congresses, colloquia, working groups, seminars...) of which 85% were in Europe. HAS staff gave 47 presentations.

The international activities of HAS in 2007 had three central themes: (i) developing a strategy of influence in Europe in the field of healthcare assessment, quality and safety; (ii) monitoring international developments in HAS' areas of interest; (iii) contributing to the international cooperation policy of the French authorities.

Developing a strategy of influence in Europe in the fields of healthcare assessment, quality of care, and patient safety

HAS participates in a number of projects funded by the European Commission. Two of the projects belong to the European Union's (EU) public health programme:

1. "Safety Improvement for Patients in Europe" (SlmPatIE) which concerns the development of a common methodological basis across the EU in the field of patient safety;
2. The "European Network for Health Technology Assessment" (EUNetHTA) which seeks to form a European exchange network of national agencies and research bodies working in the field of health technology assessment.

Two other projects are part of the Sixth Framework Programme for Research:

1. "Methods of Assessing Response to Quality Improvement Strategies" (MARQUIS) which concerns the identification of the most effective strategies for improving healthcare quality across Europe;
2. "Coordination of Cancer Clinical Practice Guidelines Research in Europe" (CoCanCPG) which seeks to reduce disparities in cancer clinical practice guidelines across Europe.

HAS is involved in bilateral or tripartite cooperation with other national regulators such as NICE (National Institute for Health and Clinical Excellence) in the UK, IQWiG (Institut für Qualität Wirtschaftlichkeit im Gesundheitswesen) in Germany, HIQA (Health Information and Quality Authority) in Ireland, NBH (National Board of Health) in Denmark, and AHTAPol (Agency for Health Technology Assessment) in Poland.



HAS also organises international consensus meetings, making proposals at a European level in fields relating to its missions (e.g. patient safety, February 2007). In general, it seeks to be involved in the discussions, decisions, and proposals relating to EU programmes in order to ensure that the French position is taken into account. For example, it wants to ensure that minimum standards in the EU are not set at a lower level than the standards currently applied in France.

This is in addition to its official involvement in defining the French positions upheld by the relevant departments of the Ministry of Health, Youth Affairs, Sports and Community Life, which consult HAS on topics such as the health services, patient information, rare diseases, and patient safety, and its indirect involvement in the work of the European Pharmaceutical Forum on patient information, assessment of the relative efficacy of medicines, and the pricing of medicines.

HAS also monitors developments in the EU so that it can incorporate the results of work done by European institutions into its own activities as soon as possible, and take part in EU discussions at the earliest possible level.



Monitoring international development

Being a scientific authority, HAS needs to compare experiences in France with those in other countries in order to share those that are successful and raise the quality of its opinions and guidelines. To this end, HAS:

- plays an important role in international bodies, such as the Guidelines International Network (GIN), the International Network of Agencies for Health Technology Assessment (INAHTA), and the

International Society for Quality in Health Care (ISQua);

- takes an active part in international meetings to promote its own work and to analyse the activities of foreign institutions with similar missions;

- posts English translations of its guidelines and opinions on the HAS website, and submits articles to international peer-reviewed journals.

Contributing to the international cooperation policy of the French authorities

HAS responds to requests from the authorities of other countries for assistance and transfer of skills. Typical questions are: How to draw up an accreditation policy for healthcare organisations? How to assess medicinal products? Which criteria to use in appraising doctors' continuing professional development (CPD)? HAS seeks to export its know-how and to promote French medicine abroad by responding to requests from key countries picked by the Ministry of Foreign Affairs.

Relations with patients' associations and users

The team in charge of relations with patients' associations and users was created in November 2006. Its aim is to establish enduring relationships with the associations and facilitate their involvement in the work of HAS.

The team's work was considered a strategic priority by the HAS Board in 2007. The team ran its daily affairs but also:

- initiated relations with the associations; for instance, it set up regular information meetings with the CISS⁽¹⁾;
- started involving the associations in HAS' work.

A working group representing the associations⁽²⁾ was established to determine the expectations of each party. HAS needed to ensure the representativity of the associations which it is inviting to contribute to its work and to supply them with a clear framework for working with HAS. At the close of three meetings, the working group gave its approval to the following two documents:

1. A framework for cooperation

This framework:

- gives formal recognition to the experience of the associations by considering their representatives as experts. This novel initiative means that representatives are treated in the same way as experts: same fees and payment of expenses, same obligation to declare interests and observe the confidentiality of documents issued by the working groups until their publication by HAS;
- provides a basis for selecting patients' associations invited to contribute to the work of HAS: this is essential to transparency; HAS undertakes to call first and foremost on approved health associations⁽³⁾, but to leave its door open to associations undergoing approval, non-approved associations, or those which are not candidates for approval (non-structured groups of associations);
- gives associations the opportunity to be involved in the work of HAS to different degrees that are in line with their wishes and capabilities⁽⁴⁾ (taking part in organising committees and/or topic-specific working groups and/or review groups).

2. A method for the production of guides for patients with chronic diseases

The production method guarantees that deadlines are met and describes each ingredient of the production process: the driving role of HAS, the contribution of the associations, and the role of the team in charge of drafting the final messages for maximum impact. The method may be downloaded from the HAS website.

For the purposes of transparency, an online consultation on both these documents was opened on the HAS website on December 7 with the agreement of the working group. Its results will be known at the start of 2008.

