Interview: Jean-Luc Harousseau â?? President, Haute AutoritÃ© de SantÃ© (HAS; French National Authority for Health), France

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The president of HAS sheds light on the seemingly complex French healthcare system, explains HASâ?? role within that context and provides an honest assessment of the systemâ??s advantages and flaws. He also discusses the issues of maintaining the sustainability of the French healthcare budget and the importance of increasing European coordination and cooperation in the healthcare sector.

The French system has been called a *millefeuille* (multi-layered) administration, with the Social Security, ANSM, CEPS and HAS. What is the exact role of HAS among all these institutions?

The French system is not as complicated as the private sector may make it out to be. We have the ANSM, which can be seen as the French European Medicines Agency (EMA), and is in charge of security, licensing, pharmacoviligance: fundamentally, the benefit-risk ratio for drugs, medical devices and all safety-related procedures.

HAS is an independent health technology assessment (HTA) body set up in 2004, with the general mission of promoting quality of care and patient safety. Within this general mission, there is the specific mission of health technology assessment, and another to promote good clinical practices, appropriate patient and hospital pathways and healthcare organization. The primary objective is quality: how to define and fund the best therapies and how to best organize the healthcare system for patients. It is equivalent to the National Institute of Health and Care Excellence (NICE) in the UK. We assess new drugs, as well as reassess old ones, every five years.

As our institution has evolved, we have gradually begun to focus on efficiency as well in the assessments of diagnostic and therapeutic strategies. Since 2013, we compare innovative new drugs or medical devices with existing treatments not only for their therapeutic added value but also for their cost/effectiveness ratio. This is ultimately done for the purposes of pricing and reimbursement negotiations (health technology assessment). We may use the same data as ANSM but for completely different purposes. Within the HAS, for drugs, this is done through the Commission de la transparence (The Transparency Commission) and for medical devices, it is done through the Commission nationale dâ??Ã©valuation des dispositifs mÃ©dicaux et des technologies de santÃ© (CNEDiMTS; the Medical Device and Health Technology Evaluation Committee).

CEPS negotiates pricing with pharmaceutical companies, based on several parameters: our ASMR (therapeutic added value) decisions, benchmark prices, other countries due to our system of reference pricing and volume considerations, and more recently cost/effectiveness ratio. We also have SÃ©curitÃ© Sociale (French Social Security) with the Assurance Maladie, which is the mandatory public health insurance, and this insurance system is complemented by private or semi-private insurers. The final decision on whether a drug should be put on the list of reimbursable drugs is then taken by the Ministry of Health.

Can you elaborate on HASâ?? assessment process?

We have two appraisal indicators: the Service mÃ©dical rendu (SMR; medical benefit) and the AmÃ©lioration du service mÃ©dical rendu (ASMR; improvement of medical benefit). The SMR looks at factors like patient subpopulations, burden of disease, and most importantly the benefit/risk ratio. This is for reimbursement and there are two decisions to be taken: firstly, whether the drug should be reimbursed at all, and secondly, to what level? There are four levels in our assessment corresponding to different reimbursement levels: insufficient, weak, moderate and important. For instance, for a drug judged insufficient, the lowest on the scale, the drug would not be reimbursed by Assurance Maladie and therefore not by private insurers at all, which means a patient would have to pay for 100 percent of the cost. Drugs that would normally fall under this category are for non-severe diseases. On the contrary, for a drug judged important, the highest on the scale, Assurance Maladie would pay 65 percent of the cost and private/semi-private insurances will cover the rest. The major exception is for chronic and severe diseases like cancer, which are fully covered. This is 15 percent of the patient population but accounts for over 60 percent of total healthcare expenditures.

The ASMR assesses the clinical added value of a therapy to either a benchmark or an existing treatment, where available. There are five levels, and for the lowest level, grade 5, the drug should technically be cheaper than existing options but this is not always feasible. For instance, new anticoagulants, developed in the past decades, had very large and expensive clinical trials but it did not constitute a great improvement over the existing option, Warfarin. However, because the R&D expenditures were so high, the CEPS could not offer a price lower than that of Warfarin, even though healthcare professionals do not consider these new drugs a major improvement over Warfarin.

A recent change in 2013 through the Project de loi de financement de la sÃ©curitÃ© sociale (PLFSS; the French Social Security Finance Bill) gave us the additional mission of conducting

medical assessments for new therapies that are simultaneously very innovative and very expensive. This is done under another committee that I chair, the Commission Ã©valuation Ã©conomique et de santÃ© publique (CEESP; the Economic and Public Health Evaluation Committee). The assessment model is based on the ratio diffÃ©rentiel coÃ»t-rÃ©sultant (RDCR; the Incremental Cost-effectiveness Ratio, ICER), which is a standard statistic used in healthcare cost-effectiveness assessment and compares drug costs with drug benefits, defined in terms of QALY (quality-adjusted year of life).

A common theme we have heard is that France has a great healthcare system but there are some areas where it could learn from other European countries. How do you think the French system compares to other European healthcare systems?

The introduction of medico-economic assessment in France led to comparisons with the UK and raised concerns as regards possible rationing. But there is a difference in France, which is that companies negotiate pricing decisions with CEPS based on HAS assessments whereas for NICE in the UK, it is a binary decision: either they reimburse you or they do not. NICE uses a threshold while we donâ??t. If the ICER is over the threshold they may decide not to reimburse, then the companies have to negotiate individually with local patient access schemes, which is more complex.

It is also not true that Franceâ??s prices are very unfavourable compared to other countries. Firstly, usually the critics only take official prices into account. There are unofficial rebates between pharmaceutical companies and authorities in all countries and the unofficial or final prices are unknown. Secondly, in France, there is a pricing contract between CEPS and LEEM, which mandates that, for a very innovative drug (which scores level 3 or higher on the ASMR scale), the price cannot be lower than those in major European countries, specifically UK, Germany, Italy and Spain.

