



HAUTE AUTORITÉ DE SANTÉ

Haute Autorité de Santé

Annual report

2005

Foreword

Professor Laurent Degos

Chair of the HAS Board

Few of us have not had to deal with illness at some time in our lives. We have witnessed the selfless devotion of health personnel and also the substantial progress made in medicine. And yet many of us have also had a glimpse of a darker side, of malfunctions within the health system. Quality and non-quality in health are subjects that affect all of us and which are of vital concern to the *Haute Autorité de Santé*.

The French Parliament has delegated to the *Haute Autorité de Santé* (HAS) a set of very broad and varied missions for regulating the health system: assessing the quality of organisations and practices; assessing the expected or actual benefit of goods and services; defining the clinical and financial management of long-term conditions; providing information to professionals and to the general public; helping to assess how well public health is managed by the health system. HAS' ambition is to weld these different approaches together and to move from the measurement of the quality of a component of the system to that of the system itself, in order to improve overall performance, and thus to generate greater efficiency, greater equality of treatment and more social justice.

This report describes how HAS has tackled the work related to these core missions. In a short space of time, HAS has launched several key initiatives: a continuing professional development initiative for doctors, focusing on continuous quality improvement; a basket of reimbursable goods and services that is linked to priorities, and changes to the clinical and financial management of long-term conditions. It has also carried out a series of actions in its own specialist areas of activity. The touchstone for all these actions is the need to adapt our health system.

This report thus also presents HAS' vision of how its regulatory missions fit into the healthcare landscape. Interactions among multiple objectives make the health system very complex: health professionals involved in demanding individual relationships with patients seek freedom of action; patients expect the best possible health outcome; funding organisations look for optimal results given the constraints on resources allocated to the health sector. Moreover, not only is the health system complex, it is constantly changing under the impetus of medical progress.

Regulators must not lose sight of this complexity and constant change when looking for initiatives that will have real impact because they are based on changes in behaviour. The last thing the health system needs is more pilots and operators cluttering the stage. HAS' aim is to be a reference providing scientific arguments for decision-making and tools for improving professional practice.

To be an enduring reference in matters of health quality, HAS seeks contributions from experts, health professionals and patient associations. It is currently researching the ingredients of quality, impact measurements, causes of non-quality and ways of inducing behavioural change. It is strengthening its ties with its main partners in Europe and in the rest of the world.

The ever greater impact of medical advances on current practice increases the pressure on stakeholders within the health system. HAS' role is to maintain the widely recognised quality of the French healthcare system and combat poor quality. This means enhancing coherence, credibility and stakeholder involvement in order to be able to offer positive strategies for improving the system.

This is the backdrop to HAS' contribution in providing the scientific basis for decision-making and giving patients, health professionals and government authorities a road map for a long-lasting improvement in the quality of our health system based on social justice.

Foreword

Alain Coulomb

HAS Managing Director

In 2005, HAS set itself six strategic objectives: (i) assess care strategies; (ii) regulate quality; (iii) integrate quality into the health system; (iv) promote user involvement; (v) maintain an international perspective; (vi) upgrade internal efficiency. HAS departments worked to implement these political orientations in 2005.

Examples:

(i) HAS' assessment of care strategies is based on an examination of the comparative performance of diagnostic and therapeutic procedures, medical devices and drugs. This cross-functional activity has meant making long-lasting organisational and cultural changes within HAS, thinking more deeply about indirect comparisons, and bringing HAS departments and Committees together as often as is necessary. It means going beyond the scheduled evaluation of a drug, a medical device or a medical procedure to provide continuous evaluation that takes account of public health interests.

(ii) Quality regulation involves the partial transfer of clinical practice guideline production to learned societies, defining homologation specifications for organisations implementing the continuing professional development initiative and working with these organisations. HAS has gradually moved from being an operator to being a regulator.

(iii) Integrating quality into the health system implies producing best practice guidelines and mobilising stakeholders through incentives. It means defining outcomes indicators that drive quality initiatives, setting up certification and accreditation procedures, and fostering proper use contracts.

(iv) Over 2000 experts contributed to HAS' work in 2005 and meetings were held with health professional and user representatives. HAS visited French regions to promote its continuing professional development initiative and to present the second version of the accreditation procedure. Qualitative studies are ongoing to improve the readability and potential impact of HAS documents.

(v) HAS has signed cooperation agreements with NICE (National Institute for Health and Clinical Excellence) and IQWiG (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen*). Ongoing discussions – with Lebanon and Morocco in particular – reflect international interest in HAS' quality initiatives.

The establishment and gearing up of HAS generated a year of intense activity. The Board set up seven specialist Committees, defined their work schedules and appointed members. ANAES teams and activities were successfully integrated with departments transferred from AFSSAPS. The departments were reorganised to improve overall efficiency.

The support services put in a sustained effort to draw up the first budget, recruit where necessary, organise logistics and prepare the legal texts underlying the workings of an independent public authority. Work priorities were defined in each of the HAS' areas of activity, some of which were new. A committed attitude from staff ensured that the new entity was operational in just a few months and that the completion and dissemination of work already begun was not interrupted. The organisation is keen to fully assume its new missions.

This report reflects HAS' dynamism and its ambitions for the next few years, namely, to make its experience available to health professionals and government authorities and to help ensure that the health system becomes more equitable in the interests of all patients and users.

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About HAS - Organisation and operation

About HAS

■ Creation

The *Haute Autorité de Santé* (HAS) (French National Authority for Health) was created by the French national health insurance law of 13 August 2004 (law no. 2004-810). It came into being on 1 January 2005. HAS has taken over the work of ANAES¹, the Transparency Committee (TC), CEPP² and FOPIM³, and has also been given new missions.

■ Expertise

HAS is tasked with assessing quality of care against scientific evidence, and with improving the equity, relevance and efficiency of the healthcare system. It contributes to maintaining a socially just healthcare system and improving the quality of care, for the benefit of patients. HAS' remit does not include healthcare safety or surveillance/vigilance.

■ Status

HAS is an independent, public, scientific authority, defined as a legal entity, and is financially autonomous. It does not come under the authority of the Ministry of Health.

The following safeguards ensure that HAS' advice and guidelines are independent:

- ◆ members of the Board are appointed by the highest authorities of the French Government and by decree of the President of the Republic;
- ◆ Board members represent a wide variety of professions;
- ◆ Board members give up their other mandates and are under an obligation to avoid any conflicts of interest;
- ◆ the validation and decision-making processes are collegiate.

■ Missions and activities

- 1. To provide the public authorities with the information they need in order to decide which medical products and services should be reimbursed by National Health Insurance (NHI)**
 - assess the clinical benefit of medicines, medical devices and procedures reimbursed by NHI
 - define the range of care that may be reimbursed to patients with long-term conditions
 - carry out health economics and public health assessments.
- 2. To promote good practice and the proper use of care among healthcare professionals and healthcare system users by producing**
 - clinical practice guidelines
 - guides to managing long-term conditions.

¹ ANAES: French National Agency for Accreditation and Evaluation in Healthcare

² CEPP: Committee for Assessment of Devices and Health Technologies

³ FOPIM: Fund for the Promotion of Medical and Health Economics Information

3. To improve the quality of healthcare structures, resources, and practice

- accreditation of healthcare organisations (HCOs)
- assessment of health centres and reference centres for treating rare diseases
- certification of doctors and medical teams
- continuing professional development for doctors, focusing on continuous quality improvement (CQI).

4. To provide information for healthcare professionals and the general public

- assess the quality of medical information: certify compliance with a medical sales representatives' Code of Practice, certify health-related websites and prescription software;
- disseminate and promote materials produced by HAS;
- provide information for healthcare users (particularly about nosocomial infections).

Organisation and operation

HAS' organisation and operation were specified in decree no. 2004-1139 of 26 October 2004. HAS' structure consists of:

- an 8-member executive Board ("*Collège*") which is accountable for the rigour and impartiality of the guidelines and advice issued. It is currently chaired by Professor Laurent Degos;
- 7 specialist Committees whose task is to examine dossiers in HAS' different domains of competence;
- departments consisting of 380 permanent staff. The current Managing Director is Alain Coulomb;
- a network of experts and practising healthcare professionals in the regions.

The Chair also has the power to approve expenditure and income.

The Board

Current Board members are (left to right):



Professor Lise Rochaix (appointed on 9 March 2006 to replace Dr Pascale Briand, who was transferred to other duties)

Professor Bernard Guiraud-Chaumeil

Professor Laurent Degos, Chair

Raoul Briet

Etienne Caniard

Jean-Paul Guérin

Dr Claude Maffioli

Professor Gilles Bouvenot

Board members were appointed on 20 December 2004, by decree of the President of the Republic.

Board members are appointed for a 6-year term, renewable once. Half the Board is renewed every 3 years. In accordance with French law, lots were drawn during the first meeting of the Board on 23 December 2004 to nominate the four members, excluding the Chair, whose mandate would end after 3 years (Professor Gilles Bouvenot, Professor Lise Rochaix, Jean-Paul Guérin and Professor Bernard Guiraud-Chaumeil).

The Board is responsible for carrying out the missions entrusted to HAS by law and for establishing strategy. It decides issues specified by law such as the annual budget and accounts, its bylaws and those of the specialist Committees and departments, regulation of the Accounts and Financial departments, loans and investment of reserves, and the HCO accreditation procedure.

Board operations are organised by a Cabinet which interfaces with the divisions.

The Specialist Committees

There are 7 specialist Committees. In addition to the Transparency Committee⁴ and the Committee for the Assessment of Devices and Health Technologies (CEPP)⁵, five other committees were created by the Board, which decided their composition and their common rules of operation. Each Committee is chaired by a member of the Board and has its own bylaws⁶. Each Committee Chair is supported by a head of department, who reports directly to the Managing Director.

■ The Committee for Assessment of Medical and Surgical Procedures

Chair: Dr Claude Maffioli

- advises on the conditions under which a procedure or service may be included on the reimbursement list mentioned in article L. 162-1-7 of the Social Security Code, and on their removal from the list;
- also gives advice on the list of diagnostic and therapeutic procedures, techniques and methods, and on the prescription of biological, medical and surgical procedures that could present a serious risk.

⁴ Article R. 163-15 of the Social Security Code

⁵ Article R. 165-18 of the Social Security Code

⁶ Information on the composition and bylaws of the committees are given in the Annex.

■ The Transparency Committee

Chair: Professor Gilles Bouvenot

- assesses applications by manufacturers for drugs that have been granted a Marketing Authorisation (AMM) to be included on the reimbursement list;
- advises on whether drugs should be covered by national health insurance (NHI) and/or whether they may be used in hospitals, by assessing their actual benefit;
- promotes proper drug use by publishing relevant and independent scientific information on a drug, its use in treatment, and any improvement in actual benefit (IAB) it may provide compared with drugs already available (i.e. its relative effectiveness).

■ The Committee for the Assessment of Devices and Health Technologies

Chair: Professor Bernard Guiraud-Chaumeil

- advises on requests for inclusion on the reimbursement list of disposable medical devices for individual use, human tissues and cells and their derivatives (irrespective of the degree of transformation), healthcare products other than drugs and associated services, and changes in the conditions for inclusion on the list of products and services that may be reimbursed;
- advises on any aspect of health technologies, at the request of the Board or on its own initiative.

■ The Committee for Healthcare Cover for Long-Term Conditions

Chair: Raoul Briet

- provides advice on draft decrees establishing a list of long-term conditions and those relating to services provided by a health network or coordinated care system that are fully covered by NHI;
- produces guidelines on its own initiative or at the request of the Board or a third party:
 - on the procedures and services required to treat long-term conditions that are fully covered by NHI;
 - on the medical criteria used to define long-term conditions.

■ The Committee for Healthcare Strategy Assessment

Chair: Professor Lise Rochaix

- proposes to the HAS Board decisions relating to the validation and dissemination of:
 - clinical practice guidelines (CPG), and tools for implementing and measuring the impact of CPGs (quick reference guides, standards for CPD in CQI, information sheets for patients and users, indicators, etc.);
 - reports on the quality of healthcare available (particularly public health programmes);
 - health economics assessments;
 - methodology guides for carrying out HAS' missions

These documents are subject to discussion by the Committee. They may have been produced by HAS departments or, under partnership arrangements, by organisations selected by HAS to carry out the work. Partnerships are covered by a contract. Organisations may also submit reports to HAS before publication for formal approval of the quality of the work on which the report is based.

- proposes to the HAS Board topics for the work programme and prioritises them [...].
- carries out the work programme validated by the HAS Board. The Committee advises on the scope of the studies, their consistency with HAS' work and their progress. All commissioned studies are reviewed in this way before work begins.

■ The Committee for Accreditation of Healthcare Organisations

Chair: Jean-Paul Guérin

- establishes the accreditation procedure and implements it in public and private HCOs;
- establishes and implements the procedure for certifying the practice of doctors or medical teams within a single specialty in HCOs.

■ The Committee for Medical Information Quality and Dissemination

Chair: Étienne Caniard

- disseminates the reports produced by HAS (good practice guides, clinical practice guidelines, healthcare quality standards and clinical practice standards, information leaflets for patients, etc.) to healthcare professionals and the general public;
- provides information for professionals and the general public;
- introduces quality initiatives covering the medical information provided by medical sales representatives, prescription software, and health-related websites. These initiatives will be certified;
- promotes objective information on the use of health products to healthcare professionals (work previously carried out by FOPI⁷).

HAS Departments

HAS departments report to a Managing Director appointed by the Chair of the Board, after consultation with Board members. Alain Coulomb was appointed on 23 December 2004 during the first meeting of the Board. He has authority over staff and carries out the functions of Chief Executive with regard to application of labour law. The Managing Director prepares and implements the Board's decisions with the Division Directors.

The departments under his authority consist of a general secretariat, four divisions, and operational departments that have been reorganised to improve efficiency (see organisational chart on next page)⁸. As at 31 December 2005, HAS had 342 permanent staff and over 40 on fixed-term contracts:

- 254 from ANAES⁹
- 64 from AFSSAPS¹⁰ (Transparency Committee, CEPP¹¹, FOPI)
- 24 posts created, by a decision taken in 2005, to carry out HAS' new missions.
- a further 24 posts were created in the 2006 draft budget to meet the scheduled workload (8 posts) and to undertake new strategic activities (16 posts, which will be filled as these activities come onstream).

HAS also has a national network of about 3 000 experts who can be called on as required (surveyors, facilitators for the CPD in CQI scheme, technical advisors, report authors, working group members, etc).

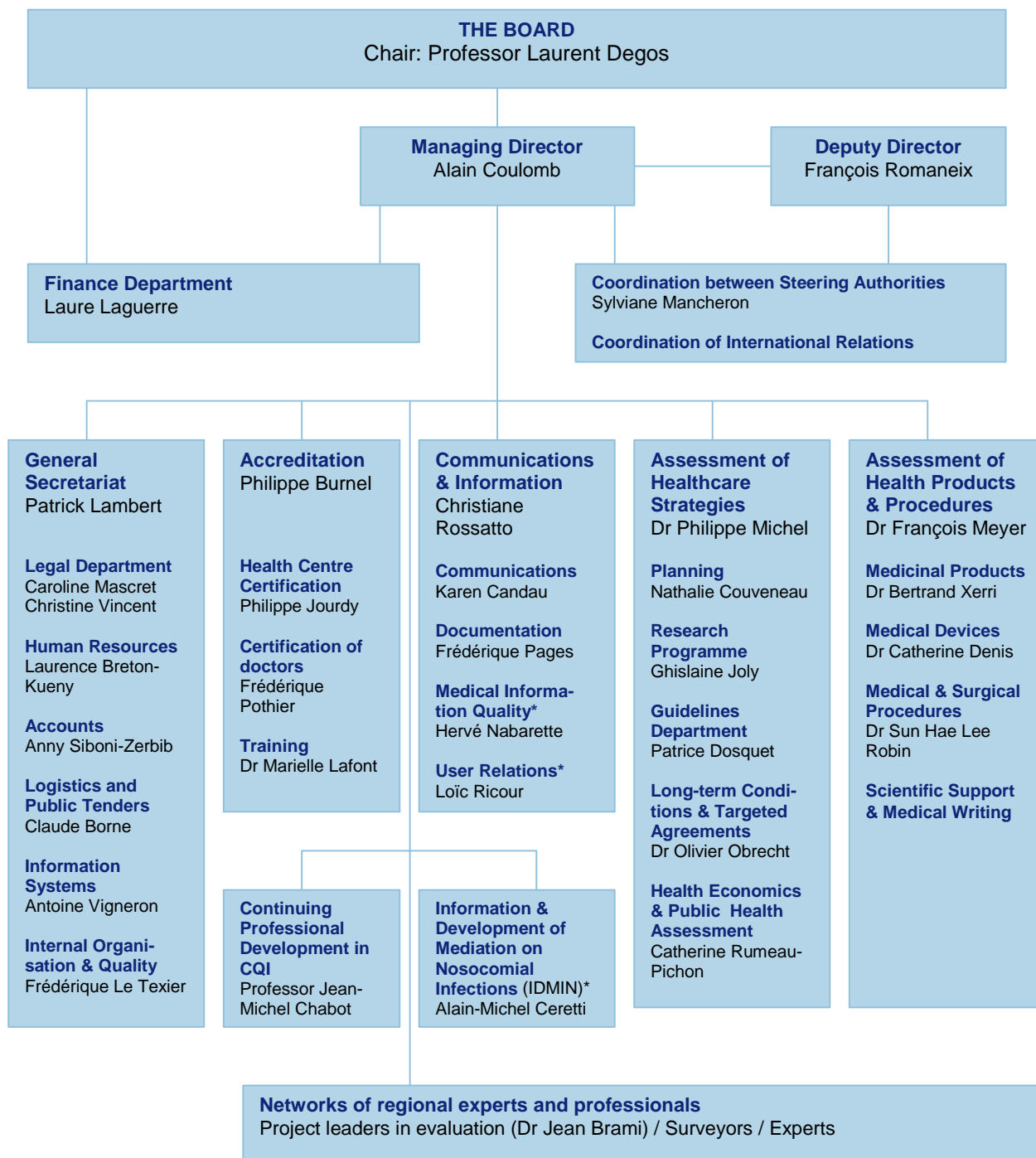
⁷ FOPI: Fund for the Promotion of Medical and Health Economics Information

⁸ Proposed by the Managing Director, adopted by the Board on 9 February 2005 and modified on 16 November 2005 and 1 February 2006. Department bylaws were approved by the Board on 21 January 2005 and modified on 3 May 2006.