Facilitating the involvement of associations in the work of HAS

The team was charged with including association representatives into work on guides for patients with chronic conditions (see box) and on:

- the V2010 version of the accreditation manual for healthcare organisations: eight representatives participated in the working groups drafting the manual. The team contributes to the programme on patients' rights and involvement;
- clinical guidelines produced by working groups on AIDS prevention, bariatric surgery procedures, management of intractable chronic pain, drug prescription during medical control, prevention of dental caries, prescription of psychotropic drugs for the elderly, use of occupational health medical records in CPD, good practice guidelines on the use of general and local anaesthetics for intractable chronic pain – home use.

17 guides for patients receiving chronic condition status

Guides for patients with chronic conditions are by-products of the guides for doctors. They include the opinion of the associations and are finalised by the team. In 2007, guides were produced on: anxiety disorders, multiple sclerosis,

schizophrenia, Parkinson's disease, viral hepatitis B and C, epilepsy, types 1 and 2 diabetes, stroke, coronary disease, peripheral occlusive arterial disease of the lower limbs, asthma, chronic obstructive pulmonary disease, and tuberculosis.

(1) CISS: *Inter-association Collective for Health* (27 patient associations)

(2) Including CISS (and some of its members representing chronic conditions and rare diseases) and consumers

(3) Articles L 1114-1 and R 1114-1 to 1114-17 of the Public Health Code

(4) Excluding participation in the 8 HAS specialist committees as laid down in the law, and thus excluding the Transparency Committee and the Committee for the Assessment of Products and Services

MIDISS office

The office for the development of assistance to mediation, information and dialogue on patient safety (MIDISS) partakes in HAS' remit to inform the public and promote the quality of care. It is a space for dialogue between users, healthcare practitioners, and public authorities. The aim of the office is to restore public confidence and participate in improving patient safety.

The main activities of the office are:

- informing users of the risks associated with care and of preventive measures;
- giving advice to individual users on their experience and medical history;
- informing practitioners after an adverse event has occurred;
- offering assistance to mediation between users and healthcare practitioners – according to the principle of subsidiarity – when dialogue has broken down (once the agreement of all concerned has been obtained);
- if required, alerting the relevant health authorities;
- providing stakeholders with feedback in order to identify appropriate preventive measures.

In the 22 months of the office's operation, almost 8,000 persons were heard, and provided with support and individual follow up. Resorting to litigation was reduced, much to the benefit of healthcare organisations and practitioners.

The office processed 7639 queries of which 68% required analysis by a doctor from the office. Most of these queries concerned surgery (75%) or resuscitation (15%). An in-depth analysis revealed that 491 cases entailed physical injury liable to involve a healthcare practitioner's legal, civil or administrative liability. With the help of the office, 47 requests for criminal prosecution and 311 cases of civil or administrative litigation were avoided, and 133 procedures for an out-of-court settlement of the dispute by CRCI⁽¹⁾ were initiated.

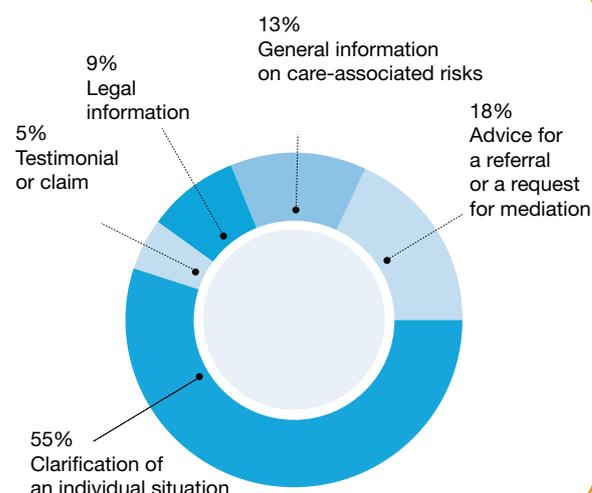
In addition, the mediation team assisted in 53 mediations. More than 600 persons were directed to local (70%) or regional (30%) mediation schemes.

The percentage of queries relating to an in-hospital adverse event that was not a hospital-acquired infection rose from 5% in March 2006 to 25% in December 2007. The office was able to distinguish a few signals from the "background noise" generated by all the data on these events, that were shown to have significance on analysis. They were communicated to the competent bodies.

The office has become:

- an independent body for listening and providing information to users and healthcare practitioners;

Main reasons for calls to the MIDISS office in 2007



- a responsive and attentive contact point responding individually to each person;
- a place of assistance to mediation gathering users and healthcare practitioners around a common objective of improving the quality and safety of care;
- a new stakeholder in health monitoring;
- an observatory for serious adverse events reported by users.

(1) CRCI: Regional Conciliation and Compensation Committees

Resources activated

The General Administration and Internal Resources Division is in charge of activating support functions within HAS. Its role is to support HAS in its work and development. It has a cross-departmental mission and manages unifying projects, such as the enterprise architecture information system, the archives structure, and the conservation of key documents. The Division comprises 80 staff members in 6 departments.



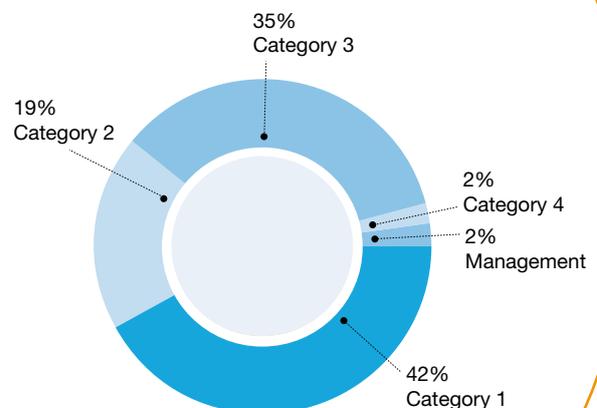
Human resources

The Human Resources Department, in collaboration with other divisions and departments, fashions and implements the human resources policy of HAS. It has a variety of activities which are carried out according to the legal and regulatory provisions in force: recruitment, administrative and payroll management of staff members and external experts, establishment and implementation of a training plan, facilitation and coordination of dialogue between management and staff, and internal communications.

