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DOSSIER DE PRESSE

MEETING OF THE HEALTH INDUSTRIES STRATEGIC ADVISORY BOARD

25 January 2012

SUMMARY

The Health Industries Strategic Advisory Board

The Health Industries Strategic Advisory Board (CSIS) was set up eight years ago under the chairmanship of the Prime Minister. It is a forum for informal, open discussion and consultation for the government to more fully understand the industry's constraints, concerns and ambitions and for industry stakeholders to grasp the requirements of the different public policies so that they can adapt their corporate strategies accordingly. Following the *Etats Généraux de l'Industrie* national industry round table talks, a Sector Strategic Committee for the Health Industries and Technologies (CSF Santé) was set up by the National Industry Conference (CNI) and immediately became involved in the work to implement the Strategic Advisory Board's guidelines. This cooperation ensures that the two bodies are perfectly and, most importantly, sustainably consistent in their work.

A new era is dawning for medicine with the prospect of increasingly personalised patient treatment. This new course implies health policy changes, building a culture of "health capital management" among patients and new strategies for the health industries.

The health industries represent a strategic sector with considerable economic weight and growth potential. Together, they form a healthcare umbrella covering human and veterinary drugs (turnover of €52 billion), medical devices (turnover of €15.7 billion) and *in vitro* diagnostics (turnover of €1.7 billion). The sector's particularity is found in the wide range of businesses that it encompasses. Major national and international groups rub shoulders with a huge number of SMEs and intermediate-sized enterprises with great research and innovative potential. The health industries are having to take on board new research paradigms and prepare for the new patient care system.

In an extremely competitive international environment, France boasts scientific, industrial, medical and infrastructure assets that, provided they adapt, should ensure that it remains one of the leading world centres for treatment innovation and attractiveness for the health industries.

The fifth CSIS meeting is focusing on the entire sector from the most basic research through to the market, covering the entire value chain (research, development, production, registration, evaluation and regulation) and taking in all the stakeholders (public laboratories, start-ups, innovative biotechnology and medical device SMEs, and the major national and international groups). This focus is based on the following observations:

- Research partnerships remain the cornerstone for the competitiveness of the health industries and are based in the main on the promotion of activities conducted with the academic sector;
- The change of model for the health industries involves restructuring the sector;
- The health industries need to promote their assets in a globalised world;
- The forecasted healthcare changes by 2020 mean that preparations need to be made to deal with their organisational implications for the sector and their ramifications for society.

The CSIS is proposing thirteen possible measures and initiatives broken down by priority.

Review of the measures and initiatives proposed by the CSIS at its fourth meeting on 26 October 2009

The fourth meeting of the Health Industries Strategic Advisory Board in 2009 built a framework for consultations to develop a shared strategic vision to form a real link between public policies and industrial firms' decisions.

Whereas these sustained consultations represent a crucial achievement in terms of method, the implementation of the strategic guidelines developed by this fourth CSIS meeting also produced particularly significant operational outcomes. This progress is presented below, taking the 2009 CSIS meeting's commitments point by point.

1. Combination of initiatives by public research partners

The establishment of the French National Alliance for Life Sciences and Health (AVIESAN), a close association between major national research institutions, teaching hospitals and universities, has radically changed the conditions for the development of research partnerships by creating structures and a culture that make it easier for manufacturers to develop their research programmes without being weighed down by the plethora of potential public partners. This principle of clarity and simplification has provided a direct response to a definite need expressed by industrial players.

The success of this measure was further boosted by the simultaneous creation of the Alliance for Research and Innovation in Health Industries (ARIIS), which plays the same role of coordination between manufacturers and has become the AVIESAN's natural institutional partner.

2. Doubling the research partnership undertakings

The major industrial groups committed to a range of undertakings, which are necessarily confidential with respect to the customary principles governing business confidentiality. The aim of these undertakings was to double the sums earmarked for research projects in partnership with public stakeholders.

These undertakings were audited on two separate occasions by the government. These audits concluded that the groups had on the whole met or improved on the goals.

In particular, the work habits created by this move and the knock-on effect of flagship projects, facilitated by the abovementioned measure and structural reforms of the universities and hospitals, generated an increase in new projects that reached far beyond the initial signatory firms and was far greater than the initial volumes concerned. The measure was therefore fully effective in terms of its targeted impact as a model and a driving force, as shown by the success of the Invest for the Future Programme. With research partnerships becoming a natural way for both sides to develop projects, it is no longer necessary to renew the quantitative commitments incentive measure.

This key methodological achievement by the CSIS was naturally taken up in the preparation of the health-biotechnology partnership projects in the Invest for the Future Programme.