⁹ ANAES: French National Agency for Accreditation and Evaluation in Healthcare

¹⁰ AFSSAPS: Agency for the Safety of Healthcare Products

¹¹ CEPP: Committee for Assessment of Devices and Health Technologies



* created in 2006

Assessing reimbursable healthcare procedures and products

Medicinal products, medical devices, procedures and health technologies are generally assessed against common criteria:

- **Actual benefit (AB¹²) – or Expected benefit (EB¹³) for a first assessment – looks at**
 - the severity of the disorder in question,
 - the performance of the procedure or product being assessed (level of efficacy relative to side effects),
 - the benefit of the product to public health, i.e. its impact on the population's health and on the organisation of care. The Committees' opinions indicate whether the clinical benefit is sufficient or insufficient to justify inclusion on the list of products or procedures to be reimbursed.
- **Improvement in actual benefit (IAB) is a measure of the added value provided by the treatment (or prevention, or diagnosis, etc.) when it is compared with existing methods (i.e. of its relative effectiveness). There are 4 levels of added value, from I (major improvement) to IV (minor improvement). Level V represents no improvement.**
- **Actual benefit and improvement in actual benefit are allocated for each indication.**

Assessment of medicinal products

Medicinal products are assessed by the Medicines Assessment Department and by the Transparency Committee (TC), assisted by a working group which addresses the products' impact on public health. In 2005, the Committee:

- examined dossiers submitted for inclusion, renewal of inclusion or modification of the conditions for inclusion on the list of reimbursable drugs;
- reassessed the actual benefit of drugs whose benefit was considered insufficient.

Examination of dossiers submitted

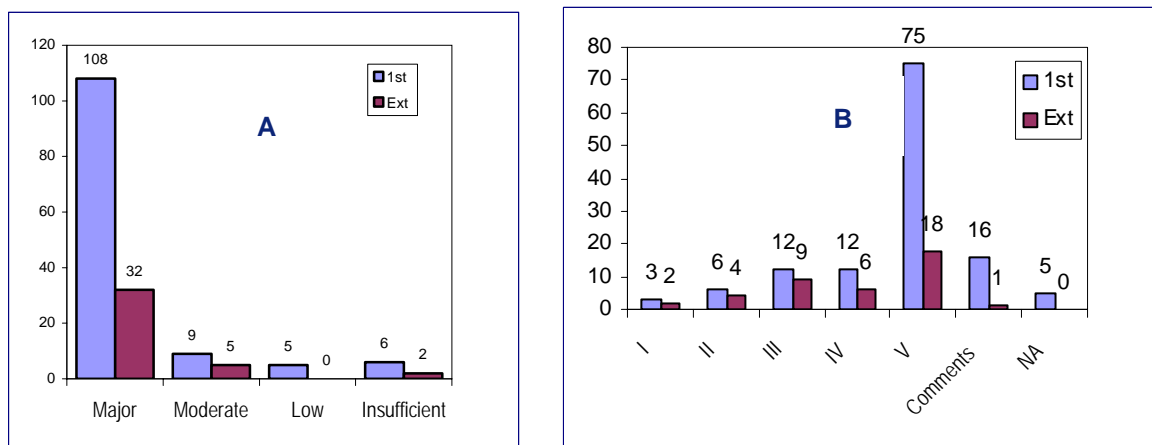
A total of 920 dossiers for inclusion, renewal of inclusion or modification of the conditions for inclusion on the list of reimbursable drugs were received in 2005 (+ 33% compared with 2004). A single dossier could include several applications.

Activity in 2005	Compared with 2004	TOTAL	First listing	Extension of indications	Renewal of listing	Sundry applications
Dossiers examined	+ 33%	692	261	47	193	191
Opinions delivered	+ 30%	622	253	37	167	165

¹² AB: SMR in French (*Service médical rendu*)

¹³ EB: SMA in French (*Service médical attendu*)

The opinions delivered by the Transparency Commission are shown in the histograms.



(A) ABs allocated in 2005; (B) IABs allocated in 2005

1st: application for a first listing; Ext: extension of the indications; NA: not applicable or unknown
(For further explanations, see introduction to this chapter)

Reassessment of medicinal products with insufficient AB

In 2005, HAS reassessed medicinal products subject to optional doctor's prescription ("*prescription médicale facultative*", *PMF*) whose AB had previously been judged to be insufficient. The main categories examined were vein tonics, expectorants/mucolytics and plant-based sedatives. Overall, 255 opinions were delivered, 231 of which confirmed insufficient AB.

Other opinions

At the request of the Minister of Health and Solidarity, the TC gave its opinion on the listing of packs designed for courses of treatment lasting between 1 and 3 months. The TC also recommended 30-day rather than 28-day packs.

A total of 95 opinions were delivered on medicinal products to be included on the list of products that can be prescribed by hospital pharmacies for outpatients.

Public health impact of medicinal products and post-listing studies

In 2005, the Committee's opinions included requests for post-listing studies of 24 medicinal products from 19 companies. Request concerned conditions of drug prescription and use, the benefit to patients in real-life situations (71% of requests), side effects (62%) and the impact on the healthcare system (12%).

The Committee's "Public health benefit (PHB)" working group met 11 times, to:

- assess PHB of 24 medicinal products for 26 indications. The opinions were: no PHB in 16 cases; low PHB in 8 cases; moderate PHB in 1 case, substantial PHB in none. The group could not come to a decision on one indication;
- approve 83 PHB proposals for 74 medicinal products drafted by the Scientific Support and Medical Writing Department: no PHB in 56 cases, low PHB in 25; moderate PHB in 2 cases; substantial PHB in none;
- assess protocols submitted for post-listing studies of 43 medicinal products, in response to requests made either by the TC (71%) or by the CEPS¹⁴ between 2000 and 2005.

¹⁴ CEPS: Committee for Pricing and Reimbursement of Healthcare Products

Assessment of medical devices

Medical devices may be included on the reimbursement list under the brand name of each individual device. Alternatively, they may be listed under a generic description which specifies the technical characteristics that devices must satisfy and for which reimbursable indications have been established. Devices satisfying these characteristics may then be listed for reimbursement by manufacturers, under the generic description.

In both cases, medical devices are assessed by the department and by CEPP¹⁵. CEPP:

- examines dossiers applying for listing, renewal of listing or modification of the conditions for listing of medical devices;
- sets up and leads working groups that will (i) refine a point of methodology; (ii) define indications and revise the nomenclature when reviewing generic descriptions specified by Decree no. 2004-1419, or (iii) respond to either an external or internal request. A category of devices is assessed under (i) and (ii).

CEPP met 18 times in 2005 and called on external rapporteurs 140 times.

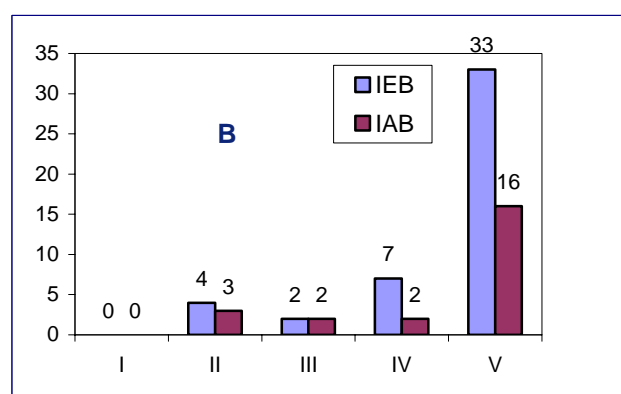
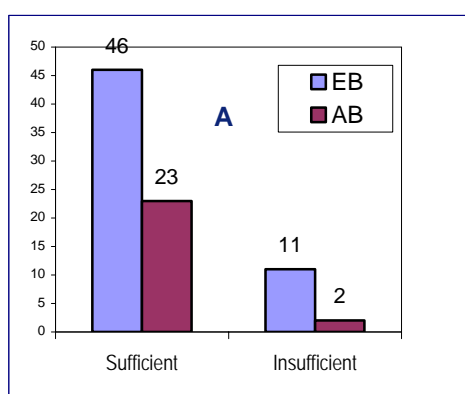
Examination of dossiers submitted

A total of 113 dossiers (applications for listing, renewal of listing, or modification of listing conditions) were registered in 2005 (136 in 2004)

Activity in 2005	TOTAL	Listing			Note
		First	Modification	Renewal	
Dossiers examined	106	67	13	21	In 18 meetings
Dossiers closed*	85	62	18	5	3 dossiers (first listing) were subsequently withdrawn by the manufacturer

* Dossiers closed in 2005 were dossiers registered at the end of 2004 and during 2005

For a first listing, the expected benefit (EB) and improvement in expected benefit (IEB) were assessed. For renewal of listing, actual benefit (AB) and improvement in actual benefit (IAB) were assessed (see histograms).



(A) EBs/ABs allocated in 2005; (B) IEBs/IABs allocated in 2005

EB: expected benefit (listing and modification of listing); AB: actual benefit (renewal of listing)

IEB = improvement in expected benefit; IAB = improvement in actual benefit.

¹⁵ CEPP: Committee for Assessment of Devices and Health Technologies

Report of the working groups

■ Generic descriptions

All generic descriptions are to be revised over the next 10 years (7-10 categories of devices per year). This involves reviewing the indications for all devices in the same category, determining technical characteristics and establishing assessment criteria by device category.

Work began in 2005 for 7 generic descriptions to be reviewed in 2005/2006 (medical devices for self-treatment and self-monitoring, hearing aids, artificial hip joints, eye and facial prostheses, compression bandages and garments, dressings, and mesh patches especially for incisional hernia repair).

■ Responses to internal and external requests

The overall schedule completion rate was 43%.

- 3 working groups dealt with methodology: producing a manufacturer's guide for generic lines (work completed), a document on CEPP's procedures for assessing medical devices, and a guide for manufacturers (work started in 2005);
- 5 groups delivered their conclusions in 2005 on the harmonisation of the opinions delivered by CEPP and CEAP¹⁶ for the following devices: NewFill (product for restoration of facial fat loss in HIV-related lipoatrophy), Activa (neurostimulation in Parkinson's disease), hyaluronic acid in the treatment of osteoarthritis of the knee, coronary stents and cardiac pacing leads.
- 5 groups are addressing aerosol nebulisation systems in chest and ENT medicine, intraocular implant lenses, oral and enteral nutrition, gastric bands and shock-absorbing foot prostheses.

Assessment of diagnostic and therapeutic procedures, and health technologies

The work of assessing medical and surgical procedures and health technologies was carried out by the relevant Department and CEAP, in cooperation with the Department for Long-Term Conditions (ALD) and Targeted Agreements (AcBUS), and with the Department for Health Economics and Public Health Assessment. The CEAP met 9 times in 2005.

Diagnostic and therapeutic procedures

■ Delivery of a formal opinion on changes in benefit lists and tariffs

HAS delivers a formal opinion on any proposed change in benefit lists without delaying the scheduled implementation of these changes by professionals. HAS issued

- 2 global opinions when the *Nomenclature générale des actes professionnels* (NGAP) switched to the *Classification commune des actes médicaux* (CCAM) version 1, and then from CCAM version 1 to CCAM version 2.
- 10 opinions on changes of tariffs in benefit lists.

¹⁶ CEAP: Committee for Assessment of Medical and Surgical Procedures

■ Assessment of the expected benefit of diagnostic and therapeutic procedures

- 54 opinions issued by HAS in 2005, 51 of them with sufficient expected benefit (EB). The improvement in EB for these 51 opinions was substantial in 7 cases, moderate in 5, minor in 9, none in 1, and unknown in 29. The improvement in EB was not assessed for 2 cases of undetermined EB and 1 case of insufficient EB;
- 60% of the work on 72 ongoing assessments of procedures has been completed.

Health technologies

Ongoing work on 21 projects from the former Health Technology Assessment Department of ANAES¹⁷ was pursued jointly by 3 HAS departments (Long-Term Conditions (ALD) and Targeted Agreements (AcBUS), Assessment of Medical and Surgical Procedures, Health Economics and Public Health Assessment).

■ 10 projects have been completed

- Guidelines on monitoring of - and safety devices for - cardiopulmonary bypass during heart surgery
- Assessment of autologous chondrocyte transplantation in the knee (progress report)
- Laparoscopy in colorectal cancer surgery
- Value of measuring FSH and LH levels in women aged 45 years and over
- Procedures for prescribing physiotherapy for common low back pain
- Indications and contraindications for general anaesthesia for everyday procedures in dentistry and stomatology
- Assessment of and status report on PET/CT scanning
- Indications for the specific IgE test for the diagnosis and monitoring of allergies
- Preliminary considerations on using psychotherapy to treat depression in adults
- Practice guidelines for diagnosing autism.

■ 11 projects are ongoing; 31% of the work has been completed.

Other projects

■ HAS representation on the Committee for Negotiating Procedure and Service Prices¹⁸

A representative from the Assessment of Medical and Surgical Procedures Department has attended meetings of this committee which is responsible for developing the CCAM¹⁹. The Committee comprises equal numbers of representatives from NHI and professional unions.

HAS' presence [...] has made it possible to anticipate requests for assessment from NHI and/or professionals, to monitor use of HAS' opinions and to provide any required clarification on these opinions.

¹⁷ ANAES: French National Agency for Accreditation and Evaluation in Healthcare

¹⁸ *Commission de hiérarchisation des actes et prestations*

¹⁹ CCAM: *Classification Commune des Actes Médicaux*

■ Agreement between HAS and UNCAM²⁰ on conditional coverage for new diagnostic and therapeutic procedures

The medical and scientific section of the general framework for future agreements has been drafted in partnership with NHI.

■ Horizon scanning

A state-of-the-art report that includes a review of the scientific literature has been produced, with a view to HAS' introduction of horizon scanning. A working method has been devised and should enable HAS to satisfy its horizon scanning needs and those of its professional and institutional partners as from 2006.

■ Participation in the European network for health technology assessment (EUNetHTA)

HAS is taking part in the development of the EUNetHTA project and its submission to the European Commission (DG-SANCO). HAS is leading the work-package on the monitoring of new and emerging technologies.

■ Exchanges with the NICE Interventional Procedures Advisory Committee

HAS exchanged experience and compared methods with this Committee which has missions similar to those of CEAP²¹, i.e. assessing novel interventional and invasive procedures before they are introduced into the British healthcare system.

List of long-term conditions (ALD) and range of goods and services that may be reimbursed

The Long-Term Conditions (ALD) and Targeted Agreements (AcBUS) Department was set up in 2005 at the same time as HAS. The department has 2 distinct missions:

- delivering opinions related to AcBUS targeted agreements in continuation of the work of ANAES²²
- a new mission relative to long-term conditions (ALD).²³

The Department began its review of the 30 listed ALDs. This review is expected to take 3 years. It review includes producing ALD guides for doctors and lists of procedures and services required on which new care protocols for individuals accepted for full reimbursement under the ALD regimen will be based. The review also includes systematic reassessment of the medical criteria for acceptance into the ALD regimen. The topics dealt with in 2005 are listed on page 20.

A projection group made up of funding bodies (UNCAM and UNOCAM²⁴ in particular) has been set up to assess the impact of the proposed care pathways and to support the rewriting of the medical criteria used to define each ALD.

²⁰ UNCAM: Association of Sickness Funds (National Health Insurance)

²¹ CEAP: Committee for Assessment of Medical and Surgical Procedures

²² ANAES: French National Agency for Accreditation and Evaluation in Healthcare

²³ Law of 13 August 2004 dealing with the care pathway and the patient's own doctor,

²⁴ UNCAM-UNOCAM: association of copayment health insurance funds

The Department also worked on two other topics in 2005:

■ Rare diseases

As part of the work on the National Plan for Rare Diseases, HAS was asked to assess whether there should be a specific ALD for rare diseases. This work was carried out with the support of the Health Economics and Public Health Department. HAS rejected the idea, proposing instead ways of improving the management of rare diseases. In addition, HAS began planning work with approved reference centres for rare diseases on the drafting of national diagnosis and care protocols as from the first quarter of 2006.