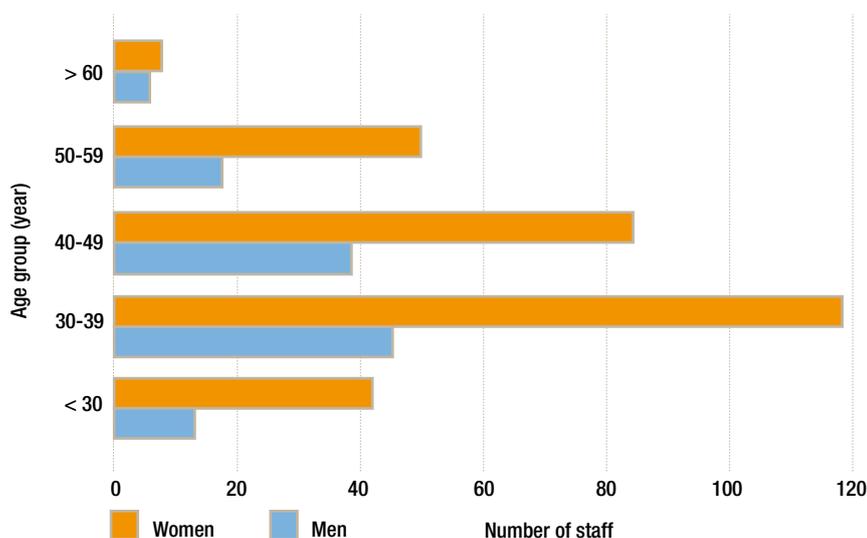
Senior managers and categories 1 and 2 employees account for 63% of staff. Categories 1 and 2 personnel are not all managers but carry out tasks requiring high-level qualifications. HAS' activities require expert skills.

Average age is a little over 40 years. A large proportion of the staff is in the 30-39 and 40-49 age categories. Almost 72% of the staff are women.

Distribution of staff by category of employment



Age pyramid



Figures on December 31, 2007

Internal quality

HAS has continued the internal quality initiative started in 2004 in order to promote improvement in performance. This initiative is founded on client satisfaction, continuous quality improvement, process management, and measurement of performance using score cards. It was developed

through departmental workshops on “Quality process and balance score cards” involving all staff. From a set of sundry quality initiatives, HAS has moved on to a cross-departmental, global quality initiative, with tools to monitor and steer performance.

Processes / Procedures	
Processes posted on the Quality–Procedures-Forms intranet site Topic I	87%
Procedures finalised	15%
Number of persons trained in drafting procedures	34
Assistance to groups for improvement and change	
Number of groups in 2007	7
Cumulative number of actions implemented by these 7 groups	146
Balance score cards	
Number of presentations of the balance score card (TBP HAS) to the <i>ad hoc</i> Committee	4
Divisions represented in TBP HAS	100%
Departments providing a balance score card	75%
Number of issues of HAS Key Figures on the website	5

In 2007,

- an intranet site (Quality-Procedures-Forms) was created to provide access to a map of the macro-processes, to the processes and procedures, and to related documents. This site holds the descriptions of 87% of the processes identified;
- the *Kifékoï* (“who does what”) intranet site gave all staff the opportunity to see the posters prepared by the departments for the *Kifékoï* forum (October 2006);
- 34 staff members were trained in the drafting of procedures. By the end of 2007, 15% of procedures had been drafted and 50% were being drafted;
- support was given to seven groups for improvement and change (e.g. groups for improving the procedures for the translation of HAS studies, the organisation of purchasing, and the assessment of medicines);
- a consensus was obtained on the new HAS balance score cards (TBP) used by the divisions. This score card helps monitor whether actions have been implemented in order to meet the objectives set at the start of the year;
- a consensus was obtained on the document “HAS Key Figures” which is posted on the HAS website.

Legal support

The legal team assists the HAS Board, specialist committees, and management with its expertise. It also intervenes at the request of departments when their work requires legal input. It sets up the tools the departments require to carry out their work, in particular by drafting contracts with partners and setting up procedures.

The team manages day-to-day legal matters such as leases, insurance policies, service provider contracts, and the prevention and management of potential litigation. It also monitors the legal landscape on a weekly basis, focusing specifically on the world of healthcare and HAS’ missions.

In 2007, the legal team:

- drafted an ethical charter for use within HAS, as part of its participation in the group “Ethics and independence of expertise”;
- reinforced the policy for prevention of conflicts of interest within HAS;
- appointed a representative to lessen the burden of the reporting formalities concerning the processing of personal data (CNIL⁽¹⁾) and to ensure compliance with the Information Technology and Freedoms Act;
- established a procedure for answering questions from users and healthcare practitioners;
- formalised partnerships with:
 - INCa⁽²⁾ in order to carry out joint or complementary actions in the field of cancer;
 - the Health On the Net foundation in order to implement certification of health-related websites;
- formalised partnerships and funding contracts with the public authorities, healthcare organisations, and scientific establishments, in order to promote the development of hospital performance and quality indicators.



