

## Summary of EPEMED's Personalized Medicine Conference, Paris, 12 October 2010

EPEMED, the European Personalized Medicine Association, a not-for-profit organization bringing together global forces in personalized medicine, organized its first conference in collaboration with the French Senate in Paris on 12 October 2010. The conference was entitled "Personalized Medicine in France and Europe: a major health economic challenge". The purpose of the meeting was to inform and educate policy makers, industrial players and other interested parties on the broad challenges associated with access to personalized medicine in Europe, with a particular emphasis on France. It was hosted by French Senator Philippe Adnot, member of the Finance Committee, who introduced the conference together with the French Member of Congress Claude Birraux. The conference attracted a diverse group of attendees from Europe and the United States. The meeting was structured as a plenary session presented by EPEMED's chairman Dr Alain Huriez, followed by a series of 3 round tables, together with several presentations followed by a discussion of the role of French industry.



Dr A. Huriez

Senator P. Adnot

The first round table was formed by five senior French academic scientists and discussed the concept of personalized medicine and in particular the innovations coming from translational research in the public sector. The session, which was chaired by Professor Fabien Calvo, Director General of INCA (Institut National du Cancer), highlighted INCA's 28-center PM testing network, whereby INCA funds emerging tests while they progress towards standard of care, thereby facilitating early access. This network currently offers or will soon offer, EGFR, K-Ras, B-Raf, EML4-ALK, and HER-2 testing.

The second round table, building on Professor Calvo's theme, was focused on market access, including regulatory and economic challenges. Chaired by Cecile Tharaud of Inserm Transfer, the panel included Cecile Vaugelade (head of Evaluation at AFSSAPS), Dr. Nadine David (Head of Drugs Office, French Ministry of Health), Vincent Fert (CEO of Ipsogen). This session included a lively discussion of the challenges associated with the commercial development and clinical laboratory provision of complex tests and of the law of Ballereau which limits the sites at which molecular diagnostic tests may be carried out, including the role of corporate sponsors. In particular, the French prohibition of the kind of commercially led activity common in the US and other markets was seen as a force driving French innovation overseas.

The third roundtable was focused on the US experience regarding personalized medicine.



Chaired by Patrick Terry, co-founder of Genomic Health, the panel included Ed Abrahams (President of the Personalized Medicine Coalition), Felix Frueh (Vice-President of Personalized Medicine, Medco), and Pierre Cassigneul (CEO of XDx). The panel highlighted the more advanced status of PM in the US versus Europe. Felix Frueh presented Medco's US data illustrating the reduction in hospitalizations (around 30%) following the introduction of CYP2C9 and VKORC1 genotyping before prescribing warfarin

in a six month study. Medco's personalized medicine program has already demonstrated improved patient outcomes by implementing diagnostic testing prior to dispensing certain drugs. The company, which can employ such approaches effectively as its data are nationally wired and real-time, has already made significant cost-savings following the introduction of its personalized medicine program. Pierre Cassigneul noted that the XDx AlloMap test used to predict organ transplant rejection is reimbursed by various US payors but, because of Europe's complexity, the test is currently not being marketed in Europe. However, an advantage for the introduction of personalized medicines in Europe was noted by Patrick Terry who stated that the European single payor systems presented an opportunity for a more cohesive approach to the market than the segmented US system.

The next session of the conference discussed the French industry perspective. Christian Parry (Vice-President, SFRL, the French Syndicate of In Vitro Diagnostic Industry) highlighted the size of the European in vitro diagnostic market with around €10 billion in annual sales (in 2008; more than a third of global sales) with Germany, France and Italy representing the largest markets. Although there are a number of companion diagnostic test on the French market, Christian Parry stressed the hindrance of new companion diagnostic development through increasing regulations and quality control processes. Also reimbursement frequently limits new test availability and the initial costs are currently often covered by the industry as a necessary interim step. Mr. Parry suggests that faster market access to novel personalized medicine diagnostic tests may be achieved by 1) collaborations between various parties (In Vitro Diagnostic industry, pharmaceutical and biotechnology companies and academic research groups), 2) adherence to in vitro diagnostic standards and development processes and 3) improvement of reimbursement procedures. In his talk on diagnostic test development in France, Andre Choulika (President of France Biotech), highlighted the fact that there is an increased delay in diagnostic development time in 2009 compared to 2008, which can be explained by an increase in financial and funding issues. Christian Brechot (Vice-President of Medical and Scientific Affairs, Institut Merieux) noted the considerable challenges and expenses associated with development of novel diagnostics, spanning the need to demonstrate analytical and clinical validity, clinical utility and health economic impact. He did, however, stress the strategic and economical benefits for both pharmaceutical and biotechnology firms to collaborate with diagnostic companies to develop personalized medicines and companion diagnostic tests.

The conference was completed with an excellent overview by Professor Phillippe Amouyel (CEO, National Foundation for Alzheimer's Disease, General Director of Institut Pasteur, Lille) of the latest clinical evidence of how personalized medicine approaches can have great impact on patient outcomes with particular emphasis on Alzheimer's disease and myocardial infarction. Philippe Amouyel also presented the recent plans of Neximed, a university hospital institute, which aims to become a premier research site uncovering novel approaches in personalized medicine.

In conclusion, EPEMED's first conference highlighted the recent advances made in personalized medicine but also discussed the difficulties in making personalized treatments available for patients in Europe. The not-for-profit organization is preparing proceedings of the conference as a white paper which may be downloaded from its website ([www.epemed.org](http://www.epemed.org)) early 2011. EPEMED is planning further events, including another conference in 2011.