■ Ambulance services

A draft standard for the ordering of ambulances by doctors was discussed by the **Committee for Healthcare Cover for Long-Term Conditions** (ALD) on 5 July 2005, in the presence of HAS, CNAMTS²⁵ and the Social Security Directorate (DSS). This is a preliminary stage to revising the legislation governing the ordering of ambulance transport, which is currently in progress.

Opinions on targeted agreements (AcBUS)

The second mission of the Long-Term Conditions and Targeted Agreements Department is to issue opinions concerning targeted agreements on the proper use of care (AcBUS), public health contracts and good practice contracts. Three opinions were issued in 2005:

- conditional approval of the AcBUS agreement relating to total number of colonoscopies during follow-up of patients who have undergone polypectomy;
- conditional approval of the AcBUS agreement on the use of acetylsalicylic acid as a platelet antiaggregant;
- approval of a good practice contract relating to the provision of ambulance transport, ISO 9001: 2000 certification.

²⁵ CNAMTS: National Health Insurance fund for salaried workers

Assessing healthcare strategies

The work of the Public Health Programmes and Disease Management Division is to develop and publish assessments and guidelines intended for health professionals, patients and the public authorities, as aids to decision-making. The work involves establishing the state-of-the-art for diagnostic, treatment, prevention and follow-up strategies in order to define best practice and improve the quality of patient care.

Clinical practice guidelines

In 2005, the Guidelines Department further developed the work of producing clinical guidelines and methodology guides, formerly carried out within ANAES²⁶. Clinical guidelines are developed using one of four methods: the clinical practice guidelines method, consensus conference, formal consensus and public hearing. A Quick Reference Guide (QRG) was produced for most guidelines. QRGs are published separately and are intended to help professionals adopt the guidelines.

Work produced in 2005 is listed on the following page.

Methods used to produce guidelines

The **clinical practice guidelines method** is used for the broadest topics, and combines a systematic review of the literature with expert opinion. This is the most commonly used method.

Consensus conferences are designed to produce guidelines on a controversial healthcare problem by establishing a consensus position after a public interdisciplinary debate. It is generally used for a limited topic that can be broken down into 4-6 specific questions.

The **formal consensus method** is less widely known; it is used to build consensus among experts when there are no data of a high level of evidence.

Public hearings bring together experts, health professionals and users to discuss issues affecting public health or society. The proceedings form the basis of a current status report, which first establishes the current state-of-the-art, and then proposes public health strategies, guidelines, etc.

In 2005, the development of clinical guidelines involved 2012 health professionals currently in practice. Of these, 1606 helped to develop guidelines using the clinical practice guidelines or formal consensus methods, 406 helped to develop guidelines based on consensus conferences or public hearings.

²⁶ ANAES: French National Agency for Accreditation and Evaluation in Healthcare

Clinical practice guidelines
Prevention of peripheral venous catheter-related infection Haemorrhage in the immediate postpartum Improving information provision for pregnant women - guidelines for health professionals Physiotherapy in preserving motor function in frail elderly people living at home Emergency involuntary commitment of a mentally disordered person Management of essential hypertension in adults (2005 update) Foot problems in the elderly: podiatric assessment and management Management of chronic painful shoulder without instability in adults Management of sickle cell anaemia in children and adolescents Summary report on screening and diagnosis of gestational diabetes Proposals for individual screening of children between 28 days and 6 years, for general practitioners, paediatricians, mother and child centre doctors and school doctors* Proposals concerning individual screening in children aged 7–18 years, for general practitioners, paediatricians and school doctors* Preparation for birth and parenthood* Assessment of caries risk and indications for the use of fissure sealants on first and second permanent molars* Preventing and managing postoperative pain after oral surgery* Choice of treatment for rectal cancer*
Consensus conferences
Discharge from hospital and return home of an adult with motor or mental deficit developing into dependence Doctors attending detainees in police custody Freedom of movement in healthcare organisations and nursing homes and the obligation to provide care and security Indications for liver transplantation Management of individuals with amyotrophic lateral sclerosis*
Formal consensus
Management of patients with <i>HFE</i> -related haemochromatosis.
Public hearing (2005)
Management of psychopathic disorders in adults and adolescents*

* will be published in 2006.

■ International work

The Guidelines Department is an active participant in the Guidelines International Network (GIN) and helped to organise GIN's annual conference in Lyon in December 2005. GIN is an international not-for-profit association of leading guidelines specialists. Within the GIN framework, HAS has started work on "evidence tables" designed to present literature review results in a standardised summary format. Cooperation with GIN will lead to the publication of a methodology guide for adapting foreign guidelines to the French healthcare system.

Methodology guides

Two methodology guides were published by the Guidelines Department in 2005:

- a written information document for patients and healthcare system users
- a general methodology guide to producing treatment protocols for conditions not covered by GHS²⁷ protocols (in collaboration with AFSSAPS²⁸ and INCa²⁹).

Doctors' guides to managing long-term conditions (ALD)

In 2005, HAS produced guides for doctors - and lists of reimbursable procedures and services - in collaboration with professional societies, leading experts, institutional stakeholders and users' representatives according to the following procedure:

Production of guides and lists
<ul style="list-style-type: none">• 7 working groups (31 specialists and 22 GPs nominated by professional societies)• Expectations of 21 patients' associations
Test of first 4 guides
<ul style="list-style-type: none">• 4 professional bodies for general practice (240 practising GPs – 60 per guide)• Medical advisers for the 3 national health insurance funds• Patients' associations and CISS*
Validation - Committee for Healthcare Cover for Long-Term Conditions (ALD)
<ul style="list-style-type: none">• GPs and specialists, allied professionals, economists, users' representatives (CISS*), medical advisers for the health insurance funds CNAMTS**, MSA***, RSI-AMPI****

* CISS: Federation of health system users; **CNAMTS: NHI fund for salaried workers; ***MSA: National health Insurance Fund for agricultural workers; ****RSI-AMPI: NHI schemes for self-employed workers

The 10 guides for doctors of the 2005/2006 programme were started on 31 December 2005:

- 3 guides were submitted to the ALD Committee: type 1 and type 2 diabetes (ALD 8); severe hypertension (ALD 12); and chronic viral hepatitis C (ALD 6).
- Technical work on a further 4 guides was completed: chronic hepatitis B (ALD 6); asthma, chronic obstructive pulmonary disease and sleep apnoea (ALD 14); chronic peripheral arterial occlusive disease (ALD 3); and coronary disease (ALD 13).
- 3 guides are in the pre-test stage: severe heart failure (ALD 5); multiple sclerosis (ALD 25); incapacitating stroke (ALD 1).

All the guides for doctors and lists of procedures and services of the 2005/2006 work programme will be completed in 2006.

²⁷ GHS: homogeneous hospital stay groups - part of the T2A scheme

²⁸ AFSSAPS: the French agency for healthcare product safety

²⁹ INCa: French national cancer institute

Health economics and public health assessments

The Health Economics and Public Health Assessment Department assesses public health actions and programmes and the economic aspects of topics included in the work programme of other HAS departments [...].

Health economics

In 2005, the Department focused on four aspects of economic assessment:

- aid to public and professional decision-making on dissemination of a new technology;
- aid to professional decision-making (economic aspects of clinical practice guidelines);
- assessment of new types of care organisations, including shared care networks;
- aid to public decision-making while comparing different strategies with major economic and organisational implications, such as screening campaigns.

In particular, the Department

- contributed to the report on drugs with insufficient actual benefit³⁰ by carrying out international comparisons and analysing the consequences of introducing a lower level of reimbursement. This work emphasised the need for HAS' recommendations to be based on criteria that include an economic dimension and implications for social justice.
- produced a report on the "Comparative analysis of chemotherapy administered in hospital or managed at home: economic and organisational aspects".
- answered many unscheduled requests from HAS departments (see table). Economic and/or organisational issues often only become apparent when questions are put by the working group responsible for the clinical aspects of a topic

HAS Department making request	Study
Assessment of drugs	Assessment of drugs with insufficient actual benefit
Health Technology Assessments	Assessment of PET/CT
	Perioperative autologous transfusion
	Assessment of IVF micromanipulation procedures
	Endovascular stent-grafts for thoracic aorta aneurysm
Guidelines Department	Indications for the use of fissure sealants on first and second permanent molars
	Management of chronic venous leg ulcers
	Discharge from hospital and return home of an adult with motor or mental deficit developing into dependence*
	Insomnia (joint CPG)
Long-term Conditions and Targeted Agreements Department	Opinion on whether a specific ALD should be created for "rare diseases"

* First consensus conference held at the initiative of a health economics professional society

³⁰ Opinion issued by HAS in September 2005

Work currently in progress includes the economic and/or organisational arms of the following topics included in the 2005 work programme:

- induction of labour (CPG³¹) (incl. non-medical indications for induction of labour)
- place of non-invasive methods for staging hepatic fibrosis (HTA³²) (incl. a cost benefit analysis of FibroScan and FibroTest)
- treatments for cirrhosis
- treatments for urinary incontinence in women (HTA)
- management of chronic depression (CPG) (i.e. epidemiological aspects, health costs of the disease, treatment costs)
- management of early rheumatoid arthritis (CPG) (incl. economic benefit of early treatment)
- structured patient education (CPG)
- sedation and analgesia by doctors who are not anaesthetists (CPG)
- good practice guidelines in foetal disease (CPG) (incl. survey of the organisation of care, coding and fees)
- angioplasty (HTA).

Public Health Assessments

The Health Economics and Public Health Assessment Department also contributes to public decision-making concerning public health programmes and actions. In particular, it carries out assessments of screening programmes (medical, economic and organisational aspects).

All the assessments of the 2005/2006 programme have been begun:

- role of digital mammography in the national breast cancer screening programme
- trisomy 21 screening strategies
- national screening programme for cystic fibrosis
- screening strategies for syphilis
- practical aspects of screening for glaucoma (preliminary report)
- melanoma
- deafness.

A methodology guide for retrospective assessment of screening programmes and a report on the theoretical aspects of assessing organisational issues are also in preparation.

In addition, the Department continued to actively disseminate the self-assessment guide for shared care networks, published in September 2004.

³¹ Clinical Practice Guideline

³² Health Technology Assessment

Improving the quality of structures, resources and practice

Accreditation of healthcare organisations

A few reminders and definitions

Accreditation aims to improve the quality of care provided by healthcare organisations and to provide the general public with information about the quality of services that they deliver.

There are 3 stages in an Accreditation procedure:

- (i) self-assessment by the HCO, which assesses its practice against standards provided by HAS (the Accreditation Manual). HCOs can thus identify any improvement actions that may be needed to comply with HAS' expectations;
- (ii) a survey by HAS surveyors to assess the HCO and its practice against the HAS standards and to judge the effectiveness of the improvement strategies implemented to correct any non-conformities;
- (iii) a report containing HAS' decisions on the level of accreditation awarded to the HCO. This level varies according to the severity of nonconformities identified during the survey and depends on the effectiveness of corrective actions begun or implemented by the HCO.

The HCO Accreditation Committee was set up on 16 March 2005 [...]. It has focussed on monitoring the launch of version 2 of the accreditation procedure and on professional practice appraisal initiatives in HCOs. It has begun to examine the development of indicators and their use both in quality improvement initiatives and in providing information for the public (to be pursued in 2006).

[...] the "Dossier Review subcommittee" met to examine accreditation dossiers (41 times to consider initial decisions and 5 times to consider appeals), to validate experts' reports and decide on the level of accreditation and on the wording of decisions. The time taken to examine accreditation reports fell to 160 days at the end of 2005 (date of sending of the report minus date of visit).

Work carried out

646 HCOs had their first accreditation survey (version 1) in 2005, bringing the total number of HCOs that have completed the procedure to 2557 at the end of 2005 (86% of HCOs). All HCOs will have undergone the procedure by the end of 2006. Considering the time needed to produce reports, examine decisions and deal with any appeals by HCOs, the mean time from survey to closing of the accreditation procedure (by uploading the accreditation report) was 6 months. At 31 December 2005, 2156 accreditation reports were available on the HAS website.

97 HCOs had their second accreditation survey (version 2) between April and December 2005.

HAS has trained nearly 800 surveyors. In 2005, 332 surveyors were trained in version 2. In addition, 271 surveyors received further training during the year.

Qualitative analysis of accreditation results

Results for accreditation version 1

There are 4 accreditation decision levels which depend on the severity of nonconformities identified and on how well HCOs are dealing with them. Results at the end of December 2005 were as follows:

- without recommendations: 12% of HCOs
- with recommendations: 61% of HCOs
- with reservations: 25% of HCOs
- with major reservations: 2% of HCOs.

27% of dossiers involving one or more reservations (or major reservations) required follow-up:

- 60% of HCOs had to produce a report by a deadline decided by the HAS Board and to report on improvements made to the process or processes which gave rise to the reservations,
- 40% of HCOs underwent a targeted survey to check on progress.

The follow-up procedure was effective since 85% of reservations were lifted by the Board after they had seen the report or the result of the targeted survey.

Results for accreditation version 2

Because relatively few version 2 surveys (n=97) have been carried out since their inception in April 2005, results are not yet significant. They have nevertheless provided useful new information beyond that observed in the first round.

The following data refer to the first 50 HCOs to have completed the version 2 accreditation procedure. These HCOs are not entirely representative. Private clinics are over-represented (52% compared with 42% of HCOs subject to accreditation) because they were the first to enrol in the first round and are therefore the first to take part in the second.

■ Decisions taken so far

Results for version 2 of the accreditation procedure differ from those for version 1 but may yet change. 42% of dossiers led to Ordinary Accreditation (similar to Accreditation with or without recommendations in the first version) compared with 74% for version 1; 12% to conditional Accreditation and 46% to Accreditation with follow-up. These results derive from more rigorous observations by surveyors who recorded how well the HCO meets the requirements for each individual criterion of the Accreditation Manual (as in an audit), whereas previously they just checked that continuous quality improvement (CQI) initiatives were in place. In version 2 involvement in CQI is judged when HAS Board decides on Accreditation level on the basis of the actions undertaken by HCOs to remedy any nonconformities identified by the surveyors.

■ Follow-up of improvement actions

During their follow-up visit, surveyors can assess the outcomes of improvement actions implemented by HCOs in response to nonconformities identified during their first visit. Of the 290 decisions notified to the 50 HCOs surveyed:

- 228 (78.6%) were not renewed during the follow-up visit, indicating that the HCOs had made improvements in the areas concerned;
- 62 decisions were renewed on the same topic to 29 HCOs, indicating that they had not carried out the recommended measures.

However, analysis showed that a number of problems could hinder the implementation of recommendations. These depended on the activity concerned. Some activities (e.g. monitoring and management of risk related to medical devices) were easier to improve (100% of nonconformities

corrected) than others (e.g. management of patient records or the drug circuit, with approximately 60% of HCOs having sufficiently improved their operation) (see table).

Percentage of non-conformities corrected at follow-up visit

Non-conformity	%	Non-conformity	%
Environmental risks	55	Policy on quality	79
Management of patient records	64	Human resources	81
Organisation of patient dossier	65	Strategic orientations	82
Logistics	67	Infection-related risk	91
Patient rights	67	Vigilance systems	100
Benefit-risk considerations	71	Risks related to medical devices	100

A look at practice appraisal in the accreditation procedure

In order to increase the involvement of medical teams and care staff in CQI initiatives, HAS included practice appraisal requirements in version 2 of the accreditation manual (standards 44, 45 and 46). Analysis of the first 97 dossiers has identified 1 015 concrete actions to improve quality of practice.

Standard 46: Assessment of care

Percent improvement actions by topic per disease

Medicine	%	Psychiatry	%	Follow-on care and rehabilitation	%
Cancer	18	Suicide	51	Pain	18
Coronary disease	16	Depression	10	Nutrition	11
Stroke	11	Schizophrenia	10	Stroke	9
Diabetes	11	Patient discharge	8	Pressure ulcers	9
Thromboembolism	4	Isolation	8	Hip replacement	5
Renal failure	4	Other	13	Other	48
Other	36				
Surgery	%	Obstetrics	%		
Cancer	16	Labour	38		
Antibiotic prophylaxis	13	Caesarean	15		
Hip replacement	10	Postpartum haemorrhage	12		
Carotid stenosis	4	Infection (mother/newborn)	6		
Pain	4	Other	29		
Fractures	3				
Arthroplasty	3				
Obesity	3				
Other	44				

Standard 45: Risk reduction

Main areas of risk reduction chosen by HCOs

Chosen in advance (Standard 45a)	%	Chosen retrospectively	%
Drugs circuit	13	Falls	24
Urinary catheterisation	10	Mortality and morbidity reviews	6
Restraint	8	Pressure ulcers	5
Use of isolation rooms	5	Restraint	5
Transfusion	5	Patient elopement	4
Indwelling central catheter	3	Violence	3
Chemotherapy	3	Wrong side	3
Drug-related iatrogenic risk	3	Suicide	2
Surgical site infection	3		

Standard 44: Assessment of appropriateness of drug prescriptions

Medical teams and carers are expected to assess the appropriateness of drug prescriptions under version 2 of the procedure (standard 44c.). To do this, 88% of HCOs carried out audits.