(1) CNIL: National Data Protection and Civil Rights Council

(2) INCa : French National Cancer Institute

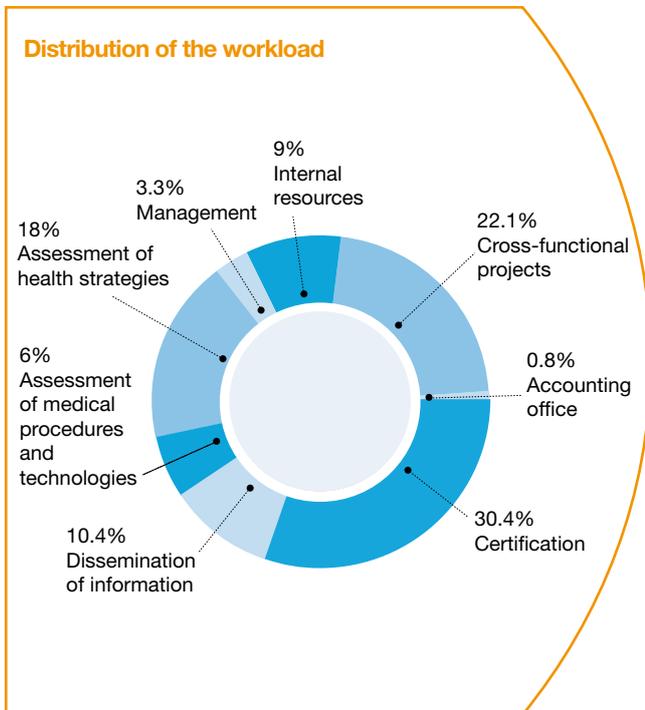
Information technology (IT) systems

2007 saw the start of five major projects:

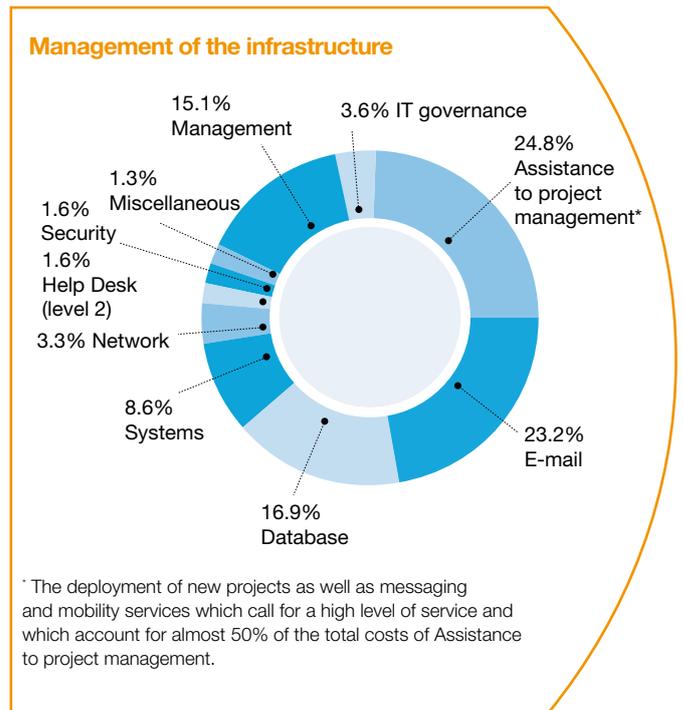
- optimisation of the internet portal – the showcase of HAS' activities - and the launch of a website on patient safety;
- successful implementation of SIAM (IT system for the certification of doctors and medical teams practising in healthcare organisations, with the aim of improving the quality of care and clinical practice) within the very short deadline laid down by decree;
- connection of the IT system to a CNAM⁽¹⁾ database;
- ensuring security of data flow;
- stepwise listing of the IT department's activities among the ITIL⁽²⁾ good practice standards so that its processes can be industrialised and the quality of its services optimised.

The IT department is making efforts to optimise its work processes and continuing to secure its architecture in terms of safety and reliability.

Its internal resources have been used by the divisions to carry out their high-priority projects. The distribution of the workload by division is as follows:



The "Infrastructure" resources needed to take on projects, consolidate the technological structure and make it secure, and run the IT system can be broken down as follows:



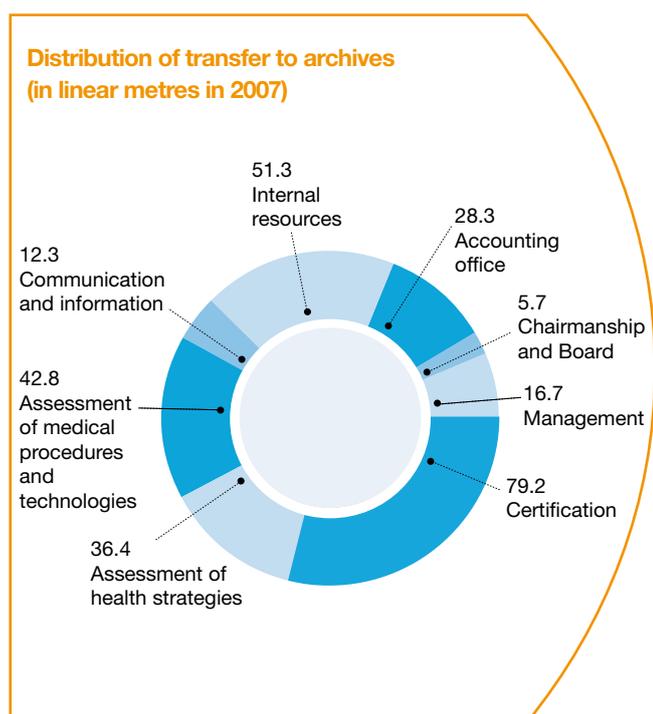
In 2008, the priority task for the IT Department will be to align the IT system with the new organisational chart of HAS.

