

# Put the **patient** at the centre

In its recently published Healthcare Manifesto EuropaBio calls for committed healthcare systems in Europe to put the patient at the centre of any medical, social, economical and ethical consideration. Stating that budgetary considerations should be secondary to this overarching political mandate and its implementation.

**HEALTHCARE MANIFESTO** More than 350 million patients have benefited from approved medicines manufactured through biotechnology and gene technology to treat or prevent heart attacks, stroke, multiple sclerosis, breast cancer, cystic fibrosis, leukaemia, hepatitis, diabetes and other diseases, including rare diseases.

Healthcare biotechnology has a tremendous impact on meeting the needs of patients and their families – as it not only encompasses medicines and diagnostics that are manufactured using a biotechnological process, but also gene and cell therapies and tissue engineered products.

Today, the majority of innovative medicines are made available by applying modern biotechnology in their development and/or manufacturing processes. And more than 600 new biotech medicines and vaccines are being tested for more than 100 diseases, pushing the frontiers of science. Biotech medicines are estimated to account for more than 20% of all marketed medicines and the industry comprised more than 1,700 companies in Europe and represented a market worth more than EUR 17 billion in 2007.

Healthcare biotechnology continues to grow with an annually average rate of 20% (more than double that of traditional pharma) and is seven times larger than it was 10 years ago. Currently, the leading classes of biotech therapies are growth factors for blood cells (used in treating anaemia, resulting from chronic kidney disease, from chemotherapy and radiation treatments, and from other critical illnesses such as heart failure); cancer treatments (new and targeted treatments for cancers such as the use of monoclonal antibodies), treatment of autoimmune diseases, enzyme replacement therapies to treat rare diseases and anti-diabetic therapies.

For the first time in the history of human healthcare, biotechnology is enabling the development and manufacturing of therapies for a number of rare and very rare genetic diseases, collectively affecting some 20 to 30 million Europeans and their families. Biotechnology has a major impact on the pro-

vision of safe and effective vaccines against infectious diseases, and provides safer recombinant alternatives to proteins derived from human blood or tissue.

## **Towards patient centred healthcare systems**

In 2004, the European Commission ambitiously launched a series of reforms at national and European level aimed at making the EU 'the most dynamic and competitive knowledge-based economy in the world' by 2010.

To support this, biotechnology and healthcare became a high priority on the political agenda of both the member states and of the union. Innovation in these two areas have been, and will continue to be, a key element in achieving this goal. However, policies in these two areas need to become more interlinked, as practically all future medicines and therapies will use healthcare biotechnology in the R&D process and/or in manufacturing.

EuropaBio calls for healthcare systems in Europe that are committed to put the patient at the centre of any medical, social, economical and ethical consideration. Budgetary considerations should be secondary to this overarching political mandate and its implementation.

Designing policy to foster innovation in biotechnology is not an easy task, however. Biotechnology is a complex field with complex potential outcomes and impacts, while new insights need to be thoroughly discussed with and within society.

The EU addresses this issue through a range of initiatives such as the introduction of the orphan medicinal products regulation to foster development of medicines to treat rare diseases, opening an SME office at the EMEA and regulating advanced therapies (cell, gene and tissue therapies).

EuropaBio was a full member of the High Level Pharmaceutical Forum for its expert input in these areas. 2009/10 will see a continuation of these initiatives. Building on the EuropaBio Healthcare Vision, this Manifesto



to sets out how EuropaBio will contribute to this process of policy development, as well as regulatory implementation in 2009/10. These actions are laid out in the Healthcare Council Mission and include:

- Communicating the value of biotechnology innovation for healthcare systems in Europe and ensure that national governments adequately acknowledge the contributions and the strategic role of the innovative healthcare sector, and of the SMEs that are at its core.
- Promoting Europe as the leading research hub for biotechnology and life sciences in the world and shape EU policy and legislative initiatives to ensure that emerging biotechnology solutions are supported and reach patients without delay.
- Supporting the EU in delivering on its vision for access to orphan medicinal products for all patients affected by rare diseases.
- Promoting reward for innovation as a key success factor to improving progress in medicine and patient safety, as well as to the overall EU-goal of rendering the EU the most competitive knowledge-based economy in the world.