Drug classes whose appropriateness was assessed by HCOs

	%		%
Prophylactic antibiotics	34	Antineoplastics	4
Curative antibiotics	22	ACE inhibitors	2
Antithrombotics	10	Proton pump inhibitors	2
Antidepressants	6	Radiopharmaceuticals	2
Analgesics	6	All	2
Neuroleptics	4	None	4
Anti-dementia agents	2		

Training surveyors for the accreditation of HCOs

The 774 surveyors trained in the first version of the procedure (1998-2005) - and who are still active - need to be trained in the second version by the end of 2006. The training programme was drawn up at the beginning of 2005. Training began in March so that implementation could begin in May 2005. So far, 9 training sessions have been held and have trained 332 surveyors. Training focuses on the move from assessing involvement in CQI initiatives (version 1) to measuring the level of quality in the HCOs surveyed (version 2). A whole day is also devoted to examining and mastering the standards for continuous professional development (CPD) in CQI.

In addition, 271 experts attended continuing training sessions to improve their practice during surveys. Training covered quality issues, report writing and decision making, and survey methodology.

Workshops aimed at harmonising practice within the regions were attended by 170 coordinators.

Evaluation of health centres and of reference centres for rare diseases

The Medical Information Quality Department is carrying out two projects to establish assessment standards, one for health centres and the other for reference centres for managing rare diseases.

The health centres project has been developed at the request of and with the participation of the National Association of Health Centre Management Organisations. Its aim is to draft assessment standards and an internal quality procedure based on a self-assessment giving rise to a shared diagnosis within the centre. Three meetings of each of 4 working groups (medical, nursing, dental care and management) have been held to draft the standard and 2 meetings of the working group to draft the procedure. Review of the standard and procedure by health centre staff and external individuals begun in November 2005. Pilot-testing in 23 volunteer centres begun in December 2005.

HAS has drawn up assessment criteria for approved reference centres for rare diseases as part of the National Rare Diseases Plan and has proposed that the assessment procedure should be incorporated into the accreditation of HCOs. The working group met 3 times in 2005 to draft the standard. Review of the standard begun in November 2005.

Certification of doctors and medical teams

■ Background

Certification for doctors and medical teams³³ is a risk management tool intended to prevent undesirable events or limit their effects. The certification procedure stems from a project (ResiRisq) developed by independent doctors (anaesthetist/intensivists; gynaecologist/obstetricians; surgeons) in response to the rise in professional liability insurance premiums. Studies by the ResiRisq group carried out under the aegis of ANAES³⁴ between September 2003 and the end of 2004 showed that a measure for reducing risk related to medical practice could be implemented at a national level. A law was passed in 2004, applying to all specialties and medical activities classified as "at risk" in an HCO, irrespective of the type of practice involved.

HAS has been tasked with implementing this quality measure. During 2005, at the request of the Ministry, it helped to draft the decree applying the law and to design the procedure with other professionals. It set up a department for certification of doctors and hired a specialist risk management contractor. Working groups made up of representatives officially appointed by the specialties concerned (a total of more than 60 doctors, representing all specialties and all types of practice) met every week between September 2005 and January 2006 to establish a detailed procedure which was completed on 13 January 2006.

■ The certification procedure

Taking part in the procedure is voluntary. It is equivalent to participating in Continuous Professional Development (CPD). Doctors who enrol must:

- notify near misses encountered in their HCO;
- implement the individual recommendations resulting from analysis of near misses that they have declared, together with general risk management recommendations for their speciality derived from feedback analysis, risk studies and horizon scanning;
- participate in the programme to improve practice safety in their speciality.

Doctors can decide whether to notify near misses via the HCO's local risk management authority or via one of the bodies approved by HAS. These bodies will also:

³³ Introduced by article 16 of the law of 13 August 2004 on national health insurance

³⁴ ANAES: French National Agency for Accreditation and Evaluation in Healthcare

- manage the administrative side of the procedure (examining requests for certification and sending opinions on certification to HAS);
- providing risk management by specialty (collection and analysis of SEs, drafting standards and guidelines, and drafting the programme for improving clinical practice safety for the specialty).

Continuing Professional Development focusing on Continuous Quality Improvement

As well as defining CPD policy, which is based on the two key concepts of incorporating CPD into clinical practice and formative assessment³⁵, the CPD Department of HAS has four main tasks:

- Producing tools and methods for assessing and improving practice;
- Supporting the procedure for certifying the professional bodies responsible for offering doctors training programmes in the CPD scheme;
- Developing novel approaches for assessing the practice of doctors and other health professionals;
- Supporting HAS' network of regional assessment project leaders.

The Department also trains:

- peer facilitators (doctors) who will support health professionals in the CPD scheme,
- professional stakeholders (professional associations, universities, etc) in the use of the methods and tools of the CPD scheme.

Tools and methods for assessing and improving practice

The Practice Assessment Department offers doctors tools and methods for assessing and improving their practice. Since July 2005, 6 CQI methods have been made available for use by public or private HCOs (particularly in the context of version 2 of the accreditation procedure). In 2006, they will be completed with several other methods intended for ambulatory care.

CQI methods for HCOs (2005)	CQI methods for ambulatory care (2006)
<ul style="list-style-type: none"> • review of appropriateness of care • morbidity and mortality review • clinical pathway • statistical control of healthcare processes • clinical audit • targeted clinical audit. 	<ul style="list-style-type: none"> • peer review groups • shared care networks • interdisciplinary cooperation meetings in oncology • staff evidence-based medicine meetings • performance indicator monitoring

Certifying bodies offering CPD in CQI

The bodies certified by HAS offer doctors programmes for assessing and improving their practice. They are mostly made up of doctors and can call on facilitators trained by HAS.

The procedure for certifying professional bodies was launched in October 2005. Its 20 criteria were developed after an in-depth consultation with Medical Committees and Medical Conferences³⁶, CNFMC³⁷, the national council of the *Ordre des médecins*³⁸ and URML³⁹. Its aim is to ensure that each certified body is capable of:

³⁵ Formative assessment is traditionally distinguished from summative assessment; the former is a dynamic CQI process; the latter is an assessment of the situation at a given point in time.

³⁶ Decision-making authorities in public and private hospital facilities, respectively

³⁷ National councils for continuing medical education

³⁸ French Medical Association

³⁹ URML: regional associations of independent doctors

- using referenced sources from the medical literature;
- applying a policy of transparency and management of conflicts of interest;
- producing assessment and improvement programmes which are:
 - acceptable/feasible (i.e. easy to implement and inexpensive in terms of time and resources);
 - valid/effective (i.e. useful for implementing "good practice" and improving quality of care).

Developing innovative approaches to practice appraisal (3 examples)

■ Targeted clinical audit

From end 2004 to end 2005, HAS carried out a programme of targeted clinical audits (TCA) in which over 700 care teams took part.

The advantage of the targeted over the classical clinical audit is that it specifically targets a practice that is particularly important to a care unit, department or HCO and that it consists of a limited number of criteria.

A pilot test was set up in 230 HCOs (public and private HCOs, and HCOs in the public hospital service (PS PH)). The eight topics chosen were public health priorities: implantation and monitoring of implantable chambers; preparation for patient discharge; antibiotic prophylaxis in elective surgery; implantation and monitoring of urinary catheters; hospital management of people attempting suicide; management of pain in the elderly; physical restraint of the elderly; assessment of labour and monitoring of delivery through completing a partogram.

The two main goals of the pilot test were to demonstrate:

- the acceptability and feasibility of TCA. This goal was achieved. 700 teams carried out both rounds of the assessment within the scheduled 6 months and sent their data to HAS for analysis.
- the validity and efficacy of the TCA programme. This goal was also achieved. A large number of improvement actions were implemented. In addition, about 70% of the care teams are continuing to perform TCAs on further topics and/or with different tools.

■ Visit from someone simulating disease

During the second quarter of 2005, the CPD Department, together with UFCV⁴⁰, an association of independent cardiologists, introduced a programme in which "patients" pretended to be ill. The patient reported what the doctor did or did not do. About 50 cardiologists in the Ile-de-France region took part in this programme, funded by the FAQSV⁴¹. It proved to be effective and very well accepted.

■ Preventing iatrogenic medicine-related problems in the elderly

The CPD Department developed a programme for preventing iatrogenic drug-related problems in the elderly jointly with CPGF (French college of geriatricians). The programme will be implemented in many long-stay HCOs in several French regions (particularly in Alsace, thanks to a partnership with the regional doctors' association).

Running the network of CPD leaders in the regions

In September 2005, HAS created a network of 35 CPD leaders (*CMRE*), all health professionals, across France. Their role is to facilitate the implementation of CPD (with a focus on CQI) in the 26 French regions. They instigate, support and disseminate assessment programmes, and are the

⁴⁰ UFCV: National association for continuing training in cardiovascular medicine

⁴¹ National fund for improving the quality of community healthcare

contact persons for the regional institutions responsible for CPD⁴² and health insurance funds for all questions concerning CPD. Between September and December 2005, these professionals presented their missions these institutions. They also helped to train doctors as facilitators (peer facilitators – PF).

Training of peer facilitators

Peer facilitators (PF) assist a doctor during appraisal, encourage them to develop a practice improvement plan and help them implement it. They are tasked by the certified bodies and encourage the development of CPD in CQI in the regions. At the request of the regional associations of independent doctors, they may also carry out annual monitoring of the quality of appraisal proposed by the certified bodies.

A number of initial and continuing training actions were carried out in 2005:

- Initial training: 17 seminars were carried out, training 351 PFs. There were 780 PFs at the end of 2005. Training will continue in 2006, to reach a goal of about 925 PFs, so that each region will have PFs who can be mobilised by the regional associations of independent doctors.
- Continuing training has been introduced to update the knowledge of the first PFs trained and will be pursued in 2006.

These training programmes have been approved by an Educational Committee made up of representatives from the regional associations of independent doctors, Medical Committees in private HCOs, the national council of the French medical association, HAS and the CNFMC⁴³ for independent doctors. This Educational Committee has been extended to other types of Medical Committee and CNFMC to encourage standardisation of the measures applicable to independent and salaried doctors.

Other training actions

- A partnership with the CNGE⁴⁴ for training staff in the teaching of quality issues.
- Joint working group with universities on the inclusion of a module on quality in the medical curriculum. A seminar for universities is scheduled for 2006.
- Supporting the French Dental Association (ADF) in CPD in CQI and an agreement between HAS/ADF for testing CPD for dentists, including training peer facilitators at the end of 2006. A pilot test will be carried out during 2006/2007.
- Designing 2 educational CD-ROMs, one on CPD in community practice, the other on CPD in HCOs.
- Working groups with the FIF/PL⁴⁵: raising awareness about CPD and proposed joint actions with physiotherapists (training and actions), midwives (designing a clinical pathway for breastfeeding), and podiatrists.

⁴² Regional associations of independent doctors, Medical Committees and Medical Conferences, the French Medical Association, Faculties of Medicine

⁴³ CNFMC: National Council for Continuing Medical Education:

⁴⁴ National College of teaching general practitioners

⁴⁵ FIF/PL: Interprofessional training organisation for professionals working outside hospital practice

Informing health professionals and the general public

The *Haute Autorité de Santé* has the mission of informing health professionals and the general public about good practice⁴⁶. It is responsible for three certification missions for improving the quality of the medical information delivered via channels such as health-related websites, prescription software and visits by medical sales representatives.

Making HAS known to a wider public

HAS started work on 1 January 2005. Several initiatives aimed at publicising the organisation and its missions were undertaken: a leaflet presenting the new organisation, press relations, a stronger presence at exhibitions and professional conferences and, as early as January 2005, a HAS website.

■ Design and dissemination of a presentation leaflet

The leaflet contained a succinct presentation of HAS, and was published in February 2005. The format, concise style and simple language made for easy reading by health professionals, institutional decision makers and the general public.

■ Press relations reorganised and developed

9 press conferences were organised, beginning with the inaugural "Presenting the *Haute Autorité de Santé*" conference in January 2005. In the second half of 2005, a new approach based on bi-monthly press briefings presenting the results of HAS departments was adopted. Supplementary press conferences dealing with issues in the news were also organised.

■ Interviews and press releases

90 interviews were carried out in 2005. 75% of them were with HAS spokespersons: the Chair of the HAS Board, the Managing Director and members of the Board. 25 press releases were sent to more than 600 general and medical journalists.

■ More than 3 000 press articles

The HAS Documentation Department identified more than 3 000 press articles referring to HAS in 2005.

■ Strong presence at exhibitions and conferences

HAS attended a number of professional events in 2005 (MEDEC in March, the European regional medicine conference in September, a nursing exhibition in October etc). Workshops were organised on specific topics and relevant documents were distributed.

Members of the Board, HAS managers, department heads and HAS project managers made more than 200 speeches and presentations at congresses and conferences in France and abroad.

⁴⁶ Law of 13 August 2004

■ HAS website redesigned

There has been no break in service for web users. Documents produced by ANAES⁴⁷, the Transparency Committee and CEPP⁴⁸ have been available online since January 2005. Texts are archived on the HAS site, which has been redesigned with HAS graphics.

Materials produced by HAS

■ Dissemination of medical information in 2005: key figures

1500	documents posted on the HAS website
800	HCO accreditation reports
600	Transparency Committee opinions
95	Committee for Assessment of Devices and Health Technologies opinions
100	practice guidelines and methodology guides
5000	requests for information (mail, telephone, fax)
3000	daily visits to the website (source: Xi Ti)
1800	documents downloaded each day (source: Xi Ti)

The 5 most frequently downloaded publications in 2005 on www.has-sante.fr were

- Management of adults with essential hypertension (2005 update)
- Prepare and carry out your accreditation procedure (Version 2)
- Accreditation Manual for healthcare organisations (Version 2)
- Continuing professional development in CQI as part of the accreditation procedure
- Organisation of the drug circuit in a healthcare organisation

■ Multi-level HAS dissemination policy

To better publicize the production and dissemination of new work, four “dissemination service levels” were defined in 2005. They start with the simple posting of a document online and go through to a complete service including printing, mailing, and press and related PR actions.

■ Hard copy formats improved

In the period September to November 2004, a survey was carried out on health professionals' perceptions of HAS' scientific publications in order to better understand their expectations and identify areas for improvement. In 2005, several working groups involving more than 80 professionals from HAS' scientific divisions and Communication Department used the main findings of the survey to suggest practical improvements to document formats. Shorter summary formats are now being published, and a suitable balance between printed and electronic documents has been found [...].

Assessing the quality of medical information

HAS has three certification missions which concern 1) health-related websites; 2) prescription software; and 3) medical sales representatives⁴⁹. The aim is to improve the quality of the information given to health professionals and the general public.

⁴⁷ ANAES: French National Agency for Accreditation and Evaluation in Healthcare

⁴⁸ CEPP: Committee for Assessment of Devices and Health Technologies

HAS first defines “good practice”, then derives a certification standard, and finally drafts the certification procedure. The standard is developed with stakeholders from the sector on the basis of a literature review, international comparisons, and the contributions of a multidisciplinary working group. The finished product is submitted to a peer review group that is representative of the various parties involved.

■ Medical Sales Representatives’ Code of Practice

The Committee for Pricing of Healthcare Products (CEPS) signed the Medical Sales Representatives’ Code of Practice with drug companies represented by LEEM⁵⁰ in 2005. HAS is responsible for translating the Code of Practice into a certification standard. The standard and procedure aim to reinforce quality process in medical representatives’ knowledge, skills and information, and with regard to ethical issues. The system chosen is a company-based technical qualification, requiring investment of resources.

The standard was developed over 3 meetings by a working group composed of representatives from drug companies, LEEM, doctors, and quality experts. The procedure was developed over 2 meetings by a working group of certification experts, members of the French Accreditation Committee (COFRAC), and LEEM. Revision began in November 2005.

■ Certification of prescription software

The aim of certifying prescription aid software is to improve prescription safety and quality, facilitate the work of the prescriber, and reduce cost of treatment without sacrificing quality. The standard integrates the software functions relevant to these objectives. The standard was developed over 4 meetings by a working group composed of representatives from software and drug database companies, doctors, and computer experts.

■ Certification of health-related websites

The Medical Information Quality and Dissemination Committee considers that certification in the strict sense would be difficult to implement. Other ways must be found to respond to Parliament’s desire to identify “good websites”. A guideline will be produced to develop tools and “critical appraisal capabilities”, to help internet users search for information and help them evaluate the quality of the information.

⁴⁹ As stipulated in the law of 13 August 2004

⁵⁰ LEEM: Les entreprises du médicament = drug companies

Developing partnerships, research and international relations

Relations with patient associations and health system users

Users have become fully fledged stakeholders in the health system, and HAS naturally needs to talk to their representatives. Users want to take part in the decision-making process and debates that concern them. HAS needs to understand what users expect in terms of being consulted and in terms of information.

[...]. Users are already involved in the life of HAS. In 2005, they took part in Committee and working group discussions, contributing their own knowledge, expertise and experience.

Issues dealt with in 2005, such as the changes to the long-term conditions (ALD) system, healthcare system performance measurement, assessment of products and procedures and the dissemination of information, have confirmed the need for HAS to set up user dialogue mechanisms. In the years to come, users will have to be further integrated into HAS' consultative and decision-making bodies, and their legitimacy will need to be reinforced. If users play a bigger role in HAS' work, that work will be better understood and accepted by the general public.