(1) CNAM: French National Health Insurance funds
 (2) ITIL: Information Technology Infrastructure Library

Logistics and public tenders

The Logistics and Public Tenders Department responds to the needs of HAS' divisions in terms of procurement, supplies and services, and contributes to the everyday running of the departments. The department plays an active role in guaranteeing that the workplace and the conditions of work are safe and appropriate.

The department is raising awareness among staff of the rules on filing and archiving paper and digital documents, by providing support and training, in accordance with the new charter on document conservation signed by HAS and the Archives of France. The transfer to archives was 22% higher in 2007 than in 2006 and represents 273.6 linear metres distributed as follows:



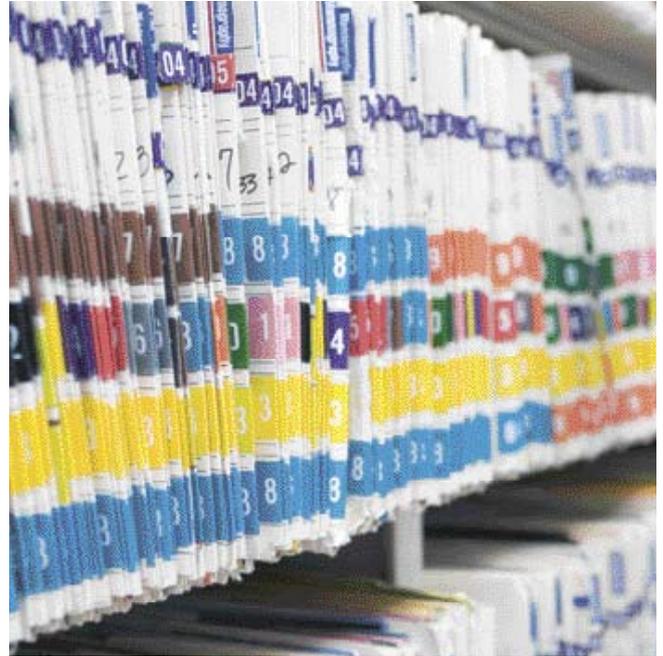
The Department has awarded contracts under the Public Tendering Code (over 90 tenders are active), particularly in response to the need to outsource scientific literature reviews (about 10% of the active tenders).

Indicator	Cumulative number (end December 2007)
Active tenders (call for tenders)	35
Active tenders (special procedure)	64
Calls for tenders published	25
Special procedures published	12
Amendments to initial tender	20

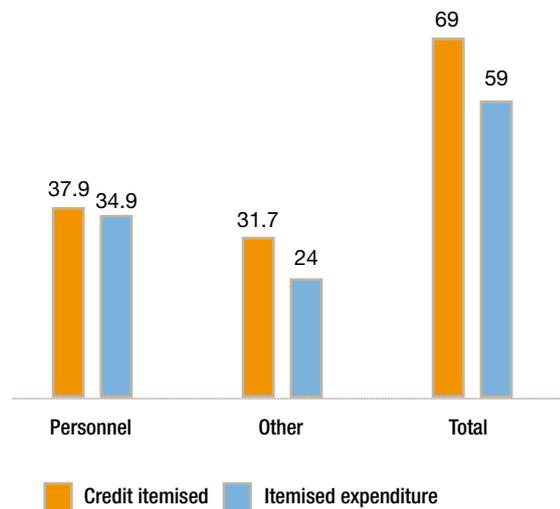
Financial resources

The HAS operating budget for 2007 – €69,690,000 – recorded a real expenditure of 85% (€59 million), this is a 6% increase in expenditure over expenditure during the 2006 financial year.

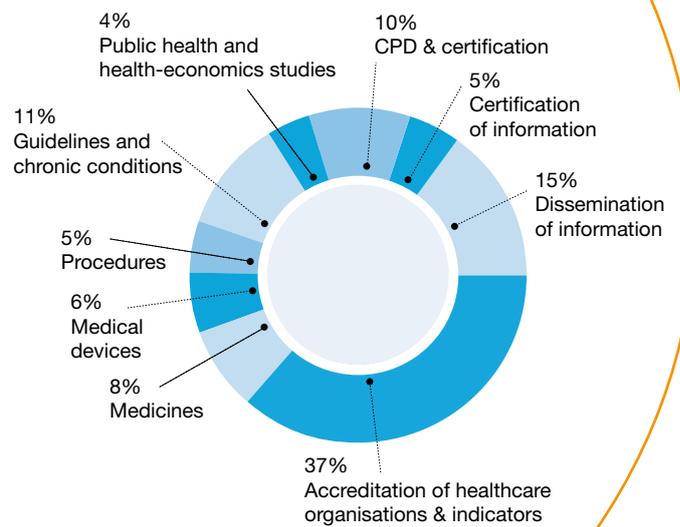
The total expenditure (59% for personnel) was distributed between the main outputs of HAS as shown in the chart below which shows that nearly 60% of expenditure is dedicated to accreditation of healthcare organisations & indicators, to continuous professional development & certification of doctors, and to the drafting of guidelines. The costs given for “dissemination of information” (15%) relate to dissemination only and not to costs of producing information which concern all professional departments within HAS.