3. Bringing new shareholders into the biotechnologies subsidiary of the French Laboratory for Fractionation and Biotechnology (LFB)

This measure tied in with the prospective strategic development of the LFB's biotechnology activities and its implementation was dependent on changes in market player strategies and possible financing conditions. These changes have not yet occurred, although they still could. The firm, under the scrutiny of its public shareholder, continues to keep a lookout for opportunities whereby, in compliance with the LFB's mission statement and operating rules, it could form partnerships with interested players to underpin its development in biotechnologies.

4. InnoBio Fund

Manufacturers provided all of the planned financing. Once the preparations had been made to get the fund up and running, the fund was able to embark upon investment transactions on the basis of joint steering by manufacturers and the FSI strategic investment fund. In keeping with the strategy it developed, it has to date made eight investments representing two-thirds of the fund's target. This is right on schedule with respect to the fund's initially planned three-year rollout. The businesses supported, in the biotechnologies sector in the broad sense of the term, form a varied portfolio whose successful development confirms the merits of its strategy to support the creation of an innovative industrial fabric.

A report on the fund is available on http://www.economie.gouv.fr/files/InnoBio.pdf

5. Support for bioproduction

Following the fourth CSIS meeting, the Ministry for Industry (Directorate General for Competitiveness, Industry and Services – DGCIS) carried out a study on bioproduction in France. This study was published on the ministry's website and presented to a number of trade conferences. 11 of the 39 industrial sites studied are expanding and 8 are new sites under construction or conversion, representing an industrial investment of nearly €1.7 billion and the creation of some 2,000 jobs between 2006 and 2012. The study also identified ten or so projects for new bioproduction sites.

A number of projects involving healthcare manufacturers and clusters have been selected for the Invest for the Future Programme. Of mention are the Technological Research Institute (IRT) project on infectious diseases, sponsored by the Lyonbiopole cluster and the *Institut Pasteur* in Paris, and the EASE factory school, sponsored by the Alsace Biovalley cluster, a training centre dedicated to clean-room production professions to meet the needs of manufacturers faced with recruitment problems in this field.

6. Action against counterfeiting

The main advance made by the CSIS was to reinforce cooperation between the relevant services mainly with staff exchanges nationally and internationally, throughout

Europe and in international organisations (such as Interpol and WHO), but also with a sharp increase in actions tackling counterfeiting in the field. The coordination set up was extended to manufacturers, in particular with a move to closely associate technical expertise to more effectively combat the falsification of medicinal products. This cooperation was developed with the adoption of a government plan in September 2011, which the fifth CSIS meeting will implement on a long-term basis.

7. Employment and training

As regards training, with the adoption of the conclusions of the Tunon de Lara report, the relevant administrations set to work with the manufacturers to gain a better grasp of training needs. This move led to the creation of the Virtual Trades Institute (IVM), which lists all the existing basic training courses in real time and is now available on a platform open to partners. One of the upshots of the improvement in the link between training and manufacturers' needs is the appearance of experimental training courses, in Bordeaux in particular.

The spread of cooperation in training – initially basic training and eventually taking in continuous training – between manufacturers and leading training establishments will necessarily improve the match between training and employers' needs on the labour market. The CSIS is behind the development of exchanges of employment forecasts, by geographic area and by sector. This should lead to the development of new manpower and skills planning methods, whose effectiveness will be based on a real link between public schemes and corporate needs.

8. Production of generic drugs

Manufacturers who own the rights to a product can now better prepare themselves for the end of the protection of their intellectual property. They are now able to sign manufacturing agreements in France with generic drug producers, thereby paving the way for production. Although it is not yet easy to report on the numbers of industrial jobs saved or created in France by this measure, there is no doubt that it has helped protect and bolster industrial sites.

9. One-stop file for innovative medical devices

The decree to align authorisation procedures for innovative medical devices with other existing procedures to reduce lead-times while guaranteeing the same level of security was published, after consultation with the manufacturers.

10. Decree on reminder advertising

There were plans to allow, for over-the-counter drugs for which television commercials are authorised, the broadcasting, within the same commercial break, of a short slot with a voiceover repeating the brand name. This measure was unable to be adopted due to technical problems over how to govern the measure, especially from the point of view of requirements of informing consumers of pharmaceutical prescription safety rules. These proved to be inextricably linked with the consideration of self-medication and its safety conditions as a whole, on which a thorough discussion will be launched by the fifth CSIS meeting.

11. Website on epidemiological data

As planned, the AVIESAN has pooled all the epidemiological data collected from its partners. This data has been available on a website since 1 January (epidemiologie-france.aviesan.fr). This major advance is just the first step on a road that the fifth CSIS meeting is mapping out, in particular by putting the more general question as to guarantees regarding the use of the data.