Research programme

Although HAS is not a research body, its missions call for a constant stream of new knowledge. In 2005, a new call for research projects for 2006 was prepared, current research projects were followed up and partnerships with other sponsors of research in France were strengthened.

■ New call for research projects

2005 was a year of reflection. As a new institution with wide-ranging missions, HAS has research needs and these were listed. Three major research themes that should have a significant impact on HAS' development were identified. They will shape the 2006 call for research projects:

- Development and evaluation of original and innovative methods for identifying and preventing clinical risk;
- Evaluation and comparison of different HCO management methods;
- Evaluation of new types of organisation of care.

■ Following-up earlier calls for research projects

In September 2005, the proceedings of the 2004 'Quality in health' symposium — organised as part of HAS' research programme — were published in a special issue of *Revue d'épidémiologie et de santé publique* (Epidemiology and Public Health Journal). In November, a research meeting reviewed progress on the projects selected in 2004. In 2006, the final results of the projects selected in 2002 and 2003 will be presented at a research meeting organised by HAS.

■ Partnerships with other research sponsors

Research partnerships with other institutions, such as INSERM⁵¹ and DREES⁵², were strengthened. New links were forged with, for example, the ANR⁵³ and the IVRSP⁵⁴. HAS will pursue research collaborations with other organisations, in particular with the DHOS⁵⁵ of the Ministry of Health and Social Justice on research being carried out as part of the Hospital Research Programme.

International relations

HAS' international activities in 2005 reflected its desire to boost its international involvement and profile. These activities take three strategic directions.

■ Monitor what is going on internationally in HAS specialist areas

HAS took part in more than 50 international conferences and other events, about two thirds of which were in the European Union. Furthermore, HAS continues to play a significant role in international bodies with activities similar to its own — for example 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).

HAS invited European and North American experts to come and present the results of their research in areas related to its missions.

■ Develop a strategy of influence in Europe in health assessment and health care quality

Several meetings were organised with national institutions such as the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom or the *Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* (IQWiG) in Germany, who have missions similar to those of HAS. HAS took an active part in the Medicine Evaluation Committee (MEDEV) working group, which is comparing European experience in evaluating drugs for reimbursement purposes. Bilateral agreements are being discussed with comparable institutions in other EU member states, and HAS also took part in four projects funded by the European Commission:

- Public health projects
 - Safety Improvement for Patients in Europe (SimPaTIE), which aims to develop a basic common European methodology in the field of patient safety;
 - European Network for Health Technology Assessment (EuNetHTA), which is building a European network of national agencies and research institutions in the field of health technology assessment.
- Research projects (6th Framework Research Programme)
 - the 'Methods of Assessing Response to Quality Improvement Strategies' project (MARQuIS) aims to identify the most efficient healthcare improvement strategies in Europe;
 - the 'Coordination of Cancer Clinical Practice Guidelines Research in Europe' project (CoCan CPG) aims to reduce disparities between European guidelines for cancer management.

HAS has opted for an international publication policy for its guidelines and opinions, which are translated into English and posted on the HAS website.

⁵¹ INSERM: the French National Institute for Medical Research

⁵² DREES: Directorate for Research, Surveys, Assessment and Statistics

⁵³ ANR: French National Research Agency

⁵⁴ IVRSP: Virtual Institute of Public Health Research

⁵⁵ DHOS: Directorate for Hospitals and Organisation of Care

■ **Work with the competent authorities to shape an international development strategy**

HAS welcomed about 10 official delegations from countries seeking to know more about its work in the areas of accreditation, continuing professional development in CQI and assessment of medicinal products. In cooperation with the relevant departments of the French Ministry of Foreign Affairs, HAS compiled a report on requests received for technical assistance and skills transfer, in particular from French-speaking countries and countries in the Persian Gulf. This activity was the subject of about 20 mission trips in 2005.

Resources and support

To carry out their work, HAS' technical departments need permanent input and assistance from the general secretariat, particularly in terms of resources and support:

- the “resources” function covers budgeting and budget resources, ongoing training, equipment and computer investments, office supplies and services, balance scorecards and procedures etc;
- the “support” function covers human resources management, legal advice, purchasing, logistics, archiving, internal communication etc.

In 2005, the year HAS was created, a sustained effort from the general secretariat made HAS operational:

- the organisation's first budget was drawn up;
- ANAES and AFSSAPS teams, and new staff, were successfully integrated into the organisation;
- internal communications and dialogue between staff and management was expanded;
- a second office site was set up, teams allocated to the two buildings and a new logistics setup developed;
- more than 100 resolutions, decisions, formal agreements, procedures, tenders and contracts covering the functional and legal aspects of the new structure were drafted.

Documentation

The Documentation Department has three missions:

- monitoring the political and scientific environment on behalf of HAS, compiling a daily press review;
- managing a document library;
- carrying out targeted documentary research for assessments that are generally based on a critical review of the scientific literature.

■ Press review

In 2005, the Documentation Department selected an average of 720 articles per month. Every month, an average of 267 articles cited ANAES or HAS (170 in 2004). Apart from compiling the press review, the Department contributed to the weekly legal landscape bulletin set up by the legal team.

■ Document library

HAS' missions have become more diverse and its activity has increased, leading to an expansion of the document library: 730 works were indexed and 22 new titles purchased in 2005.

■ Documentary research

In 2005, the Documentation Department managed 116 projects, 72 of which were completed and a further 69 begun. Twice as many internal staff made use of Documentation Department services in 2005 as in the previous year.

The new legal mission meant that a legal documentary research department had to be set up.

➤ Actions undertaken for 2006

In 2006, the Documentation Department will continue to adapt to HAS' new missions — giving particular assistance to the drug and medical device assessment departments, whose teams, which previously were part of AFSSAPS, only physically moved to HAS at the end of 2005. It will also focus on information about nosocomial infection and dissemination of medical information, to patients in particular. This involves:

- *diversifying the document library to cover a range of subjects and to cover legal issues that are increasingly a part of the healthcare landscape;*
- *adapting documentary research methods to the time constraints of the drug and medical device assessment departments;*
- *adapting the press review to cover the information needs of the whole institution.*

Internal quality process

HAS has implemented an internal quality process to help it achieve its strategic objectives. This process aims to optimise the way HAS works and improve the quality of materials it produces. It is based on three principles: customer satisfaction, continuous improvement of processes and performance measurement using performance indicators.

■ Developing the quality process across HAS functions

A steering committee and quality coordination committee run the process using a process management method based on describing activities and activity interfaces. The method provides formal descriptions of the conditions that lead to success, making it easier to attain goals. It reduces nonconformities and improves the final results of HAS' work.

A detailed map of HAS' activities has been produced so that the overall operation of the institution can be steered and coordinated more effectively. This quality process has resulted in the drafting of new processes, improvement action plans and performance indicators. In 2005, 16 out of 20 departments took part in workshops (average overall attendance: 77% of all staff). 72 of the 100 meetings scheduled for 2005 took place. [] An example of a successful improvement group is the one that succeeded in reducing from 60 to 4 days the time needed to reimburse experts' expenses.

■ Balance score-cards — development of new indicators

The departments currently produce monthly balance score-cards, which are then analysed by the Executive Committee and presented to the Board every two months. They measure how far goals have been attained. Current performance indicators are being fine-tuned. Twelve new balance score-cards have already been developed.

➤ Actions undertaken for 2006

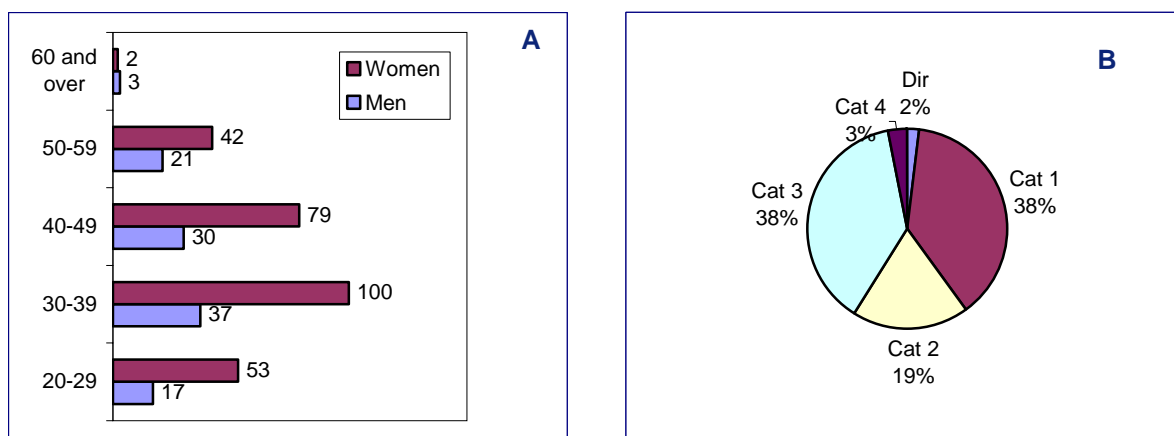
- *Performance indicators developed for all departments;*
- *Each department was helped to draft procedures for its own quality processes;*
- *An internal forum was created to allow people to share experiences.*

Human resources

In 2005, the main goal of the Human Resources Department was to integrate permanent and non-permanent staff from ANAES and AFSSAPS into the new structure.

■ Managing permanent staff

A recruitment campaign was carried out to fill posts created by the new missions. At the end of 2005 there were 342 permanent staff as well as 30 fixed-term contract staff. Contracts at HAS foster job stability: 92% of staff have permanent contracts, 30% of staff on fixed-term contracts signed permanent contracts in 2005, and the staff turnover rate dropped from 6% to 4.7%.



(A) Age pyramid; (B) Staff structure by employment category

As scientific expertise is HAS' core business, the educational and qualifications and level of experience required for HAS staff are high. Most staff (57%) fall into high-level professional categories (categories 1 and 2).

■ Managing casual staff

More than 1 000 new non-permanent staff were called upon in 2005. The number of experts contributing to HAS each year is now almost 3 000. The management of non-permanent staff by the Human Resources Dept led to the creation of expert profiles, the updating of contract types and the extension of the fee payment system for part-time work.

■ Staff/management relations

The administrative committees that must be established in a non-public organisation (works council, staff representatives' committee, and hygiene, safety and working conditions committee) were set up and are operating. Communication between staff and management has been increased by regular and frequent meetings of these committees and working groups, and cemented by the signing of two agreements between staff representatives and management.

At the end of the annual round of staff appraisals, 75 members of staff were promoted.

■ Coaching for change

This process was a priority. Two tools were used:

- internal communication: 22 issues of the internal email newsletter *Ressources* appeared, dealing with aspects of the internal life of HAS, and presenting the new bodies, the Committees and the development of strategic projects; there were 3 open conferences and 4 information meetings for staff on the subject of assessment;

- training plan: the training budget was increased from 298 000 euros in 2004 to 504 000 in 2005. Staff numbers grew 30% during the year but the number of training actions increased by 60%.

➤ Actions undertaken for 2006

To develop professional skills and careers with appropriate human resource management tools, particularly by using a forward planning system for jobs and skills.

Legal support

The setting up of HAS — an independent public authority — required new skills, particularly to ensure its legal security. A legal team was therefore created to assist the Board, the specialist Committees and management.

HAS departments can call on this team when they need legal input. The team provides tools for their missions, drafting contracts with partners and establishing procedures.

More generally, the legal team manages the everyday legal matters such as leases, insurance policies, and service provider contracts required by all organisations. It monitors the legal landscape on a weekly basis, focusing specifically on the world of health and HAS' missions. It also manages disputes (writing opinions on administrative procedures and representing HAS in court in cases not requiring a barrister, or as a support for the barrister).

The legal team has been structured into two sections:

- the “General Affairs” section's work includes writing contracts, establishing procedures, maintaining relations with CNIL⁵⁶ and CADA⁵⁷, etc.;
- the “Health Procedures and Products” section deals with questions relating to drugs, medical devices, diagnostic and therapeutic procedures, healthcare services etc.

In 2005, the legal team contributed to the following procedures: accreditation of HCOs, bylaws of the Board and the specialist Committees, formal approval of the organisations which are to carry out the doctors' CPD scheme, prevention and management of conflicts of interest, and declaring personal data files to CNIL.

It wrote a number of opinions, in particular on the legal status of assessment activities and the legal force of good practice guidelines.

The legal team was also involved in designing, drafting and monitoring draft laws, decrees and orders related to HAS' areas of activity.

➤ Actions undertaken for 2006

- *defining a legal framework for all CPD activities;*
- *providing a legal framework for Transparency Committee opinions (particularly for the third round of decisions on removing products from the reimbursement regimen);*
- *producing a guide to conflicts of interest inside HAS, explaining how they can be avoided or managed.*

Information systems

An enterprise architecture information system was chosen as a way of strengthening HAS' new organisation and facilitating its future development. This approach provides the flexibility and reactivity required by HAS' evolving strategy.

⁵⁶ Data Protection and Civil Rights Council

⁵⁷ Council for Access to Administrative Documents

The enterprise architecture information system, launched on 1 January 2005, involves:

- 4 organisation projects
- 14 projects for developing information system (IS) services
- 15 technological projects aimed at providing the technical platform for the various IS services.

The organisation of the computer team was reviewed in the light of the requirements of the IS plan and to improve the level of service to users (a mutual commitment service agreement was established between computer staff and users). A project was launched to pool expertise. Given the cross-functional nature of the projects, and to get the divisions more closely involved in the goals, results and implementation of the projects, the plan required leadership with two levels of management:

- a global coordination and synchronisation level
- an operational project level.

A change management cell was created to ensure that the services developed were used properly. An iterative prototyping process was also established to respond more quickly and efficiently to users' expectations. Communication and change management were introduced in order to help users accept and become familiar with the new services. Specific actions included:

- a charter for use of the information and communication system
- a seminar attended by all managers (February 2005)
- a project gallery (April 2005)
- a seminar to implement the plan, attended by both computer staff and project managers (December 2005).

The www.has-sante.fr website was created from the www.anaes.fr site; the activities of the Transparency Committee and CEPP⁵⁸ and HAS' new missions were all incorporated into the new site. New payroll software and a solution for computerising public tenders were introduced at the beginning of 2005.

To ease AFSSAPS staff into the new structure and facilitate their daily work, a project was launched to improve the follow-up of drug and medical device assessments.

Finally, in line with HAS' new challenges, information system security was reinforced to ensure better availability of services and guarantee data integrity.

➔ Actions undertaken for 2006

Implement the enterprise architecture information system in order to:

- *meet cross-functional requirements (e.g. the single internet/extranet/intranet portal);*
- *increase efficiency, in particular introduce a system to manage the certification of doctors and medical teams.*

Logistics and day-to-day operations

Since 2005 was the year in which the authority was set up, the logistics targets for the year were ambitious, in terms of both time and scope:

- get the Chair and Board members installed in suitable office space;
- house all permanent staff (including about a hundred staff either from AFSSAPS or newly recruited) in two sites (the head office and the nearby Stadium building). This required 3 moves spread over 2 months, and concerned 340 staff members;
- organise the work areas and deal with new equipment needs (4.3 M€ of investment in removals, furnishing and computer work were required);

⁵⁸ CEPP: Committee for Assessment of Devices and Health Technologies

- sign the contracts necessary to launch HAS and its day-to-day operations; these come under the provisions of the Code of public contracts (79 active procedures);
- be able to access data in total security (computer rooms/servers, technical premises /network equipment);
- guarantee secure telecommunication links between the two HAS sites (Stade de France and Stadium) and the AFSSAPS site (Pleyel).

HAS now has a 900 m² meeting space where training seminars can be held for surveyors and peer facilitators. Rooms are equipped with all the necessary audiovisual and communication equipment.

Apart from logistical operations related to buildings, equipment and computer equipment, the logistics teams also contributed to day-to-day activities (room management, photocopying services, purchasing office supplies and services, postal services etc.).

The change was managed by the general secretariat teams, was based on consultation and involved users in defining the technical and organisational responses to their needs. The teams successfully fitted out the second site and incorporated the new services into the head office.

➤ Actions undertaken for 2006

- *Improve purchasing and supply procedures to develop the internal service provider policy*
- *Ensure the continuity of day-to-day services (access to information and communication networks) and the practical efficiency of the premises, and optimise computer and logistical assistance to users.*

Financial resources

HAS' operating budget for 2005 (draft budget + modification) was proposed by the Managing Director and approved by the Board at a figure of €60 062 857 (personnel costs represent 53% of the total). With HAS' activities and new missions picking up speed over the course of the year, 75% of this budget was used, covering HAS' initial set-up costs. After a year's operational experience, it will be possible to set a more accurate budget for 2006.

Revenue structure is determined by article L.161-45 of the Social Security Code. The distribution of 2005 fiscal year revenue is shown in the tables on the next page. Total expenditure was €44 773 039 and was distributed as shown in the histogram.