Total expenditure (in millions of euros)



Distribution of operational expenditure



The investment budget of €2.230 million, characterised by a better control of needs in comparison with 2006 (€3.2million) recorded a real expenditure of 64.4% in 2007. This expenditure mainly concerns investment in the enterprise architecture IT system.

The income structure is determined by article L. 161-45 of the Social Security Code. The income for 2007 was broken down as follows:

Income structure in euros

	Projected income	Income received
Government subsidy	€1,000,000	€958,402*
Total contribution from National Health Insurance	€2,000,000	€2,000,000
10% of the tax on pharmaceutical company spending on advertising	€19,646,673	€28,801,103
Healthcare organisation accreditation fees	€8,860,000	€9,537,600
Fees from manufacturers	€4,243,500	€3,598,350
Miscellaneous (investment income)	€200,000	€2,042,034
Total	€35,950,173	€46,937,489
Working capital	€18,500,000	€13,500,000

* 5% freeze on the government subsidy.

The greater than expected income (+€10.9 million) is only apparent. The sum of €28.8 million in the above table corresponds to the balance brought over from 2006 and recorded in 2007 (€3.1 million) plus an amount of €25.7 million which was the income forecast for 2007 communicated by ACOSS⁽¹⁾. However, the final amount confirmed for 2007 was only €20.2 million, thus significantly modifying the forecast and results. The working capital at the end of 2007 was no longer €35.6 million but €30.1 million (€48 million end of 2006).

In adopting a 2008 budget of €66.205 million, a decrease of 5% with respect to the 2007 budget, HAS intends to engage

in a cost-containment initiative. The income forecast for 2008 is €50 million. With forecasted investments of €1.9 million, the budget initially voted shows a working capital of €18.5 million at the end of 2008.

Nevertheless, the overestimation of income expected in 2007 from ACOSS will lead HAS to record an exceptional charge of €5.5 million in its accounts for 2008, thus reducing its estimated working capital at the end of 2008 to €13 million.

(1) ACOSS: Central Agency for Social Security Organisations



03

Appendices

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Organisation of HAS



The Board, from left to right: Jean-Paul Guérin, Raoul Briet, Professor Lise Rochaix, Étienne Caniard, Professor Laurent Degos (chairman), Dr Claude Maffioli, Professor Gilles Bouvenot, Professor Jean-Michel Dubernard.

The Board

The HAS Board is responsible for programming, steering, and implementing the missions assigned to HAS by law and for developing its strategy. As the deliberative body of HAS, it is accountable for the rigour and impartiality of HAS' output. Apart from issuing opinions, guidelines and accreditation decisions, the Board examines subjects such as the annual budget and accounts, bylaws (for the Board, committees and departments), accounting and financial rules, borrowings and the investment of reserves, and the accreditation procedure for healthcare organisations.

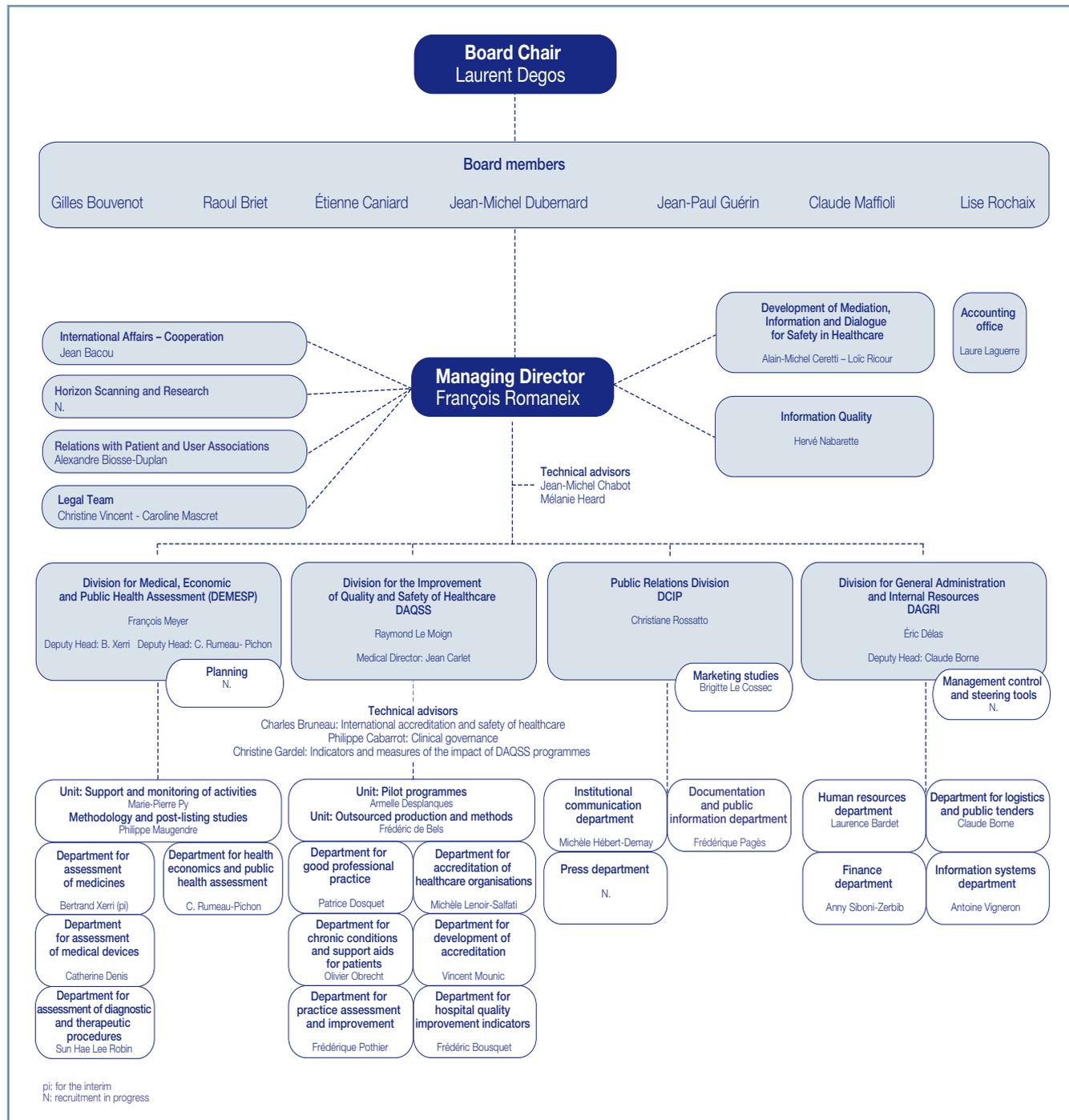
The Board is made up of eight members proposed by various State authorities and appointed by decree of the President of the Republic. Two are proposed by the President of the Republic, two by the Speaker of the Senate, two by the Speaker of the National Assembly, and two by the Chair of the Economic and Social Council. They are appointed for a six-year term, renewable once. Half the Board is renewed every three years. Lots were drawn at the first meeting of the Board on December 23, 2004, to nominate the four members whose mandate would terminate at the end of 2007, after just 3 years. Professor Lise Rochaix, Jean-Paul Guérin and Professor Gilles Bouvenot had their mandates renewed and Professor Jean-Michel Dubernard was nominated following the end of the mandate of Professor Bernard Guiraud-Chaumeil.