12. Dual pricing for exports

Following a first attempt that was blocked by the *Conseil constitutionnel* (Constitutional Council) purely on procedural grounds, Parliament adopted a measure included in the bill to improve the safety of healthcare products. This measure will remove some of the structural obstacles hitherto encountered by manufacturers established in France endeavouring to export the healthcare products they produce. In the coming weeks, this provision will be made fully effective by an implementing decree and the negotiation of an implementation agreement.

List of measures and initiatives proposed by the CSIS

Develop research partnerships

1. Scale up public-private research partnerships
2. Step up translational and clinical research
3. Develop France's work on excellence in pharmaco-epidemiology
4. Launch a debate on the continuous assessment of drugs and innovative therapeutic solutions

Structure the health industries sector

5. Create an observatory for the French health industries sector
6. Develop France's attractiveness for innovative medical device firms
7. Conduct an audit of the tax environment for healthcare product firms in France and Europe

Promote our assets in a globalised world

8. Maintain and develop industrial production in France, including for biodrugs
9. Prevent and combat counterfeiting and the falsification of healthcare products
10. Deploy an assertive policy to build employment and youth employment and to adapt training

Make preparations for the healthcare changes

11. Make France a leader in groundbreaking innovations, multi-technological solutions and personalised medicine
12. In a context of improved safety for healthcare products, develop responsible self-medication in France
13. Launch a multidisciplinary debate on developing local healthcare in the future

Measure no. 1: Scale up public-private research partnerships

With the CSIS's work in 2009 and the Invest for the Future Programme, government and manufacturers have laid sound foundations to facilitate and development public-private R&D partnerships. Without needing to create new structures, a certain number of recommendations are made here to optimise the basic research - innovative industrial research - development continuum.
The Invest for the Future Programme forms part of this public-private partnership strategy to embark on major programmes in support of excellence in healthcare and biotechnologies. Two specific programmes have been set up for biomedical research (teaching hospital Institutes -IHU- and the healthcare and biotechnology programme), giving it a huge opportunity to support the vitality of French research and catch up on its lag in the acquisition of certain technological equipment. The French government has earmarked €2.4 billion for these two programmes in a move to boost excellence in research and innovation in this sector.

The CSIS proposes the following measures or initiatives:

Simplify the partnership formation process
The CSIS proposes defining a framework research contract negotiated by representatives of academic research, market segment development consortiums and industry to stream line and speed up the contract procedure. The French National Alliance for Life Sciences and Health (AVIESAN) and the Alliance for Research and Innovation in Health Industries (ARIIS) will work with the technology transfer acceleration companies (SATT) on finding alternative ways of organising flat-rate remuneration for the public partner based on joint research findings able to facilitate contractualisation in certain situations. In addition, it is important to be able to take more account of the formation of public-private partnerships in the evaluation of the researchers.

Promote the cross-disciplinary nature of all innovative healthcare research
The idea is to foster the creation of shared platforms and the financing of cross-disciplinary healthcare projects (backed by shared platforms or set up by direct public-private interaction) associating public and industrial laboratories (especially innovative SMEs) and involving at least two technological fields and an innovative health care challenge (e.g. biology pharmacology and diagnosis, diagnosis and remote treatment, etc.).

Optimise the use of medicinal compounds as a research tool
The goal here is to make advances in therapeutic research by encouraging AVIESAN and ARIIS to work on how to organise exchanges between firms and academic laboratories of molecules and targets for potential drugs while remaining in compliance with intellectual property rights.

Support the development of public-private partnerships
In harmony with the French fabric of SMEs and scientific and technological services, the CSIS is requesting AVIESAN and ARIIS to put forward a charter of best practices for services and research in research partnerships.

Measure no. 2: Step up translational and clinical research

Translational research bridges the gap between basic research and clinical research, considering the patient in both a complex individual context and within a patient community setting. Public-private partnerships should be established in an appropriate environment driven by infrastructure and facilities, particularly those financed by the Invest for the Future Programme, the emergence and consolidation of which should be accelerated. In a context of international competition, France's clear coordination structures and simplified contractual relationships make it an attractive country for clinical research.

The CSIS proposes the following measures or initiatives:

Foster translational research

Projects selected for the Invest for the Future Programme provide unprecedented opportunities. They include the six teaching hospital Institutes (IHU) and the Lyon Biotech Technological Research Institute, innovative platforms in clusters, pre-industrial demonstrator facilities, laboratories and equipment of excellence, biology and health facilities (e.g. F-CRIN, biobanks and cohorts) and integrated cancer research facilities selected by the *Institut National du Cancer* (INCa) under the government's Cancer Plan.