Total revenue structure

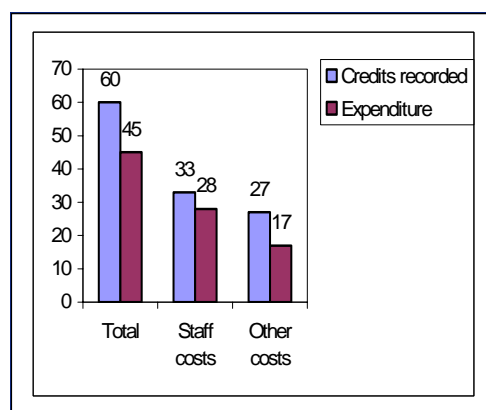
	Provisional income (€)	Income to be collected (€)
Government subsidy	10 131 790*	8 849 790
Total contribution from national health insurance	20 263 580	19 620 913
10% of the tax on pharmaceutical company spending on advertising	18 338 807	21 000 000
HCO accreditation fees	8 521 680	9 222 600
Fees levied on the industry	2 807 000	4 243 500
Miscellaneous (including investment income)		352 236
Total	60 062 857	63 289 039

* €9 649 790 registered under Chapter 37-05 of the Finance Law, plus €482 000 to compensate for the loss sustained by AFSSAPS activities transferred to HAS.

Structure of 2005 income to be collected

	%
Tax on pharmaceutical company spending in advertising	33.18
Contribution from National Health Insurance	31
Accreditation fees	14.58
Government subsidy	13.98
Fees levied on the industry	6.70
Miscellaneous	0.56

Expenditure in M€



Subsidies account for 45% of income, special taxes 40%, and equity 15%.

Extra revenue and savings on expenditure produced a profit for the 2005 fiscal year of € 18.5 M.

42% of the € 4 794 500 investment budget for the 2005 fiscal year was used. Investments – totalling € 2 030 274 – mainly concerned purchases of equipment, office furniture, computer stations and software required for the new structure. The enterprise architecture information system project originally included in the 2005 programme has been delayed a year because of the workload generated by setting up HAS, implementation of the project governance plan and the time required for the studies needed to launch a tender.

➤ Actions undertaken for 2006

The 2006 operating budget is up 10% in relation to 2005. The increase is self-financed by calling on working capital. It is due to the launch of new activities and the strategic orientations defined by the Board (in particular, dissemination of information, research programme, international action, quality indicators and nosocomial infection information and action).

Five directions

The cross-functional nature of HAS' activities means that several types of skill and competence have to be brought together to address public health issues.

All HAS' work is based on the concept of actual benefit for the patient (SMR)⁵⁹. The five areas of HAS' work described below are concrete examples of how HAS' assessment tools are used in synergy to meet the expectations of health professionals and users. This is aided by its organisation into complementary Committees.

From innovation to medical advances

Any innovation that is likely to significantly improve treatment, compensate for a handicap or have a major impact on the healthcare system must be identified early in order to ensure its optimal deployment. This means being able to distinguish between novelty, which is not an end in itself, and a real medical advance. Technical prowess can hide more fundamental progress, for example when considering chronic conditions related to ageing, which are the main factor in the increasing morbidity within the population.

Today, the main criterion used by the Committees - Transparency Committee, CEPP⁶⁰ and CEAP⁶¹ - in their assessment of innovation is the improvement in expected benefit, IEB, in other words, the added value in a comparison with other products and services. IEB measures the expected additional contribution in terms of efficacy and/or safety (in one sense, it forecasts clinical progress). However, it does not take account of the organisational and economic dimensions, which are also essential factors in defining innovation.

A working group of HAS has addressed issues relating to innovation in the area of medical devices. Its conclusions have prompted a cross-Committee discussion on better deployment of innovation, i.e. providing access to clinical progress without undue delay and without sacrificing the rigour of scientific assessment.

Taking account of public health benefit

The Transparency Committee is incorporating assessment of public health benefit into its work in assessing drugs, with the support of ISPM⁶².

There are three dimensions to assessing public health benefit:

- population (the impact on the state of health of the population)
- organisational dimension (the impact on the organisation of healthcare)
- economic dimension (the economic impact on the health system).

So far HAS has mainly assessed impact on population. Putting assessments into context gives them meaning. For example, the re-assessment of drugs with insufficient benefit only makes sense if reimbursements are prioritised in relation to national choices in social justice, conditions of access to care and the financial constraints of public funding.

⁵⁹ SMR: *Service medical rendu*

⁶⁰ CEPP: Committee for Assessment of Devices and Health Technologies

⁶¹ CEAP: Committee for Assessment of Medical and Surgical Procedures

⁶² ISPM: Working Group on Public Health Benefit of Drugs

The HAS Board has therefore decided that all the Committees concerned will put assessments into context. A cross-functional group, chaired by Lise Rochaix, will identify the knowledge, skills and fields of expertise - as well as the tools and methods - that will be needed for HAS to assess all three dimensions of impact on public health.

Assessing in real life

There are two aspects to assessment in real life:

1. It needs to be cross-functional so that different treatment strategies can be compared.

The data available for scientific expertise are often too incomplete and too dependent on patient inclusion and exclusion criteria to be able to make indirect comparisons. Marketing authorisation is based on examination of the product's benefit/risk ratio, i.e. its undesirable effects and its efficacy compared to placebo. HAS has included the study of scientifically validated assessment tools for indirect comparisons into its research objectives in order to be able to compare treatment strategies and measure differences in performance whenever possible.

2. *Ex ante* assessments, being imperfect, need to be completed by post-marketing studies.

Post-marketing studies relate to the conditions of use of the product or procedure in real-life. Assessing a dossier raises the question of how far trial results can be transposed into normal practice, given the many uncertainties that exist (differences between trial and treated populations, differences in practice etc). The relevance of post-marketing studies is widely accepted, but the methods used – based on pragmatic trials, *ad hoc* observational studies, registries, or the use of databases – must be improved.

As well as sponsoring research, HAS will work on this issue with its European partners, and share methods with them.

Increasing the independence of HAS' scientific expertise

HAS needs to be able to rely on external expertise. HAS' specialist Committees call on working health professionals to assess health technologies and propose professional guidelines. HAS has laid down strict rules on the management of conflicts of interest for Committee members and external health professionals. These rules take account not only of positive conflicts of interest (an interest in the company whose product is being examined) but also of risks related to negative conflicts of interest (an interest in a firm competing with the firm whose product is being examined). They are strictly enforced (e.g. when assessing reimbursement applications submitted by commercial firms for their health products (drugs and medical devices)). HAS wants to make these rules more transparent, and is looking into the setting up a body made up of members of HAS and external members that will guarantee compliance with the rules. A working group, chaired by Raoul Briet, is examining the issue.

Introducing quality into practice

The objective of all of HAS' work is to introduce quality into professional practice. This determines, for instance, priorities in guideline development. Public bodies, including HAS, must produce guidelines – in collaboration with learned societies and professional associations – that meet the expectations of stakeholders and which can be systematically incorporated into initial education for the medical and allied health professions. One example is the current review of all long-term conditions, which focuses on guides to managing major health problems and considers the patient, their diseases and risk factors as a whole.

Another example is Continuing professional development (CPD) in CQI where assessment becomes part of medical practice. Doctors must undertake to base their clinical practice on protocols, and must analyse their practice and results against these protocols. When applied to HCOs, CPD in CQI is a good example of HAS' determination to take account of all stakeholders; improvement in individual practice is incorporated into the HCO's collective improvement process. Another facet of collective improvement is Version 2 of the accreditation procedure; it concerns improvement in the HCO as a whole and also the key role of management in the dynamics of a hospital. In the future, management could also be assessed with a form of CPD.

Assessing reimbursable healthcare products and procedures

Assessment of medicinal products

During 2006, the Transparency Committee will carry out the third and final stage of the review of drugs whose actual benefit was judged in 2001 to be insufficient to justify their cost being reimbursed. This involves about 150 drugs.

The Transparency Committee has decided to review certain drug classes in 2006 (e.g. drugs for Alzheimer's disease and for osteoporosis).

"Proper use of drugs" sheets for new drugs with a high potential impact and summary reports on the drug classes which have been reviewed will be produced and made available to health professionals.

There will be enhanced coordination on post-marketing drug assessments between HAS and AFSSAPS.

Finally, HAS will contribute to the changes to regulatory provisions (publication of a new decree relating to the Transparency Committee) in 2006.

Assessment of medical devices

Some new medical devices are only replacements for devices that have outlived their commercial life. Such devices may be new, but they are not clinically innovative. Although most new devices fall into this category according to assessments of improvement in expected benefit, others are real innovations likely to improve patient care. Members of CEPP⁶³ have been discussing HAS' approach to these truly innovative devices, i.e. how to identify them and how to ease their pathway.

There are three stages in their assessment:

- a horizon scanning stage, where they are identified;
- a consultation stage, where the clinical trials programme is established and optimised;
- an assessment stage, when reimbursement is proposed.

CEPP will establish an organisational framework to encourage clinical trials and their assessment, taking account of the systems and structures dealing with innovation and its funding.

The position on innovative medical devices and the conditions under which they will be introduced into the basket of care will be discussed. The aim is to encourage early acquisition of relevant data that will allow access to these devices under the best possible conditions.

In 2006, CEPP will publish:

- the methods for assessing reimbursement applications and for revising generic lines;
- a guide to help manufacturers compile their reimbursement application;
- treatment information sheets for health professionals, which encourage the proper use of particularly expensive health products.

CEPP will continue its review of generic descriptions and complete the assessment of the 7 generic descriptions scheduled for 2005/2006. Together with the Device Assessment Department, it will produce standards for using medical devices reimbursed outside GHS groups⁶⁴.

⁶³ CEPP: Committee for Assessment of Devices and Health Technologies

⁶⁴ GHS: homogeneous hospital stay groups - part of the T2A scheme

Finally, post-listing monitoring (studies after approval for reimbursement) will also be examined, with discussion about the organisation and coordination that will be needed to ensure that these studies are useful and are conducted properly.

Assessment of medical and surgical procedures and health technologies

A major objective in 2006 will be to develop a method for assessing further aspects of professional procedures (public health benefit, health economics assessment, etc.) and to adapt the method to the question raised. The first agreements between HAS and UNCAM⁶⁵ are due to be implemented in 2006 for procedures in the clinical research stage.

HAS will develop a horizon scanning programme and participate in the European Information Network on New and Changing Health Technologies (EuroScan). HAS will also lead the work package on the development of a common tool for monitoring new and emerging technologies within the European Network for Health Technology Assessment (EuNetHTA) which was approved in January 2006 and co-founded by the European Commission.

Coordination

Several technical and scientific coordination projects will be continued or launched with stakeholders concerned by the following: descriptions, aids to dissemination, approval for reimbursement and monitoring of procedures, medicinal products and devices. The aim is to encourage production of relevant data for their assessment; to provide information for potential users; and to encourage proper use.

⁶⁵ UNCAM: Association of Sickness Funds (National Health Insurance)

Assessing healthcare strategies

Increased dialogue with other stakeholders

HAS works in close collaboration with ministerial departments, health insurance funds, learned societies and agencies. This dialogue is to be extended to all stakeholders.

Strengthening relationships with learned societies and the professional Colleges

HAS wants to move away from being the main producer of clinical practice guidelines (CPGs) to being the regulator. It will continue to carry out work on cross-functional topics which involve a number of specialties, particularly topics where there is controversy between specialties or disciplines. It will encourage societies and associations to develop most CPGs

- either through partnerships with HAS: the society or association will take the responsibility for developing a guideline, with HAS helping with funding, methodology, logistics, documentary research and dissemination,
- or with HAS' formal approval ("*labellisation*"). This consists of recognition by HAS of the methodological quality of the development of the CPG after it has been produced.

Close links with international partners (European projects, agreements on cooperation with structures with missions similar to those of HAS) will make it possible to help societies and associations identify and make use of guidelines that already exist or are being produced abroad. HAS also wants to develop a scientific watch system to update existing guidelines jointly with the societies and associations.

Strengthening relationships with patients' associations

Relationships with patients' associations need to be strengthened. They will be particularly important when producing guides for doctors. Users are already represented on HAS Committees. They will be encouraged to suggest topics for CPGs and public health assessments and will be involved in guideline development whenever this is appropriate. This work will be carried out as part of HAS' general policy of developing relationships with users.

Developing new forms of consultation

To ensure that its work programme closely matches the expectations of all stakeholders, HAS wants to extend the ways in which it consults professionals in everyday practice and patients by using methods such as focus groups. In 2006 it will test new procedures for wide consultation of all parties concerned, i.e. health professionals, patients and users, funding bodies, manufacturers and public authorities. This procedure will be used first for targeted agreements, but may be extended gradually to other areas of HAS' work.

Increasing impact on practice

The aim is to enhance impact on practice and awareness by establishing a work programme that meets stakeholders' concerns, by carrying it out using a wide range of methods and by ensuring acceptance and use of guidelines.

A relevant work programme

In March 2006, HAS will introduce a single application procedure for public authorities, patients' associations, professional societies and associations who ask for specific topics to be included the HAS work programme. The same criteria will apply for all applicants. The procedure will ensure the best use of resources with regard to current priorities for improving the quality and equity of the healthcare system.

The impact of HAS' work will increase as major topics are addressed on an interdisciplinary and cross-functional basis, with all departments working in synergy. An example is work on the management of osteoporosis. This will be followed by other major public health priorities, such as management of cardiovascular risk factors.

Once the 2006 work programme has been established, a memorandum will be drafted outlining the rationale and objectives of each CPG and public health assessment in order to see how the issues can be tackled. It will be submitted to the Committee for Assessment of Healthcare Strategy. [...]

Broader range of working methods

In 2006 new methods will be developed and interdisciplinary working will be increased.

- A formal method for adapting foreign CPGs for France will be used to produce three guidelines. It should, in future, increase the use of available high-quality foreign CPGs.
- Rapid response methods will be tested, based on literature reviews and the use of formal consensus.

To respond to complex problems for which there are few published data, HAS will carry out specific surveys or studies, possibly in partnership with external organisations. This could be particularly useful for obtaining information to support the health economics and organisational aspects of decision-making, an area for which there is little published international data.

The effectiveness of the recommended healthcare strategies will be studied, whenever this is felt to be relevant. Analysis of the economic and organisational dimensions, both in terms of potential impact and mobilisation of resources or optimisation of the existing offer of care, is a key aspect of HAS' mission of providing aids for decision-making. The Health Economics and Public Health Assessment Department will therefore continue its review of working methods (ongoing since 2004). New approaches will be introduced to complete the critical literature review, e.g. modelling of different or alternative strategies, simulation of the impact of the diffusion of a technology, practice surveys, analysis of the availability of care on offer, etc. Disciplines such as human and social sciences and political sciences could be usefully called upon for certain types of work such as organisational assessment of care strategies.

Maximising the use of HAS' materials

A Quick Reference Guide will be produced for all CPGs. It will be completed by an assessment tool, and possibly by indicators and information documents for patients. A new way of indexing CPGs on the HAS website will be introduced to improve access to all these documents. Other ways of disseminating them among stakeholders will also be looked into. The impact of the implementation of guidelines and opinions should be monitored by healthcare quality indicators.

Extending the range of action

At present, HAS is mainly concerned with screening in the field of preventive medicine. This concern will be extended to all areas of prevention related to HAS' missions. The Division concerned thus changed its name in November 2005, to become the Healthcare Strategy Assessment Division.

In addition, HAS will address the assessment of organisations in order to improve the quality and safety of the healthcare system. The main issues involved include collaboration between health professionals and the introduction of the personal medical record. HAS will also continue its work of assessing shared care networks, and preparing their accreditation as specified in article L.6113-4 of the Public Health Code.

Improving the quality of structures, resources and practice

The four main goals of the 2006 work programme

The first goal is to take account of the feedback from the first 100 surveys carried out in 2005 with version 2 of Accreditation, i.e. review how work is organised in house and the improvements to be made to the procedure, and publish a new version of the Accreditation Manual, in which errors identified by HCOs and surveyors have been corrected. A special version of Accreditation reports, based on a grading system, will be posted online to improve the general public's access to Accreditation results.

The second goal is defining the directions the Accreditation procedure will need to take over the next few years to reinforce its efficacy while reducing the burden on HCOs. A programme for the gradual phasing in of new features, in particular of quality indicators for hospital services, will be decided in 2006. There will be a public debate involving users, professionals and public authorities so that a solid consensus can be achieved around the directions chosen.

The third goal is to make the system of certification of doctors fully operational so that doctors can commit to the new procedure before the end of 2006.

The fourth goal concerns training peer facilitators in their new missions, particularly in private HCOs. A major programme of continuing training will be implemented in order to draw on available peer facilitators within the URML⁶⁶.

Accreditation of HCOs

The last 420 surveys for the version 1 procedure will be carried out during 2006. At the same time, version 2 will continue to come onstream, with 330 surveys performed and 800 surveyors trained.

In application of the legal and regulatory provisions, HAS will develop systems for accrediting plastic surgery facilities (decrees of 11 July 2005) and shared care networks in 2006 for implementation in 2007.

The use of indicators to measure service quality reinforces the efficacy of certification and accreditation initiatives. HAS has therefore carried out work on the collection of data from which indicators can be calculated jointly with the Ministry of Health which has published information on measures and results for nosocomial infection control within HCOs. The gradual introduction of indicators, mostly derived from research work by COMPAQH^{67*} will give rise to annual, factual reports and thus reduce the information that HCOs have to collect during the self-assessment prior to the Accreditation survey.