However, there is some merit to the argument that the current appraisal system is too complex. In 2011, HAS proposed replacing both the SMR and ASMR with a single index called the Index thÃ©rapeutique relatif (ITR; Relative Therapeutic Index), similar to Germanyâ??s â??added valueâ?? approach. This is to increase transparency, predictability and objectivity. Currently, the SMR/ASMR is done by a committee, which has some element of subjectivity. An algorithm, not as strict as Germanyâ??s, may be an improvement. In addition, as the SMR focuses on the benefit-risk ratio, it does duplicate and overlap significantly with ANSMâ??s assessment process. The single index system would be more in line with those in other European countries, but this proposal has yet to be accepted by the relevant authorities.

To be very frank, HAS is an independent public authority, not a government agency. As a result, there is some reluctance on the governmentâ??s part to give HAS too much power, which has made it difficult for us to push for any significant improvements to the system.

Patrick Errard, President of Les entreprises du mÃ©dicament (LEEM; the French pharmaceutical association) has called for new measures to ensure the fairness and transparency of the system after the decision was made to no longer allow the pharmaceutical industry to be represented on HASâ?? Transparency Commission. What does this mean for the relationship between health authorities and the pharma industry?

This decision was enforced by a law that came into effect in 2011 after the controversial Mediator scandal in 2011, which resulted from conflicts of interests regarding off-label prescriptions that resulted in severe adverse events and ultimately some fatalities. The law was expressly intended to increase transparency within the healthcare system and particularly in terms of situations where potential conflicts of interest could arise. Having a representative from LEEM on the Transparency

Committee is an example of a potential conflict of interest and so we had to change our system. It is understandable that pharma companies want to understand our decision-making processes. We will provide more channels of communication with them. We will set up regular meetings with LEEM to discuss key issues. We have made audio and stenotyping recordings of our sessions available to pharmaceutical companies. Finally, there is a mechanism through which pharma companies can request hearings with us if they do not agree with our decisions. There are ample opportunities for discussions and interaction between the public and private sector in this regard.

Given the dramatic increases in medicine costs in recent times, will the French system of universal and unlimited access to the latest healthcare innovations be sustainable in the future or will something have to be sacrificed?

France is currently a very generous country that provides equal healthcare access for all patients, local or foreign, and we have rapid access to innovation through the Autorisation temporaire dâ??utilisation system (ATU; the French Temporary Authorisations for Use system). However, the recent emergence of very innovative drugs will affect this. There are already examples of this: the Sovaldi issue in 2014 and some recent immuno-oncology drugs, which are all very expensive and have a huge budget impact. This raises concerns about sustainability of our health care system and free access for all.

It is not simply about the price but the number of affected patients. The saving grace of Sovaldi was that its treatment period was very short and at the end, the patient will be fully cured. Hence, despite its hefty official price tag of EUR 41,000 per patient (USD 46,000), it may still represent a good investment when compared to some of the newest oncology drugs, which do not cure the patient.

It is not only a question of medico-economic assessment, but also a question of the overall impact on Franceâ??s healthcare budget. The key question is how to find a new system for funding these expensive but efficient drugs. There are a few potential solutions Firstly, some version of the contrat de performance (performance-linked contracts) with a clause requiring companies to refund the government if their drugs are not as effective as agreed. The problem is that the French system is not currently sufficiently well-organized to accurately assess this; one would require post-licensing and post-inscription studies and a good patient registry, among other things. A second option is to give different prices for different indications. A drug can have vastly different efficacy levels for different indications and this is not currently reflected in their prices. A third possibility is to pay for a given disease status instead of a drug. This is not simple either. In France, all these solutions are currently discussed but not implemented.

When possible another strategy is to prioritize indications. With the Hepatitis C last year, under the request of Ministry of Health and Social Security, we used clinical data indications to determine which patients should be treated first. We decided that patients with level three or four liver fibrosis should be treated immediately, which represented around 15,000 to 20,000 patients in the first year.

This strategy is not possible for all conditions, however. For instance, with metastatic melanoma, where all patients are in severe conditions, the government may need to take a difficult decision to implement a budget cap. For Hepatitis C, the cap was EUR 700 million/year. Tough decisions will need to be made eventually.

Last month, you organized the â??Forum HAS Health Technology Assessment sans frontiersâ?•, a conference on health technology assessment in collaboration with the European Commission. What are the benefits of European cooperation in this field?

It is not that difficult to have a common European licensing agreement, because it is based on a benefit-risk ratio, and there is no reason for that to differ across countries. Pricing and

reimbursement, however, depends on a host of factors: economic resources, healthcare priorities and the overall healthcare system. The French health minister, Marisol Touraine, when introducing this international conference, said that each country should remain responsible for domestic pricing and reimbursement decisions. This political attitude is widely shared by other European governments, which partly explains why it is much more difficult to have a unique price across European countries.

What HAS is trying to do is to standardize the assessment process and framework across Europe. We have started with the design of guidelines on issues like how to choose a benchmark and how to define a primary objective. NICE is working on a template for data presentation. There was a French initiative a few years ago to assist pharma companies in posing the best and most helpful questions to health authorities in order to facilitate market access. Two years ago, HAS also begun conducting joint assessment reports with HTA bodies in other countries, which could also be used as a template in the future. Ultimately, more cohesion and cooperation would be beneficial. It may not necessarily mean more convergence in terms of results, because of intrinsic constraints relating to the diverse domestic healthcare systems present in Europe, but more cooperation would undoubtedly generate efficiencies and cost savings.

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