To make the most of these opportunities, the CSIS proposes the following initiatives:

- Coordination between the people running these facilities;
- Publishing a best practices guide for public-private research, including how to access clinical data and/or biological resources;
- Raising the profile of existing facilities and areas of excellence, and posting a list of all facilities on a single site with contact names and a description;
- Promoting training and specific careers in translational medicine and clinical research, with gateways between academic and clinical, public and private research.

Promote clinical research

A key priority is to secure resources devoted to recruiting patients for large-scale clinical trials in a hospital environment through the CeNGEPS public-private partnership.

It is important to build an optimum relationship between existing facilities (clinical investigation centre, clinical research centres, etc.), facilities created under the Invest for the Future Programme (see above) and other clinical research programmes (PHRC, PSTIC, CeNGEPS, etc.) in order to guarantee a nationwide level of excellence and international recognition of French clinical research. The CSIS will carry out a census of all facilities and units.

The CSIS recommends working on simplifying contractual relationships and making financial flows more transparent within the hospital setting. This could be done through a national foundation overarching the hospital foundations created by the act on hospital reform, patients, health and regional organisation. This initiative should result in the signing of a single contract.

Measure no. 3: Develop France's work on excellence in pharmaco-epidemiology

Pharmaco-epidemiology is a key means of acquiring and improving knowledge in healthcare, research and development, observing and monitoring practices, and measuring and monitoring the real benefits and risks of drugs and other healthcare products. It guides public health policies. It must make France an attractive location by restoring its role on the world stage in this area through a valuable contribution to international research.

The 2009 CSIS meeting already underlined the importance of this area and identified measures to promote its development. The "Epidemiology France" portal,[1] established in June 2011, came about as a result of cooperation between government and industry – the French National Institute of Health and Medical Research (INSERM), the Public Health Research Institute (IReSP), the Directorate General for Competitiveness, Industry and Services (DGCIS) and the industry association *Les Entreprises du Médicament* (health industry representative association - LEEM). The portal must now be made into a fully operational ongoing resource.

The CSIS proposes the following measures or initiatives:

Continue to develop the "Epidemiology France" portal
Improvements will involve:
- Developing its functionalities, particularly in the English version which has just been put online;
- Enriching its content in terms of research, reports and publications;
- Strengthening communication to ensure a satisfactory profile and optimum use both in France and internationally.

Facilitate new research and studies using data provided by the SNIIR-AM database and the PMSI

Encourage the development of research and expertise in pharmaco-epidemiology focusing on the patient's care record
The goal is to:
- Develop training programmes in pharmaco-epidemiology and pharmaco-economics in relationship with the universities and *grandes écoles*, particularly within a continuous professional training setting;
- Make resources available to provide health industry players (health authorities, academic research, industrial research) with information in the area of public health, patient safety and pharmaco-economics.

Providers of healthcare data in France agree to contribute to enriching the "Epidemiology France" portal. Ongoing funding must be secured and allocated among the various public and private stakeholders.

As regards public health studies, the method of interaction between industry and the public interest group (GIP) established under the recent act on improving drug and health product safety will be set out in the implementing decree.

[1] https://epidemiologie-france.aviesan.fr/

Measure no. 4: Launch a debate on the continuous assessment of drugs and innovative therapeutic solutions

Following a series of health scares, new ways of improving the process of assessing drugs and therapeutic solutions that meet real health needs must be found. This focus on health safety is crucial to maintaining the French people's confidence in health products. Measures were set out in the act of 29 December 2011, which was the result of in-depth collaboration between the government and the health industry.
The current economic environment also dictates the need for better assessment in order to identify which health products should be eligible for reimbursement. The French assessment model, which is based primarily on medical benefit, should be the forerunner of an emerging European model to be developed in a spirit of co-operation between all parties.

In keeping with the spirit of the act on improving drug and health product safety, the authorities wish to obtain a sufficient level of scientific certainty to eliminate any reasonable doubt over potential harm to patients, while at the same making sure that patients have access to therapeutic progress. In other words, we need to reconcile patient protection and safety with the ethical need to ensure that patients do not miss out on the benefits of innovative treatment. The health industry has perceived a wind of change in the assessment paradigm, related to an increased fear of uncertainty. This is an underlying, lasting trend that is not specific to the health sector.

<u>The CSIS proposes the following measures or initiatives:</u>

The CSIS proposes a broad, concerted debate on continuous assessment methods and criteria as well as their purpose, particularly in terms of listing and reimbursement decisions.