⁶⁶ URML: Regional associations of independent doctors

⁶⁷ COMPAQH: French national project to select and test indicators of hospital quality

Assessment of health centres, centres for rare diseases and Ethics Committees

The structure of the initiative and the standards by which health centres and centres of reference for rare diseases are to be assessed will be completed in 2006. In addition, HAS will produce a standard for assessing Ethics Committees⁶⁸.

Certification of doctors

Publication of the decree applying article 16 of the law of 13 August 2004 will allow HAS to deploy an operational system with representatives of the medical specialties concerned.

Based mainly on the specifications for approved bodies, which will be published by HAS, it will be up to doctors from the specialties concerned to organise themselves to form professional risk management structures which will support the certification system. HAS would like to be able to approve the first bodies during the second half of 2006 so that the system becomes functional before the end of 2006.

Continuing Professional Development focusing on Continuous Quality Improvement

HAS is developing a policy for incorporating CPD into everyday medical practice. Commitment by professionals to assessment initiatives assumes that the systems introduced possess the basic qualities needed for their acceptance, which are validity, efficacy, feasibility and acceptability.

In implementing CPD, HAS has relied on close cooperation with professional structures. The first round of approvals for bodies able to implement CPD and CQI actions and programmes started in 2005 and will continue in 2006. A system for joint monitoring of the initiative by all the institutions concerned will be introduced in 2006.

There will be an increased number of access routes to CPD as all doctors should be able to find a way of incorporating CPD into their everyday practice. Peer facilitators (PF) were originally trained in a procedure defined in close collaboration with the URML. In 2006, their missions will be more diverse:

- the initial training programme will continue so that the URML will have access to PFs in all regions;
- continuing education will bring the PFs trained first up to date with recent advances (200 PFs);
- further training will be provided for PFs working with HCOs (300 PF). PFs can currently provide information and raise awareness at the request of an HCO's Medical Committee. In future, they will be able to support initiatives directly at the request of their colleagues. They will also be able to intervene in validating actions carried out by individuals in medical teams, in view of the individual legal obligation to engage in CPD, particularly within the context of version 2 of Accreditation.

Finally, HAS will discuss extending the CPD system to all care professionals, in close collaboration with the public authorities and representatives of the professions concerned.

⁶⁸ In accordance with the Public Health law of 9 August 2004.

Informing health professionals and the general public

The Committee for Medical Information Quality and Dissemination has identified three principles underscoring the significance and consistency of HAS' many missions.

These principles are:

- The need to recognize the complexity of information and the multiplicity of sources issuing it, in other words, avoiding the trap of issuing "official information".
- Scientific expertise may help move from opinion to fact, but it should not entertain any illusions about consensus in areas of science that are constantly evolving and subject to controversy.
- To achieve long-term changes in behaviour, tools that promote critical review and awareness of the complexity of information are needed.

[...] In 2006, HAS' information and communication policy will focus on two key goals:

- Improving the quality of medical information issued by stakeholders by engaging them in quality initiatives;
- Developing an information strategy for health professionals and the general public that will induce behavioural changes and help to improve the healthcare system.

Improving the quality of medical information

Certification of the work of medical sales representatives

The aim of certification is to encourage pharmaceutical companies to improve quality in the implementation of the medical sales representatives' Code of Practice. In 2006, a feasibility study will be performed to test the standards and procedures for certification. The system should be operational by the end of 2006.

Certifying bodies will be accredited by COFRAC⁶⁹ and manufacturers will be able to enrol with these bodies.

It will be necessary to support and assess the introduction of the certification system and in particular to measure its impact on medical practice. Monitoring of medical sales representatives' visits and the quality of their practice will also help identify potential developments within the certification system

Certification of prescription software

The standard should be completed in 2006. The aim of the certification procedure is to help health professionals make prescription decisions during a consultation. In 2006, the procedure will be defined; the type of certification system will be decided (certification of products, allocation of a label, etc.) and the assessment procedures will be determined (audit methods, allocation of a certificate/label, etc). The certification system will be operational in the first half of 2007.

⁶⁹ The French Accreditation committee

Developing a positive information strategy

Two ways have been chosen to better inform health professionals and the general public and to trigger the anticipated changes in behaviour:

- **Providing tools that sharpen critical acumen**, i.e. that help identify reliable scientific information and filter information. The certification of health-related websites is one part of this process. In 2006, guidelines on the proper use of websites (how to search for information, how to assess its quality) will be developed. In addition, a strategy for identifying "good websites" will be established, and the tool will be finalised in 2007.
- **Increase the dissemination of information on health-related subjects**. More scientific information that is credible and rigorous because it is guaranteed by the scientific assessment method used by HAS and by regular input from working health professionals, learned societies and patients' associations should be made available and accessible.

■ Making HAS' publications easier to read

- Upstream, stakeholder participation (learned societies, users' representatives, institutions with an interest in the topics dealt with, etc.) will enable to take account of practice and encourage people to adopt guidelines, etc.;
- Downstream, testing documents on target audiences will determine corrective actions and improvements needed; in 2006, new formats, in particular the first "proper use of drugs" sheets, will be tested.

■ Increasing visibility

- Developing press relations in the regions. As regional press journalists rarely come to Ile-de-France, a virtual press room on the new HAS website will allow them to take part in remote press conferences arranged by HAS.
- Extending HAS' policy of taking part in professional conferences and congresses. In 2006, HAS will continue to take an active part in professional events. It will also organise new *ad hoc* events such as public hearings and seminars on specific topics.
- Looking for institutions that can disseminate HAS' work. 2006 will see the launch of a policy of actively looking for institutional partners to help disseminate HAS' work more widely (such as the Regional associations of health insurance funds (URCAM), the URMLs, learned societies, etc.).

■ Develop accessibility and encourage interactivity

- The new website launched in 2006 will be HAS' shop window, offering internet users rapid and easy access – notably via a new and more powerful search engine – to all HAS' scientific publications. The new site will also have more editorial content written for specific targets (health professionals, drug companies, journalists, institutional stakeholders and the general public).
- An electronic newsletter to disseminate information about CPD among health professionals, "EPP Infos", will be launched in the first half of 2006.

Other plans for 2006 include:

- **Launch of an online newsletter:** This two-monthly newsletter, posted on the HAS website (www.has-sante.fr), is intended to demonstrate HAS' ability to apply cross-functional expertise to healthcare issues. The newsletter will emphasise the wide range of HAS' work and publications, and publicise the methods HAS uses to produce its scientific publications.
- **Deciding whether to start public debates:** HAS will discuss in 2006 whether public debates should be held on key subjects concerning the functioning of the healthcare system and the efforts needed to safeguard it. HAS would like to use these debates to share its values of solidarity, equity and efficiency in the healthcare system, and to encourage the commitment of all stakeholders to the use of resources to preserve a health system that is fair to all members of society.

Developing partnerships, research and international relations

Relationships with learned societies and the professional colleges

HAS would like to consolidate and develop its relationships with learned societies and professional colleges. Currently, HAS departments regularly call upon learned societies and professional associations in various areas of their work (guidelines, CPD initiatives, etc). However, HAS wishes to introduce a more formal relationship with learned societies. [...] In 2006, it will organise a meeting focusing on accreditation and CPD in CQI, and another on assessment of healthcare strategies, with the aim of defining forms of future partnerships between HAS and learned societies.

HAS is highly aware of the importance of initial and continuing training in gaining acceptance of quality initiatives by doctors. It has therefore established contacts with the Conference of Deans of Faculties of Medicine and has met coordinators of medical schools' DES and DESC courses. In May 2006 a seminar will take place for lecturers in faculties of medicine, arranged by HAS and the Conference of Deans of Faculties of Medicine, on introducing the teaching of quality processes during medical studies.

Information for patients about nosocomial infection

The Minister of Health and Solidarity has made improved information for patients on their rights one of the strategic actions in the fight against nosocomial infection. In December 2005 he asked HAS to provide information and develop mediation in relation to nosocomial infection (IDMIN⁷⁰).⁷¹ The aims of the mission are: to listen to and support victims of nosocomial infection; to ensure individual case monitoring; to limit routine recourse to the courts; and to encourage dialogue in order to preserve trust among users, health professionals and public authorities. [...]

Research programme

A strategy for a medium-term programme has been defined after broad-ranging consultation of operational teams, the HAS Board, and of institutions and researchers working on topics related to HAS' work. HAS would like to help bridge the gulf between academic research and the concerns of decision-makers. This means widening the scope and redefining the procedures of the research programme:

- Externally: Improve coordination of calls for projects by HAS and other bodies; coordinate research commissioned and develop a reactive approach to methods and results; initiate partnerships with external teams involving joint publication of results and presentation at national and international conferences.

⁷⁰ IDMIN: French mission for information and mediation about nosocomial infection

⁷¹ Part of a mission of providing information to health professionals and healthcare system users entrusted to HAS by the law of 13 August 2004.

- Internally: Consolidate and develop the mission of support and expertise that the research arm of HAS can offer other departments; bring together internal skills in the field of research; structure the research programme around two main themes: (i) calls for research projects that mobilise external teams on general topics (see page 34), (ii) calls for tender for studies answering an identified need of HAS departments.

■ Develop new lines of research

Lines of research come within the framework of health services research and health technology assessment. They borrow from many research disciplines, i.e. epidemiology, biostatistics, economic sciences, human sciences and management sciences.

A number of lines of research have been identified, e.g. fine-tuning and using existing databases to calculate healthcare quality indicators; assessing and measuring the impact of HAS' actions; conduct and measurement of change.

■ Calls for tender for studies

This involves meeting targeted needs of HAS departments. For 2006, studies will be part of the following programme: developing new assessment tools to help in public decision-making, refining tools for piloting quality initiatives in hospitals; measuring and assessing healthcare strategies implemented by the stakeholders.

International relations

The international, and especially European, dimension is becoming increasingly important from both a scientific and a regulatory point of view. [...]

Within its areas of competence, HAS will liaise with the competent departments of the Ministry of Health and Solidarity, participating in discussions to establish and defend the French position at European level. The European Commission may in fact determine political orientations in domains corresponding to HAS' missions since the open method of coordination has been adopted (communication - COM(2004) 2 final - of 13 January 2004).

Further downstream, HAS will continue to participate in and coordinate projects funded by the European Commission, notably the public health programme which is likely to have political consequences in the shorter term.

Collaborations initiated with institutions similar to HAS in other member states will be continued in order to develop an independent European position, that may have more influence at the Community level. HAS will monitor health developments within the Community, so that it can incorporate into its activities, at the earliest stage possible, the results of the work of European institutions which come within the scope of its own missions, and also so that it can participate at an earlier stage upstream in discussions within the Community.

In addition, HAS will pursue its traditional partnerships with international organisations such as the Guidelines International Network (GIN), the International Network of Agencies for Health Technology Assessment (INAHTA), the International Society for Quality in Health Care (ISQua), etc., to carry out and validate research work carried out in its areas of competence. In the long-term, international scientific recognition contributes to HAS' credibility. The organisation and publication of the proceedings of research meetings and seminars will also enhance HAS' position at national and international levels.

Finally, the activity of international cooperation will be carried out in collaboration with the competent departments of the Ministry of Foreign Affairs. Priority programmes will be established in accordance with needs expressed by third party countries, the national development strategy, and the resources that can be mobilised within HAS.

Specialist committees – members and bylaws

Transparency Committee (Assessment of medicinal products)

Chair: Professor Gilles Bouvenot

Vice-Chairs: Professor Claire Le Jeune and Professor Jacques Massol

Full members: Professor Élisabeth Autret-Leca, Professor Jacques Jourdan, Dr Denis Pouchain, Dr Alain Cariou, Professor Olivier Chosidow, Professor Denis Duboc, Professor Bruno Falissard, Professor Hervé Vespignani, Professor Bernard Bannwarth, Dr Marie-Agnès Koenig-Loiseau, Professor Mathieu Molimard, Professor Michel Petit, Dr François Tremolières, Dr Jean-Marie Vetel, Patrick Wierre, Dr Olivier Wong, Professor Marie-Christine Woronoff-Lemsi

Deputy members (in order of nomination): Professor Jean-Noël Fiessinger, Professor Anne Gompel, Professor Antoine Flahault, Professor Nicolas Danchin, Dr Patrice Nony, Frédéric Courteille
Membership established by Board decision on 7 March 2005 (*Journal officiel*, 25 March 2005).

The bylaws were adopted by decision of the Board on 22 June 2005 (*Bulletin officiel du Ministère de la Santé*, 15 September 2005).

Committee for the Assessment of Devices and Health Technologies

Chair: Professor Bernard Guiraud-Chaumeil

Vice-Chairs: Dr Élisabeth Féry-Lemonnier and Pierre Maillard

Full members: Professor Régis Beuscart, Jean Deregnacourt (until November 2005), Professor Olivier Goëau-Brissonnière, Dominique Goeury, Professor Salem Kacet, Dr Didier Lambert, Professor Paul Legmann, Professor Jacques Machecourt, Professor Francis Navarro, Dr François Parquin, Professor Richard Rochwerger, Professor Éric Vicaut

Deputy members: Professor Alain Bernard, Professor Bernard Guillot, Professor Claude Manelfe, Professor Jean-François Mathé

Membership established by Board decision on 10 February 2005 (*Journal officiel*, 9 March 2005), modified 2 June 2005 (*Journal officiel*, 28 June 2005).

The bylaws were adopted by decision of the Board on 12 July 2005 (*Bulletin officiel du Ministère de la Santé*, 15 September 2005).

Committee for the Assessment of Medical and Surgical Procedures

Chair: Dr Claude Maffioli

Vice-Chair: Professor Bertrand Dureuil

Members: Professor Marie-Christine Béné, Dr Hubert Dechy, Professor Olivier Goëau-Brissonnière, Professor Patrick Goudot, Dr Yves Grillet, Dr Jean Lannelongue, Dr Anne-Sylvie Poisson-Salomon, Professor Jean-Pierre Pruvo, Dr Gérard Very

Membership established by Board decision on 9 March 2005 (*Journal officiel*, 25 March 2005), modified 2 November 2005 (*Journal officiel*, 16 December 2005).

The bylaws were adopted by decision of the Board on 27 April 2005.

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

Chair: Raoul Briet

Members: National medical advisor on reimbursement, CANAM, or their representative, National medical advisor on reimbursement, CNAMTS, or their representative, National medical advisor on reimbursement, MSA, or their representative, Dr Hervé Berche, Professor Isabelle Caubarrère, Michel Delcey, Benoît Dervaux, Jean-Michel Lardry, Professor Michel Leporrier, Dr Didier Ménard, Nadine Noblet, Catherine Sermet, Sylvaine Seveignes
Membership established by Board decision on 28 April 2005 (*Journal officiel*, 24 May 2006).

The bylaws were adopted by decision of the Board on 14 June 2005.

Committee for Healthcare Strategy Assessment

Chair: Professor Lise Rochaix

Vice-Chairs: Franck Lazorthes, Pierre Lombrail

Members: Corinne Alberti, Joël Belmin, Daniel Benamouzig, Philippe Bergerot, Yann Bourgueil, Jean Canneva, Marie-Odile Carrère, Mme Christine Chemorin, Dominique Costagliola, Brigitte Dormont, Eric Drahi, Gilles Gaebel, Nicole Garret-Gloanec, Michèle Kessler, Franck Lazorthes, Pierre Lombrail, Luc Martinez, N.T. Françoise Nguyen, Fred Paccaud, Michel Paparemborde

Membership established by Board decision on 24 March 2006 (*Journal officiel*, 12 April 2006).

The bylaws were adopted by decision of the Board on 24 March 2006.

Committee for Medical Information Quality and Dissemination

Chair: Étienne Caniard

Members: Dr Anne Boiteux, Professor Patrick Choutet, Claire Compagnon, Professor Stéfán Darmoni, Dr Gilles Errieau, Brigitte Fanny-Cohen, François Lafragette, Yann Le Cam, Dominique Leboeuf, Dr Anne-Marie Magnier, Jacques Mopin, Pierre Louis Rémy, Antoine Vial

Membership established by Board decision on 17 June 2005 (*Journal officiel*, 6 August 2005).

The bylaws were adopted by decision of the Board on 12 July 2005.

Committee for Accreditation of Healthcare Organisations

Chair: Jean-Paul Guérin

Vice-Chairs: Olivier Debay and Dr Laurent Jouffroy

Members: Christian Anastasy, René Caillet, Christian Caoduro, Dr Édith Dufay, Marie-Françoise Dumay, Professor Patrice François, Dr Jacques Glikman, Professor Dominique Grimaud, Dr Anne Gruson, Pierre Huin, Anne Laurin-Inizan, Marie-Claude Lefort, Bruno Lucet, Aline Maserak, Monique Mazard, Yvonnick Morice, Jean-Philippe Mousnier, Dr Jean-Paul Ortiz, Dr Bernard Ortolan, Emmanuel Rodriguez, Jean-Daniel Simon, Professor Philippe Vinceneux

Membership established by Board decision on 24 March 2005 (*Journal officiel*, 5 April 2005), modified 14 June 2005 (*Journal officiel*, 7 August 2005).

The bylaws and the HCO Accreditation procedure were adopted by decision of the Board on 13 April 2005 (the accreditation procedure was published in the *Journal officiel* on 22 September 2005).