The specialist committees

Together with the Board, the seven specialist committees are responsible for examining the dossiers prepared by the operational departments in HAS' areas of competence. Each committee is chaired by a board member and has its own bylaws. Each committee chair works closely with a department head. While functionally

attached to the committee, the department head also reports directly to the Managing Director of HAS. The department heads and their staff carry out the preparatory work needed for the specialist committees to make their decisions.

Organisation chart for 2008



Specialist Committee members

Committee for the Assessment of Medical and Surgical Procedures

Tasks

- To issue opinions on medical and surgical procedures (procedures, techniques and methods used by healthcare practitioners for preventive, diagnostic or therapeutic purposes) with a view to their being covered by National Health Insurance;
- To validate and disseminate health technology assessments (excluding those on medicines and medical devices for individual use).

Membership

Chair: Dr Claude Maffioli

Vice-chair: Professor Bertrand Dureuil

Members:

Professor Marie-Christine Béné

Dr Christian Espagno

Professor Olivier Goëau Brissonnière

Professor Patrick Goudot

Dr Yves Grillet

Dr Jean-Marie Mussini

Dr Nathalie Pelletier Fleury

Professor Jean-Pierre Pruvo

Dr Gérard Very

Committee membership was established by Board decision on March 9, 2005, (*Journal Officiel* (JO), March 25, 2005), modified on November 2, 2005 (JO of December 16, 2005) and November 22, 2006 (JO of January 30, 2007).

Transparency Committee (assessment of medicines)

Tasks

- To assess applications by manufacturers for drugs that have been granted a Marketing Authorisation to be included on the reimbursement list;
- To give an opinion on the reimbursements of medicines by National Health Insurance and/or their use in hospitals by assessing their "Actual Benefit";
- To promote the proper use of medicines by publishing relevant and independent scientific information on each medicine, its therapeutic use, and any Improvement in Actual Benefit (added value) that it may provide compared with treatments already available.

Membership

Chairman: Professor Gilles Bouvenot

Vice-chairs: Professors Claire Le Jeunne and Élisabeth Autret-Leca

Full members:

Professor Bernard Bannwarth

Dr Alain Cariou

Professor Denis Duboc

Dr Lise Duranteau

Professor Bruno Falissard

Professor Jacques Jourdan

Dr Marie-Agnès Koenig-Loiseau

Professor Emmanuel Oger

Dr Patrice Nony

Professor Michel Petit

Dr Claude Sichel

Professor Jean-Paul Stahl

Dr Jean-Marie Vetel

Professor Patrick Villani

Patrick Wierre

Dr Olivier Wong

Professor Marie-Christine Woronoff-Lemsi

Alternate members:

Frédéric Courteille

Professor Marc Bardou

Dr François Trémolières

Dr Florence Mathonière

Dr Patrick Maison

Dr Mahmoud Zureik

Member in advisory capacity, representative of pharmaceutical manufacturers' trade unions and proposed by them:

Catherine Lassale

Membership established by Board decision on March 12, 2008.

Committee for the Assessment of Devices and Health Technologies

Tasks

- To advise on applications for inclusion on the reimbursement list of medical devices for individual use, human tissues and cells and their derivatives (irrespective of the degree of transformation), and health-

care products other than medicines and associated services;

- To advise on healthcare-related technologies, at the request of the HAS Board or on its own initiative.

Membership

Chair: Professor Jean-Michel Dubernard

Vice-chairs: Professor Alain Bernard, Dr François Parquin

Full members:

Professor Bernard Fraysse

Dr Pascal Giraux

Professor Olivier Goëau Brissonniere

Dr Jean-Claude Guimberteau

Professor Bernard Guillot

Professor Paul Legmann

Professor Jacques Machecourt

Professor Daniel Maitrot

Dr Noël Martinet

Professor Christian Partensky

Professor Richard Rochwerger

Professor Éric Vicaut

Alternate members:

Dr Philippe Debodinace

Dr Nathalie Elbaz

Anne Florence Fay

Anne Grumblat

Members in advisory capacity:

Dr Bernard Avouac,

Odile Corbin (alternate), representatives of manufacturers and distributors of products mentioned in article L.165-1

Claudine Grouzelle, Christophe Divernet (alternate), representatives of providers of services mentioned in article L. 165-1

Membership established by Board decision of March 19, 2008.