The debate will focus on the following areas:
- Improving quality monitoring of the benefit/risk ratio for products marketed in a real life context, based on an objective and controllable methodology;
- Defining the concept of medical need for assessing therapeutic strategies;
- Ensuring that patients have swift access to innovative therapies by basing reimbursement decisions on medical need and a prior exchange with the authorities on the development plan;
- Agreeing on continuous benefit assessment methods incorporating a medico-economic dimension in order to confirm and strengthen the benefits to the community;
- Ensuring transparency, clarity and predictability;
- Strengthening the two-way procedure.

Measure no. 5: Create an observatory for the French health industries sector

The French health and health technology industry is a strategic sector with substantial economic power and growth potential. In an extremely competitive international environment, France has the scientific, industrial, medical and infrastructure strengths to remain one of the leading global centres for therapeutic innovation and industrialisation of health products.
The sector must be able to compile the key data required for analysis and action plans shared by the public authorities and the industry.
The creation of an observatory for the French health industry will contribute to this.

The health industry is a strategic sector with substantial economic power and growth potential. It embraces human and veterinary drugs, medical devices and *in vitro* diagnostics, all of which have a common objective. One of the specific features of the sector is the number and diversity of its constituent companies. Alongside the large national and multinational groups there are many SMEs and intermediate-sized enterprises with huge research and innovation potential... France needs a strong industrial base to ensure that it has the ability to develop tomorrow's innovations, companies and jobs in France. The strength of the industrial base over the next few years will depend on the ability of industry players to maintain a sector supported by an ambitious industrial health policy.

The CSIS proposes the following measures or initiatives:

The CSIS proposes to establish an observatory for the health and health technology industry, for the purpose of:
- Compiling shared data and building indicators in order to:
  - anticipate changes in the sector,
  - draw up and follow sector or non-sector public policies and their impact on the industry,
  - measure the impact of industrial strategies on the national economy;
- Convincing foreign investors to come to France and create wealth and jobs.

The DGCIS and the *Fédération Française des Industries de Santé* (FEFIS) will inaugurate this project using available public data (INSEE, data.gouv.fr, etc.) and private data (professional bodies, Cartéofis, etc.).

Measure no. 6: Develop France's attractiveness for innovative medical device firms

France has always been at the forefront of innovation in medical devices. It was a pioneer of minimally invasive surgery, interventional cardiology and percutaneous valve replacement. However, it does not have a highly structured industrial base and is not considered an attractive enough country for this industry. Its regulatory environment is changing rapidly (act on improving drug and health product safety, master agreement with the Economic Committee on Health Care Products – CEPS).

The CSIS proposes the following measures or initiatives:

Create a investment fund dedicated to medical devices (InnoMedTech)
This fund will invest in innovative SMEs involved in medical technologies (imaging, instrumentation, diagnostics and medical devices), providing equity to young companies from the experimentation stage right through to concept proof and product marketing. It will operate in a similar way to the InnoBio fund. The purpose is to accelerate the creation and development in France of innovative SMEs in the field of medical technologies and to create a mesh of companies that could produce one of tomorrow's European or global leaders. InnoMedTech will be capitalised by the FSI strategic investment fund and industrial companies in the sector, which will be involved in the fund's governance.
A description of the InnoMedTech fund is available here http://www.economie.gouv.fr/files/InnoMedTech.pdf.

Strengthen biomedical research into innovative medical devices
France has genuine expertise in technological and clinical research that can help increase its ability to attract companies involved in innovative medical devices.
The CSIS proposes initiating a debate on how to develop centres of specific expertise geared towards assessing medical devices and developing skills and resources in clinical research.

Accelerate the process of listing a medical procedure associated with a new health product
These are procedures associated with a medical device or another health product such as an innovative therapeutic drug. An innovative medical device is only available to patients if the new medical procedure required for its use is assessed and created by the CCAM and then priced by the CNAM. The faster the procedure is created and priced, the sooner it will become available on the market. As recommended by the CSIS in 2009, a decree has been published enabling a procedure associated with an innovative medical device to be priced within 180 days. Today, three innovative technologies (2 medical devices and one procedure) have been listed under this exceptional process under article L165-1-1 of the French Social Security Code.
At present, only the learned societes can apply to the National Commission for the Assessment of Medical Devices and Health Technologies (CNEDiMTS) for assessment of a new procedure. In these conditions, we need to accelerate the timeframe and application process for the CNAM's pricing of new procedures associated with innovative medical devices assessed by the French National Authority for Health (HAS), by implementing the coordination procedure advocated by the CSIS in 2009.

