About the authors

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About the ETP Nanomedicine

The ETP Nanomedicine, an initiative led by industry and set up together with the European Commission, is addressing the application of nanotechnology to achieve breakthroughs in healthcare. Nanotechnology pushes the boundaries of conventional therapeutics, diagnostics and provides for the development of regenerative medicine. The ETP believes that by involving industry it can accelerate the path to the market and provide the effective and safe radical healthcare products that patients expect.

The ETP supports its members in coordinating their joint research efforts and improves essential communication amongst the members, as well as towards the European Commission and the European Member States.

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ETP Nanomedicine – Opinion paper

The Impact of Open Innovation on (Nano-) Healthcare R&D in Europe

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The pharmaceutical industry has a track record of success in treating patients by producing new drugs, helping the economy and encouraging world class science. Drug research and development has created many jobs (636,000 in 2007) as well as supporting the prosperity of the West European economy (€ 48bn trade balance in 2007)[1]. Corporate research centres were major employers for scientists and the money invested was a direct and indirect funding source for European science. Pharmaceuticals is one of Europe's top performing high-technology sectors, however it is increasingly seen as a less attractive area for investment. For example from 2001-6 Europe lost sixteen research sites, Asia gained thirteen and the US gained one, this trend is continuing. The global significance of the European pharmaceutical sector has reduced over the last decade, partly because of its lack of adaptability to a changing global environment.

Globally we see that many drug patents are expiring, fuelling an increase of the generics sector to more than 60 % in some markets. Furthermore, political pressure has reduced reimbursement rates for drugs and called for more regulations. The R&D cost for new drugs has risen to over € 1bn, making it difficult to get a sufficient return on investment given the *effective* patent life. These financial and political pressures have led to pharmaceutical companies outsourcing R&D and production to lower cost economies, because the cost of European R&D has become significantly greater than the outsourced cost. In this climate Asia has a cost advantage but the US has demonstrated that it can maintain its pharmaceutical sector due to its culture of entrepreneurship and a history of translation of its science base.

The outsourcing of corporate research (Open Innovation) combined with the search for radical innovation has the consequence that companies have to identify globally competitive academic researchers or SMEs who can provide the early products to fill their pipelines. Historically European industry has not needed to engage with academia; as a consequence, academia lacking industrial know-how has often researched non-translatable areas. This can be defended on the grounds of academic freedom, but nevertheless much funded work is still also derivative, rather than the translational innovative research that industry requires. With the advent of Open Innovation the gulf between the two stakeholders will become more evident and this lack of knowledge flow will seriously handicap the European science base with respect to its competitors. In fact, the lack of translatability of publicly funded European and national applied healthcare research becomes a more important issue than the level of funding itself!

Industry, operating under global Open Innovation, will not make a costly effort to explain translation to academics across the whole of

Europe, when they can source lower cost quality research elsewhere. At this level Europe competes with the US, where translation of research into products is more effective, and with Asia, where costs are low and where there is a major interest in translational science.

The growth of Open Innovation coincides with the emergence of Nanotechnology, which adds an additional level of complexity to the introduction of new concepts and outsourcing, because new disciplines such as physics and engineering enter the R&D process of nano-pharmaceuticals. The integration of these unfamiliar disciplines requires a big effort on all sides; physicists and engineers are not familiar with the pharmaceutical R&D process and its ethical or regulatory requirements. Therefore, new communication and collaboration structures have to be developed and it will need good organisation and guidance to establish them quickly and efficiently. Again, Europe is lacking behind, because most academic organisations lack professional structures to support or enable translation of research and many academics are not used to working in large interdisciplinary teams.

Global outsourcing has caused disruption to the existing pharmaceutical sector, with a loss of staff experienced in translation. On the other hand the globalisation of applied science has significant benefits for entrepreneurs (conversely real disadvantages for those not engaged) and it provides new hope for patients. For example, changes in reimbursement policies have led companies to seek novel treatments in areas of unmet medical need, which *inter alia* involves Nanotechnology and Nanomedicine. This new focus should be welcomed by patients as it offers new treatment modalities with lower side effects, for diseases which currently have been seen as difficult to treat.

Europe has to be aware of the potential negative and positive impacts on its science base and has to create the structures and means to take on the global challenge of Open Innovation. To successfully meet the challenges Europe needs a bottom-up approach of academia and industry and a top-down strategy of the European Commission and member states, to provide incentives to optimise translation of R&D results into marketable products.

On the academic side efforts should be to:

- Enable experienced individuals to teach translation skills to students and lecturers.
- Encourage universities' strategic science management (where they exist) to balance academic freedom with exploitable nano-healthcare research.
- Understand patient, industrial and regulatory needs.
- Establish professional and funded communication channels to use industrial contacts fully. Establish best practice in Europe.
- Ensure academics benefit from successful applied research.
- Understand that a high level of innovation is required for reimbursement; derivative products are no longer reimbursed.
- Recognise exploitable patent filings.

There is a one off opportunity for academic institutions to capture the specialised knowledge being lost by major Pharma companies, but it needs a strategy to do so, including appropriate tools and financial motivation.

To create appropriate tools and to provide the financial incentives, European and national funding systems need to:

- Improve industrial peer review of applied research proposals, because applied research quality assessment and public funding still is dominated by academic criteria, with industrial impact being only a minor component.
- Reimburse (travel and/or time) industrial experts to achieve 50% industrial presence in evaluation panels.
- Include and fund external translational experts in project consortia.
- Reward institutes appropriately for their extent of industrial involvement and strategic choice of research direction.
- Invest in the upgrading and networking of regional interdisciplinary centres of excellence, which have a clear and sustainable development strategy supported by local politics, research institutions and companies.
- Improve communication to citizens to make them aware of the importance of these issues.

In the longer term it will also be necessary to reconsider the lifetime of patents and to balance regulation requirements with the cost of meeting these requirements. Both should be negotiated and agreed on at the global scale to create fair conditions for European companies.

Industry should increase its interest in optimising the translation of R&D in Europe; Europe is still leading in many areas of research, as shown by the numbers of publications. However in 2008 European Pharma produced 7% less patents than the previous year, compared with 5% more from the US and a massive 49% increase from China (albeit from a low base)[2]. Nanomedicine especially requires the collaboration of many disciplines, which is more easily managed if basic, applied and translational research teams are in close proximity to each other and to the production facilities. Therefore, industry has to:

- Actively support and co-finance the set-up of professional structures, supporting the translation of academic research.
- Train academic researchers to understand industrial requirements.
- Provide academics with relevant unpublished information.
- Send experts to review panels of funding agencies.

The reward for industry would be the high quality and safety standards of the R&D and production processes in Europe, combined with the experience and high standards of European academics.

To summarise, Open Innovation is radically changing global R&D in the pharmaceutical industry and Europe must improve its translational activities in a pro-active manner to increase its global competitiveness. This will require new structures and processes of industry/academia collaboration and public funding. The ETP Nanomedicine with its industrial, academic and clinical members provides a working platform to develop these structures and processes. Only the most adaptable industrial and academic sectors will survive!

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[1] EFPIA website
[2] WIPO statistics database