Committee for Healthcare Cover for Long-Term (Chronic) Conditions

Tasks

- To advise on draft decrees establishing the list of chronic conditions and specifying entitlement to services provided within a health network or coordinated care system;

- To produce guidelines on its own initiative or at the request of the Board or a third party on the procedures and services required to treat chronic conditions, on their reimbursement, and on the medical criteria used to define chronic conditions.

Membership

Chair: M. Raoul Briet

Members:

National medical adviser of RSI⁽¹⁾ or their representative

National medical adviser of the CNAMTS⁽²⁾ or their representative

National medical adviser of MSA⁽³⁾ or their representative

Dr Hervé Berche

Professor Isabelle Caubarrère

Benoît Dervaux

Christophe Duguet

Jean-Michel Lardry

Professor Michel Leporrier

Dr Didier Ménard

Catherine Sermet

Sylvaine Seveignes

Membership established by Board decision on April 28, 2005 (*Journal Officiel* (JO) of May 24, 2005), modified on January 7, 2007 (JO of March 10, 2007).

(1) RSI: National Health Insurance fund for the self-employed

(2) CNAMTS: National Health Insurance fund for salaried workers

(3) MSA: National Health Insurance fund for agricultural workers

Committee for Healthcare Strategy Assessment

Tasks

To advise the HAS Board on whether to validate and authorise the dissemination of:

- clinical practice guidelines and tools for implementing them and measuring their impact (quick reference guides, standards for appraising Continuing Professional Development, information sheets for patients and users, indicators, etc.);

- reports on the quality of care provision, particularly public health actions and programmes;
- health economics assessments;
- methodology guides relating to the implementation of HAS' missions.

Membership

Chair: Professor Lise Rochaix

Vice-chair: Professor Franck Lazorthes, Professor Pierre Lombrail

Members:

Dr Corinne Alberti
 Professor Joël Belmin
 Daniel Benamouzig
 Dr Philippe Bergerot
 Dr Yann Bourgueil
 Jean Canneva
 Professor Marie-Odile Carrere
 Christine Chemorin
 Dominique Costagliola
 Professor Brigitte Dormont
 Dr Eric Drahi

Gilles Gaebel
 Dr Nicole Garret-Gloanec
 Professor Michèle Kessler
 Dr Luc Martinez
 N.T Françoise Nguyen
 Professor Fred Paccaud
 Michel Paparemborde
 Dr Patrice Van Amerongen

Membership established by Board decision of March 24, 2006 (*Journal Officiel* (JO) of April 12, 2006), modified on January 10, 2007 (JO of March 10, 2007). The mandate of the members was extended until November 21, 2007 (JO of December 30, 2007).

Committee for Accreditation of Healthcare Organisations

Tasks

- To establish the accreditation procedure and deliver accreditation certificates to public and private healthcare organisations.

Membership

Chair: Jean-Paul Guérin

Vice-chair: Olivier Debay and Dr Laurent Jouffroy

Members:

Christian Anastasy
 Geneviève Baheu
 Dr Sylvia Benzaken
 Professor Patrice Beutter
 Marie-Lise Biscay
 Christian Caoduro
 Marie-Françoise Dumay
 Denis Frechou
 Dr Jacques Glikman
 Dr Jean-Claude Gourheux
 Dr Anne Gruson
 Pierre Huin

Anne Laurin-Inizan
 Marie-Claude Lefort
 Professor Pierre Lombrail
 Bruno Lucet
 Monique Mazard
 Yvonnick Morice
 Jean-Philippe Mousnier
 Dr Jean-Paul Ortiz
 Claude Rambaud
 Emmanuel Rodriguez
 Jean-Daniel Simon

Membership established by Board decision on March 20, 2008.

Committee for Medical Information Quality and Dissemination

Tasks

- To promote acceptance of HAS' publications (good use guides, clinical practice guidelines, standards) through appropriately targeted dissemination to healthcare practitioners and the general public; with a view to improving healthcare and professional practice;
- More generally, to inform practitioners and the public, and to monitor the quality of the information delivered;
- To introduce quality initiatives relating to medical information delivered via medical sales representatives, prescription software, and e-health websites. These initiatives will result in certification procedures;
- To develop information for healthcare practitioners on the proper use of healthcare products, as an extension to the objectives of FOPIM⁽¹⁾.

Membership

Chair: Étienne Caniard

Members:

Dr Anne Boiteux
Dr André Chassort
Professor Patrick Choutet
Dr Isabelle Colombet
Claire Compagnon
Professor Stéfan Darmoni
Dr Gilles Errieau
Brigitte Fanny-Cohen
Thomas Heuyer
François Lafrayette
Dominique Lebœuf

Dr Anne-Laure Le Doriol-Serero

Dr Anne-Marie Magnier

Jacques Mopin

Pierre-Louis Remy

Antoine Vial

Membership established by Board decision on June 17, 2005 (*Journal Officiel* (JO) of August 6, 2005), modified on April 15, 2007 (JO of May 15, 2007).

(1) FOPIM: Fund for the Promotion of Medical and Health Economics Information

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