The CSIS proposes setting up a monitoring group dedicated to the medical devices sector.

Measure no. 7: Conduct an audit of the tax environment for healthcare product firms in France and Europe

The health sector is subject to a set of specific taxes that are applied in different ways. The resulting overall taxation structure is complex. Whilst preserving the level of expected resources and in order to ensure that the right incentives are put in place, it would seem appropriate to perform an overall audit of this structure factoring in the specific features of the three main segments of the industry: drugs, medical devices and *in vitro* diagnostics. The General Inspectorate of Finance (IGF) and the General Inspectorate for Social Affairs (IGAS) will be mandated to perform the audit and outline any recommendations to be included in the regulations, for implementation as of 2013.

Apart from standard national and local taxes, health product companies are subject to thirteen specific taxes and levies that were originally intended to finance the health agencies and control health insurance expenditure. The successive introduction of these taxes and levies for various purposes and in varying ways has led to a complex tax structure for the health sector, which in some respects can lack coherence with the regulatory tools. In addition, we need to make sure that the resulting incentive effects are actually those sought more generally by the public health and sector competitiveness support policies.

The CSIS proposes the following measures or initiatives:

Without changing the level of expected resources, the aim is to examine how the current tax structure could be made more efficient, particularly by better incorporating industrial issues and issues related to France's attractiveness. Areas to be explored are:

- Simplifying tax collection processes;
- Providing incentives to innovate, invest and pursue good commercial and environmental practices;
- Ensuring consistency, clarity and predictability.

Following the CSIS meeting, the IGF and IGAS will be asked to:

- Carry out a review and a comparison with the main European countries;
- Set out the political guidelines on which to base taxes adapted to sector and health insurance issues, on a level yield basis;
- Recommend the implementation instruments and tools (2012 social security finance bill, master agreement between the Economic Committee on Health Care Products – CEPS and the health industry representative association (LEEM) to be revised before the end of 2012, decrees, etc.).

The work will be carried out in the first half of 2012.

Measure no. 8: Maintain and develop industrial production in France, including for biodrugs

Industrial production plays a pivotal role in the life cycle of a drug. Whilst France has historically been a major industrial player, the changes sweeping through the sector are weakening its pharmaceutical manufacturing industry.
In order to preserve the manufacturing base and maintain production volumes in France and Europe, the following initiatives are proposed:

- **Encouraging, for reasons of clarity for the consumer, the provision of simple, clear information about where the key stages of health product manufacturing take place and making the social and environmental service provided an element of government/industry negotiations;**
- **Providing incentives to develop bioproduction on an industrial scale based on recently developed innovative technologies, in line with the increase in national and international demand.**

The CSIS proposes the following measures or initiatives:

In keeping with the last CSIS, the following initiatives will be introduced:

- Continue the measures agreed by the 2009 CSIS meeting to preserve European pharmaceutical sub-contracting facilities that manufacture pharmaceutical specialties, especially generics;
- Encourage, for reasons of clarity for the consumer, the voluntary provision of simple, clear information about where the key stages of health product manufacturing take place, leveraging the social and environmental service provided (e.g. controlling air and water emissions and medical waste management). The method of doing this will be determined by the industry in conjunction with the professional organisations;
- Support the growth of biotechnology SMEs by giving them the means to progress from R&D to industrial production and marketing of biodrugs;
- Promote knowledge of new French bioproduction players (precompetitive public platforms, SMEs involved in technology and innovative industrial production) particularly among other biotechnology companies developing innovative therapies (therapeutic proteins including antibodies, new generation vaccines, gene therapy, synthetic biology products, etc.), the pharmaceutical manufacturing industry and investors. The idea is to incorporate this industrial dimension into the health industry observatory.

To give various projects a better chance of coming to fruition, public and private stakeholders will be able to draw on support from the relevant competitiveness clusters in conjunction with the DGCIS.

Measure no. 9: Prevent and combat counterfeiting and the falsification of healthcare products

Counterfeit and falsified health products are a threat for both patients and the industry. This is a national issue that requires concerted action by the government departments through tangible measures involving all public and private operators.

The CSIS proposes the following measures or initiatives:

The general plan for combating counterfeit health products presented to the *Conseil des ministres* (Council of Ministers) on 7 September 2011 will be fully rolled out. It will ensure that public-private initiatives are complementary and properly coordinated and will strengthen national and international co-operation between the relevant government authorities. The priority implementation of this operational project will not only provide the essential protection for industry innovations but will also help strengthen consumer confidence in health products.