**HEALTHCARE  
MANIFESTO 2009-2010**  
EuropaBio

The European Association for Bioindustries

# Computer models predict dietary effects on health

The EU project ETHERPATHS develops computer assisted models to study the dietary effects mediated by gut microbiota on lipid metabolism, with the aim to accelerate the development of health-promoting foods.

**THE ETHERPATHS** project focuses on the balance of lipid metabolism in the body, the effects of foods in tissues and the role of gut microbiota in these processes. Lipid metabolism disorders are associated with several common healthcare problems, such as ageing, diabetes and cardiovascular diseases. The balance can be influenced by dietary means. The risk of chronic diseases decreases with a diet containing particularly omega-3 fatty acids and foods that contain fibres and phenol.

Therefore, fatty fish, berries, fruits and vegetables may be favourable foods in terms of lipid metabolism balance. The body's own phospholipids are assumed to mediate the health-promoting effects, but their mechanisms of action are still unknown.

The project develops computer-assisted

models that emulate the changes in lipid metabolism brought about by eating fish and vegetable oil, berries, fruits and vegetables. The use of models makes it easier to combine

## Project partners

The ETHERPATHS project is part of the EU FP7 Cooperation Work Programme: Food, agriculture and fisheries, and biotechnology programme (KBBE-2007-2-2-08).

The project partners are: VTT (Finland), University of Barcelona (Spain), University of Gothenburg (Sweden), University of Cambridge (United Kingdom), Institute for Systems Biology SPb (Russia), Federico II University of Naples (Italy), Noray Bioinformatics S.L.U. (Spain), BioMotif AB (Sweden), Advion Biosciences, Ltd. (United Kingdom) and Nestle Research Center (Switzerland).

data from animal studies and cell-level data in the interpretation of research data from clinical trials, thus promoting research in the health effects of foods and development of foodstuffs. The results of the project and the tools developed in it will in time also be available, in addition to food companies, to companies and research institutions that develop diagnostics of health and disease.

The ETHERPATHS project is coordinated by Research Professor Matej Oresic at VTT Technical Research Centre of Finland, the biggest contract research organisation in Northern Europe. The total project budget for 2009–2012 is EUR 8 million, of which VTT's share is EUR 2.5 million. The project involves a total of 10 European research institutions and companies.

## Could a change of gut bacteria make people lose weight?

When obese people went on a diet and lost up to a quarter of their body weight, their gut flora changed too, becoming more like those of lean people.

**METAGENOMICS** The EU project – Metagenomics of the Human Intestinal Tract (MetaHIT) – is investigating the links between gut bacteria and obesity and inflammation. Research has already found a big difference between the bacteria population in the guts of fat and thin people. Moreover, when obese people went on a diet and lost up to a quarter of their body weight, their gut flora changed too, becoming more like those of the lean group.

So, could giving more of the lean type of gut bacteria to fat people help them lose weight? That is one of the questions the project hopes to answer. There is evidence it

may. Certain probiotics can affect the production of bile acids, which in turn affect how much fat people absorb.

MetaHIT is also looking at how metabolites in the gut influence the efficacy of drugs in patients with inflammatory bowel disease. Certainly gut bacteria and inflammation are intimately entwined. Marika Kullberg of the University of York recently described how a molecule produced by one type of bacteria can calm the inflamed guts of mice.

She suggests that a massive rise in inflammatory bowel disease in recent years may be the penalty we are paying for such medical advances as antibiotics, vaccines and

improved sanitation. By banishing various parasites from the gut, people have made the bacterial response to any challenges far more inflammatory.

MetaHIT is a project financed by the European Commission under the 7th FP program. The consortium gathers 13 partners from academia and industry, a total of 8 countries. Its total cost has been evaluated at more than EUR 20 million and the funding requested from the European Commission has been set with an upper limit of EUR 11.4 million. The project was initiated on January 1, 2008, and will run for 4 years.