Financial report 2005

From budget forecasts to the financial report

Table comparing budgeted expenditure and real expenditure according to the financial report

The comparison of forecasts (page 66) with real expenditure for each two-figure account highlights the following differences:

- Postponed equipment and office supply purchases bring the figure for realized investment down to 42%
- Day-to-day operating costs (rent, maintenance etc.) absorbed 68-73% of the credits approved by the Board under these headings. These budget lines represent 10% of total costs for the fiscal year
- External services, including expenses related to expert missions, travel and representation, come to nearly 20% of total operating expenditure. 60% of the budgeted amounts were utilised.
- Salaries and related costs are the principal item of expenditure and account for 57% of operating costs. 85% of the credits affected under this heading were utilised.
- Subsidies granted and costs assumed in regard to ANAES totalled 49% of budget forecasts.

Origin and structure of HAS resources

- Government subsidy: € 8850 K
 - Social security subsidy: € 19 621 K
 - ACOSS⁷² contribution: € 21 000 K
- i.e., a total of € 49 471 K. In 2005, these sums represented 78% of current renewable resources. Financial contributions derived from HAS' missions:
- Accreditation: € 9295 K
 - Transparency: € 4 082 K
 - CEPP publicity: € 171 K
- total € 13 548 K and represent the second source of income, and less than a third of operating costs.

Cashflow generated by HAS activity

The cashflow table on page 67 underlines the disparity between revenue and expenditure, especially at the beginning of the fiscal year.

The only income received monthly is the 31% of income from national health insurance.

The Financial Controller monitors the cashflow situation and every three months provides useful financial management data. This monitoring makes it possible to visualise the rate at which authorized expenditure is being realized and assists investment and cashflow management decisions.

Financial report and global financial situation at the end of 2005

2005 activity results

The 2005 operating account lists all financial flows generated by HAS' new missions and by the continuation of work initiated by ANAES before it was absorbed on 1 January 2005:

- Debt securities total + € 63 289 039.
- Total costs - € 44 773 039.

Operating profit is + € 18 516 000.

Depreciation allowances of + € 1 575 522 are listed as costs but since they do not involve expenditure, these funds increase HAS' capacity for self-financing, boosting it to € 20 091 522.

This figure represents the long-term new resources created by 2005 fiscal year activity.

These resources were used for investment purposes – buying software, computer equipment, rights and tangible fixed assets – to a net value minus depreciation and transfer costs of - € 2 030 274.

Similarly:

- staff loans (not budgeted in 2005): - € 7014
- deposits (non budgetary operation): - € 448 151 €

further reduce working capital – after regularisation of € 637 of costs related to previous fiscal years – to € 17 606 082.

⁷² ACOSS: Central agency for Social Security organisations

Financial structure at the end of the 2005 fiscal year

The balance sheet permits a qualitative analysis of the structure of HAS' financial resources. The balance sheet summarises HAS' rights and obligations and describes the financial resources that are available to HAS for its missions. The balance sheet takes into account intermediate gains and losses which can be analysed in terms of the global financial situation and cashflow movements.

NB: The financial controller is not aware of any commitments that do not appear on the balance sheet (guarantees, guarantees provided etc.).

■ Stable resources and expenditure

When it was created, HAS did not receive any allocation of capital funds from the State. Its long-term resources are derived from:

- contributions from FOPIM and ANAES: € 28 281 806
- the 2005 allowance for depreciation which will finance the renewal and heavy maintenance of office buildings: + € 1 575 522.

HAS therefore has € 29 857 328 at its disposal (excluding allocation of funds to reserves or operating profit).

HAS has not contracted any loans and enjoys total financial independence in relation to any future lenders.

Apart from equipment inherited from ANAES, HAS has not received any equipment subsidy to allow it to buy the equipment required for its missions.

The operating profit increases HAS' "permanent capital" resources by € 18 516 000 to reach € 48 373 328.

Equipment and office furniture, plus financial assets (loans and deposits paid) generate a gross fixed asset value of - € 5 011 426. They absorb 10% of equity, leaving € 43 361 902 of available working capital.

■ Cashflow movements and working capital requirement:

Cashflow

At the end of the 2005 fiscal year:

- investments: € 15 908 854
- bonds deposited with the State Treasury: € 19 102 898
- cash: € 20
- cheques being processed: € 616 546
- minus cheques issued: - € 403 805

generate an active cash position of € 35 224 513.

Working capital requirement

The working capital requirement is determined by the excess of short term investments (€ 11 881 647) over short term debt (€ 3 744 257) and generates a figure of -€ 8 137 390.

HAS' available working capital covers all unforeseen events and gives the institution a solid financial structure, opening up the possibility of earning revenue from the authority's financial resources.

While the situation is relatively comfortable, the financial dependence created by HAS' statutes means that outstanding payments must be actively recovered.

HAS' financial autonomy is effectively limited in legal terms.

Operating subsidies from the State and the social security fund provided 45% of HAS' annual revenue in 2005 (28 471 M out of € 63 289 M). The 10% of contribution income that ACOSS is expected to provide (articles L.245-1 to L.254-6) represents 33% of annual revenue. However, HAS has no control over the intervals at which these payments are made.

Resolutions proposed to the Board

After reading this report on HAS' financial situation for 2005 the Board will need to approve:

- The grand total of 2005 fiscal year operations (operating and investment sections):
 - operating expenditure: € 44 773 038 79
 - operating revenue: € 63 289 039 03
 - investment expenditure: € 2 030 911 45.

- Amount and allocation of 2005 fiscal year results (1st section)

The operating profit is € 18 516 000 24.

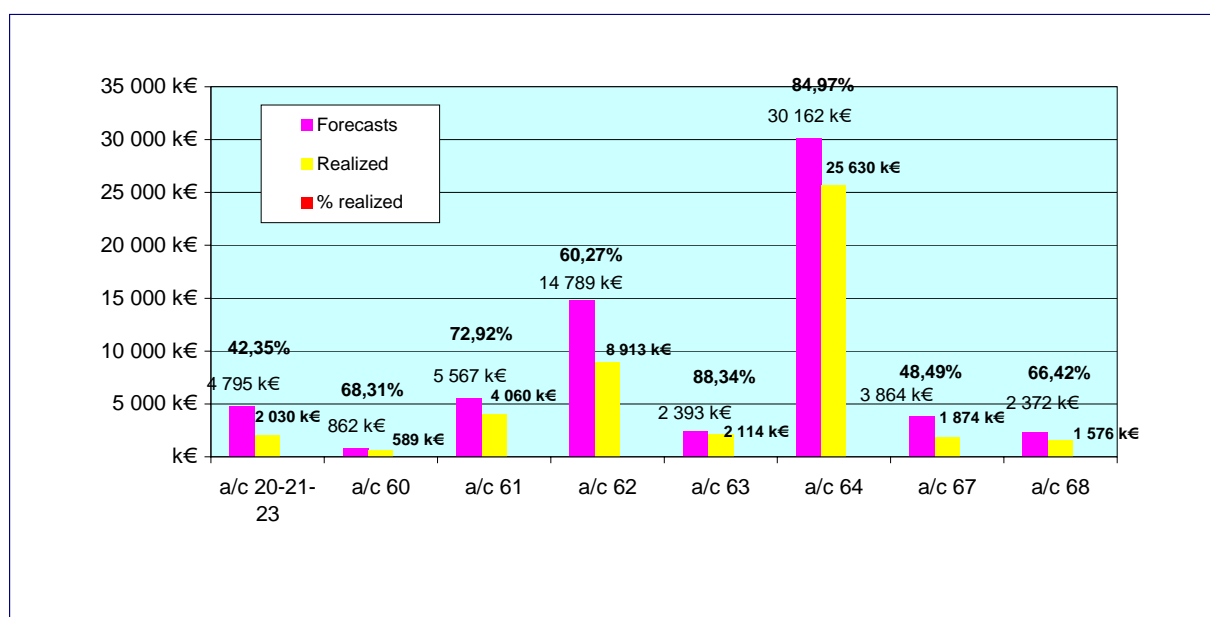
This amount is transferred to reserve funds: € 18 516 000 24.

However, the financing of fixed assets to a value of € 2 030 273 84 *de facto* reduces long-term reserve funds to € 16 485 726 40 (sum actually available).

- Depreciation periods

The depreciation periods comply with HAS' accounting and financial rules.

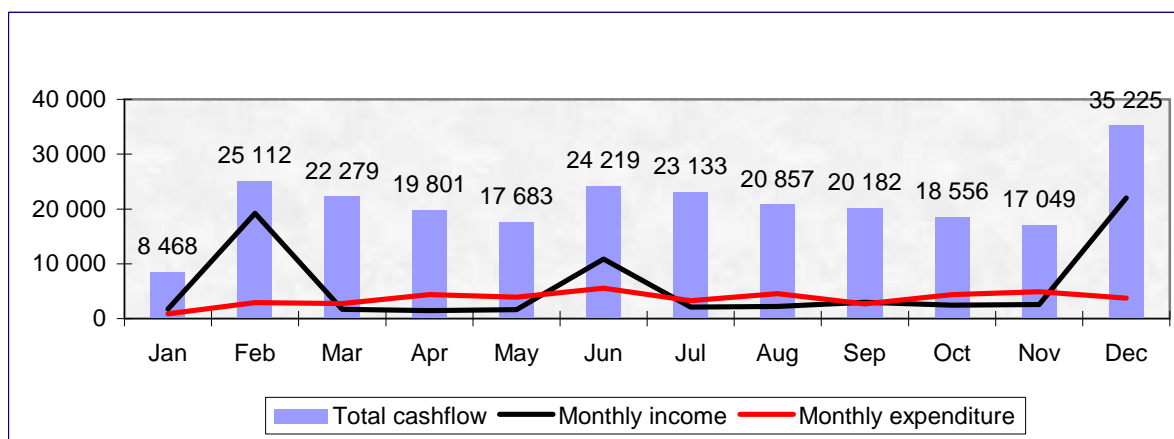
2005 budget forecast/realized (K€)



Balance sheet and results at 31/12/2005 (2005 fiscal year)

EXPENDITURE (tax not included)	In euros	REVENUE (tax not included)	In euros
Operating costs	13 561 250.78	Revenue (tax not included)	
Unstocked purchases of equipment and supplies	588 570.30	Income from operations	28 470 718.25
External personnel		Sale of goods	15.25
- temporary personnel	24 962.13	Operating subsidies	28 470 703.00
- other personnel	1 515 484.46	Total I	28 470 718.25
Other external services	11 432 233.89	Specific income	34 466 100.00
Tax and related expenditure	2 113 829.53	Financial income	186 426.72
On salaries	2 064 723.26	Other interest and assimilated income	186 403.15
Other	29106.25	Exchange gains	23.57
Personnel costs	25 630 069.36	Extraordinary income	165 794.06
Salaries	19 566 864.62	On management operations	165 794.06
Welfare charges	6 063 204.74	Total II	34 818 320.78
Allowances for depreciation and provisions	1 575 521.70	Total income	63 289 039.03
Fixed assets: allowance for depreciation	1 575 521.70	Debit balance = loss	
Other costs	18 257.00	Grand total	63 289 039.03
Total I	42 898 928.37		
Specific costs			
Financial costs	405.82		
Interest and related costs	72.21		
Exchange losses	333.61		
Extraordinary costs	1 873 704.60		
On management operations	629 985.37		
On operations in previous fiscal years	1 240 659.23		
On capital operations			
- other	3 060.00		
Total II	1 874 110.42		
Total costs	44 773 038.79		
Credit balance = profit	18 516 000.24		
Grand total	63 289 039.03		
		Summary	
		COSTS	REVENUE
		44 773 038.79	63 289 039.03
		Profit 18 516 000.24	
		63 289 039.03	63 289 039.03

Tracking 2005 cash position (in K€)



Balance sheet for 2005 fiscal year (in euros)

Assets	Gross	Depreciation & provisions	Net	Liabilities	
Fixed assets				Reserve funds	28281 806.42
Intangible fixed assets	869 242.57	647 626.65	221 615.92	Other	28 281 806.42
Concessions & similar rights	824 537.29	647 626.65	176 910.64	Carried forward	
Intangible fixed assets in progress	44 705.28		44 705.28	Profit or loss for the financial year	18 516 000.24
Tangible fixed assets	3 670 646.86	927 895.05	2 742 751.81	Total I	46 797 806.66
Other tangible fixed assets	3 670 646.86	927 895.05	2 742 751.81	Provisions for risks and costs	
Long-term investments	471 536.75		471 536.75	Total II	
Loans	23 385.50		23 385.50	Debt	
Other	448 151.25		448 151.25	Financial debt	
Total I	5 011 426.18	1 575 521.70	3 435 904.48	Operating debt	2 505 953.89
Floating assets				Accounts payable and related	2 283 432.89
Stock and work in progress				Tax and welfare charges debt	203 491.14
Advance payments on orders	21 672.26		21 672.26	Other	19 029.86
Operating debts	11 859 974.89		11 859 974.89	Miscellaneous debt	1 238 303.74
Accounts receivable and linked account	5 002 685.00		5 002 685.00	Fixed asset and related debt	1 215 282.25
Other operating debts	6 857 289.89		6 857 289.89	Other debt	23 021.49
Miscellaneous debts	35 628 318.14	403 805.48	35 224 512.66	Total III	3 744 257.63
Marketable securities	15 908 854.30		15 908 854.30	Equalization account	
Funds available	19 719 463.84	403 805.48	19 315 658.38	Liability conversion difference	
Prepayments and accrued income				Total IV	
Total II	47 509 965.29	403 805.48	47 106 159.81	Grand total (I+II+III+IV+V)	50 542 064.29
Regularisation accounts					
Expenses to be distributed over several fiscal yrs					
Total III					
Other					
Total IV					
Credit conversion adjustments					
Total V					
Grand total (I+II+III+IV+V)	52 521 391.47	1 979 327.18	50 542 064.29		

Legislative and regulatory texts

Decree no. 2006-650 of 2 June 2006 concerning continuing medical education and modifying the fourth part of the Public Health Code (regulatory provisions). (*Journal officiel*, 3 June 2006)

Decree no. 2006-651 of 2 June 2006 concerning continuing pharmaceutical education and modifying the fourth part of the Public Health Code (regulatory provisions). (*Journal officiel*, 3 June 2006)

Decree no. 2006-652 of 2 June 2006 concerning continuing dental education and modifying the fourth part of the Public Health Code (regulatory provisions). (*Journal officiel*, 3 June 2006)

Decree no. 2006-653 of 2 June 2006 concerning continuing professional development. (*Journal officiel*, 3 June 2006)

Decree no. 2006-550 of 15 May 2006 concerning sub-committees of the Medical Committee mentioned in article L.6144-1 of the Public Health Code and modifying that Code (regulatory section).

Decree of the President of the Republic dated 9 March 2006 nominating Lise Rochaix member of the Board of the *Haute Autorité de Santé*, replacing Pascale Briand, who has been assigned to other duties. (*Journal officiel*, 11 March 2006)

Decree no. 2005-346 of 14 April 2005 concerning continuing professional development. (*Journal officiel*, 15 April 2005)

Decree no. 2005-216 of 7 March 2005 concerning the *Haute Autorité de Santé* and modifying the Social Security Code. (*Journal officiel*, 9 March 2005).

Order of 13 January 2005 determining the amount of reimbursement of fixed amounts to the *Agence française de sécurité sanitaire des produits de santé* for expenses it incurs for managing FOPIM⁷³, excluding the cost of internal staff who manage the fund.

Decree no. 2004-1419 of 23 December 2004 concerning reimbursement of the cost of the products and services mentioned in article L. 165-1 of the Social Security Code and modifying the said Code. (*Journal officiel*, 29 December 2004)

Decree no. 2004-1399 of 23 December 2004 concerning the agreements mentioned in article L. 6113-12 of the Public Health Code. (*Journal officiel*, 26 December 2004)

Decree no. 2004-1398 of 23 December 2004 concerning medicinal products reimbursable by national health insurance and modifying the Social Security Code. (*Journal officiel*, 26 December 2004)

Decree of the President of the Republic of 20 December 2004 nominating the members of the *Haute Autorité de Santé* and its Chair. (*Journal officiel*, 21 December 2004)

Decree no. 2004-1368 of 16 December 2004 concerning the conditions for producing the list of reimbursable procedures and services specified in article L. 162-1-7 of the Social Security Code and modifying the Social Security Code (*Journal officiel*, 18 December 2004)

Decree no. 2004-1305 of 26 November 2004 taken in application of article L. 161-45 of the Social Security Code concerning contributions paid to the *Haute Autorité de Santé* with regard to the procedure specified by articles L. 6113-3 and L. 6113-4 of the Public Health Code. (*Journal officiel*, 30 November 2004)

Decree no. 2004-1139 of 26 October 2004 concerning the *Haute Autorité de Santé* and modifying the Social Security Code and the Public Health Code. (*Journal officiel*, 27 October 2004)

Law no. 2004-810 of 13 August 2004 concerning health insurance, articles 6 (long-term conditions – protocol), 14 (doctors' obligation to engage in continuing professional development in continuous quality improvement), 16 (accreditation of hospital doctors), 31 (medicinal products), 35 (HAS), 36 (HAS) and 42 (inclusion of procedures – administration of the Nomenclature). (*Journal officiel*, 17 August 2004)

⁷³ FOPIM: Fund for the promotion of medical and health economics information



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