The plan is based on the following priority initiatives:

- Conducting a wide-scale national campaign to raise public awareness about Internet risks, in partnership with health professionals (pharmacists and doctors);
- Fully mobilising the French authorities at European and international level on the importance of implementing the following legislation:
  - the Medicrime convention: by promoting a French initiative aiming to extend the convention beyond the Council of Europe;
  - the "falsified medicines" directive: mainly by establishing a legal secure online system, strengthening controls and developing technological security measures;
  - revised Customs Regulation 1383/2003: by asserting the customs authority's responsibility in supervising compliance with intellectual property rights, including products in transhipment or transit;
- Promoting ongoing national and international cooperation between the relevant government authorities, introduced as part of various initiatives such as Operation Pangea – in particular in the form of shared warning and cooperation arrangements;
- Setting up an "anti-counterfeit drugs taskforce" that will compile data from all sources (public and private) and publish results and trends. The taskforce will seek to involve other internet players such as ISPs, payment services providers, data carriers, domain name hosts, etc.;
- Strengthening operational cooperation by setting up partnerships ("LEEM Customs Charter", anti-counterfeiting online charter) at national and international level, and rationalising contacts points between the various players.

A report on anti counterfeiting initiatives is available here http://www.economie.gouv.fr/files/Contrefacon.pdf

Measure no. 10: Deploy an assertive policy to build employment and youth employment and to adapt training

The health industry is faced with a changing economic, technological and regulatory environment forcing it to adapt its organisation structures and occupations. The sector is resilient in terms of employment compared with other industrial sectors. However, sector restructuring is putting pressure on some activities, in particular medical sales representatives, whilst leading to the emergence of new unsatisfied needs (in R&D, bioproduction, etc.). These changes require finer and even more forward-looking business management and planning, as well as gearing skills to evolving jobs and technologies.

The CSIS proposes the following measures or initiatives:

Develop the virtual health industry jobs institute

The virtual health industry jobs and training institute (IMFIS) is being launched at the same time as this CSIS meeting: www.imfis.fr. This website, which was built by the National Office for Education and Career Information (ONISEP) in partnership with the Ministry for Higher Education and Research and the health industry, will be enriched during 2012. It will include occupations specific to certain segments of the industry, followed by an area dedicated to partnerships and education/industry cooperation and learning innovation. In due course, it will enable the industry and the universities to jointly forecast needs related to the emergence of new occupations or trends in certain sectors.

Promote the employment of young people in the health industry and preserve jobs in the sector in France

This initiative involves:

- Establishing a “Industry/Youth” employment pact to act as a springboard for providing young people with jobs: welcoming and mentoring young people coming out of secondary and higher education by businesses, communication on occupations in training institutes, making training courses more vocationally-oriented, etc.;
- Doubling the number of work/study contracts in the next five years, taking account of the current ratio of work/study employees to total employees, in particular by supporting the introduction of apprenticeship diplomas for the health industry. This effort will be taken into account in the government/industry agreements;
- Continuing with 2009 CSIS measures, particularly the next stage in the programme to plan and forecast changes in the sector with regard to employment in R&D and manufacturing, and pilot tests in regional employment/training (forward planning contracts – CEPs).

Encourage excellence in training

This involves preparing for tomorrow’s jobs and talent in the sector by promoting teaching and training platforms specialising in life and health sciences.

Promote training in strategic health biotechnology skills

This will involve supporting a pilot university/industry cooperation project for training in systems biology/biological engineering and rolling out a continuous training programme for staff in biotech SMEs.

Measure no. 11: Make France a leader in groundbreaking innovations, multi-technological solutions and personalised medicine

Groundbreaking innovations (cellular and regenerative medicine), multi-technology solutions and personalised medicine involve combining one or several curative or preventive medical therapies (pharmaceutical or biological), surgical therapies or interventional therapies (medical procedures or devices) with diagnostic tests and/or predictive tests (of effectiveness or toxicity), or with services (remote consultation for example). These new solutions are booming in France and therefore require specific effort in terms of assessment and reimbursement, which must be coherent with or even play a driving role in European practices.

The CSIS proposes the following measures or initiatives:

Promote R&D partnerships in emerging fields

The main objective is to set up a platform of exchange between the industry and information solutions providers to promote joint research and development of multi-technology solutions.

With the aim of developing cellular therapy and regenerative medicine, which as innovative therapies are considered to be drugs, we also need to support the development of specialised industrial platforms.

As regards telehealth, in line with the national strategy for e-health adopted by the *Conseil des ministres* (Council of Ministers) in June 2011, all players in the value chain should be involved, including future users. The design and development of living labs should factor in the organisational dimension, including non-standard services and new medical procedures, as well as the human and social dimension.

Deal with the issue of reimbursement and price setting of groundbreaking innovations and multi-technology solutions

The HAS's implementation of a coordinated and concurrent assessment procedure for the overall multi-technology solution would provide greater clarity for the industry.

Coordination between the Economic Committee on Health Care Products (CEPS) and the National Union of Health Insurance Funds (UNCAM) would facilitate a synchronised listing of all the modules of a multi-technology solution in line with the measures proposed by the 2009 CSIS meeting. By setting up a quick, clear procedure for making these groundbreaking innovations available on the market, France would play a leading role.

The CSIS proposes creating a steering committee for groundbreaking innovations bringing together research organisations, industrial companies and financing agencies. It recommends that France commit to developing targeted programmes for these groundbreaking innovations.

The industry and the government undertake to work together on all the regulatory procedures for getting groundbreaking innovations onto the market, in particular as regards the maximum time period for the listing application process, including the concurrent listing of the associated procedure or test, and on leveraging the development of the accompanying bio-marker in the CEPS's master agreements with the industry representative organisations.

Measure no. 12: In a context of improved safety for healthcare products, develop responsible self-medication in France

Self-medication following the advice of a pharmacist is a therapeutic response adapted to the needs of patients for benign pathologies.
It implies having a sufficiently wide range of drugs available on a pharmacy care and advice basis to meet patient needs, provided that the indications specifically include self-medication on this basis.
The delisting of some drugs may lead to growth in self-medication. In this case, it is essential that a drug's indications are compatible with self-medication criteria: self-administration by the patient without the intervention of a doctor to identify the clinical situation, the need for and length of the treatment.
It also means that the status of the drug will have to change from prescription to non-prescription for a specific indication, presentation and dosage adapted to self-medication purposes.
France does not have the same approach as some of its European neighbours: some drugs that have already been delisted in other countries could also be delisted in France. The delisting process must be strictly defined in order to reconcile patient safety with sufficient incentive for the pharmaceutical companies, based on the quality of assessments and opinions expressed.

The CSIS proposes the following measures or initiatives:

Making new drugs available to pharmacists and patients for self-medication purposes would drive growth in this market. It would enable pharmacists to play a full advisory role in the areas of responsibility devolved to them and would give patients the option of treating themselves with drugs specifically approved for self-medication use. These new pharmacy care drugs would be made available chiefly through delisting. The process would involve changing the status of a drug from prescription to non-prescription for a specific indication, presentation and dosage adapted to self-medication use.

It must be made quite clear that the decision to delist a drug, relating to the scope of reimbursed drugs, for certain indications is not a judgement on its quality and does not preclude its use in self-medication where the indications permit.

The public authorities and the non-prescription drugs industry will initiate a discussion on this issue and review the position in other European countries. Pharmacists and patient representatives should be involved in the process. The discussion will consider the safety and effectiveness of long-term use for the relevant pathologies and on that basis define the delisting conditions or conditions for making new molecules available to pharmacists and patients for self-medication purposes.

Measure no. 13: Launch a multidisciplinary debate on developing local healthcare in the future

French people consider their health system to be a "pillar of the republican pact". The system guarantees everyone health insurance and quick access to the care they need throughout the entire country.
To preserve this system, a new approach to care must be developed:

- **Shift from a medical model focusing primarily on care (overall treatment of acute illnesses), which takes place in specific places (hospitals, doctor's surgeries, analysis laboratories, etc.) to a more individualised medical model focusing on caring for patients in their homes, which is mobile;**
- **Supplement the curative model with prevention: support people throughout their lives, both in sickness and in health, in their homes, with a view to preventing the occurrence of chronic disease and to limit its effects;**
- **Take advantage of the healthcare profession's desire to work in a more cooperative way and people's desire to take a more active role in protecting their health to propose different organisational models, for example by involving families and social workers.**

The CSIS proposes the following measures or initiatives:

The CSIS proposes initiating a forward-looking, multi-disciplinary debate to examine ways to promote and develop health in the community:

- The debate will be led by a committee made up of citizen and patient representatives, healthcare professionals and institutional and industrial stakeholders**;**
- The committee will be tasked with thinking about how to promote and develop health in the community and how to make France a leading, attractive country in this respect;
- The committee's work will focus on four areas: prevention and screening, critical medical care, chronic medical care, disability and dependency. In each of these areas, the committee will:
  - conduct a review of the parties involved and practices, healthcare needs, supply to fulfil these needs, and obstacles identified by the parties involved,
  - make an assessment of experiments conducted and in progress,
  - define a shared strategy on development priorities,
  - draw up a list of organisational, legal, regulatory and financial proposals to help implement the strategy.