Background
The research-based pharmaceutical industry in Europe plays a vital role in discovering and developing new medicines. According to EUROSTAT data, the pharmaceutical industry is the European high technology sector with the highest value-added per person employed. It is also the industrial sector with the highest ratio of R&D investment to net sales. Europe therefore has a great deal to gain in health and economic terms from a strong and competitive industry, and has many of the necessary preconditions for success in pharmaceutical research, such as sound IP protection, highly skilled scientists and high quality scientific companies and research institutes. However Europe’s ability to attract R&D investment from pharmaceutical companies has been declining over the past 20 years, relative both to the US and to emerging competitors including Singapore, China and India. The situation has long been recognised by the European Commission, but while some important measures have been taken, in particular the establishment of the Innovative Medicines Initiative (IMI), further steps are needed to enhance Europe’s attractiveness as a location for pharmaceutical R&D.

Since the early 1990s, the research-based pharmaceutical industry in Europe has been losing competitiveness with respect to its main competitors, in particular the US. Between 1990 and 2011, R&D investment in United States grew 5.6 times whilst in Europe it only grew 3.5 times (Source: EFPIA). Global companies now have a choice of locations which meet the scientific and technological preconditions for R&D investment, and they tend to be attracted to the largest and fastest growing markets, and those with the quickest adoption of new medicines. In 2011, North America accounted for 41.8% of world pharmaceutical sales compared with 26.8% for Europe (Source: IMS). According to IMS data, the US market accounted for 56% of sales of new medicines launched during 2006-2010, compared with just 24% for the European market.

There is also rapid growth in the market and research environment in emerging economies such as Brazil, China and India. In 2011 the Brazilian and Chinese pharmaceutical markets grew by more than 20%, compared with an average market growth of 2.6% for the five major European markets and 3.6% for the US market (Source: IMS). A number of major EU pharmaceutical research sites have closed in recent years, while substantial industry R&D investments have been made in China and other emerging economies. However Europe still has much to offer as a location for pharmaceutical R&D provided that the right policies are pursued with determination.

Although the total EU pharmaceutical market is second only to the US, each of the 28 Member States operates its own pricing and reimbursement system for medicines, so that the EU does not actually comprise a genuine single market. This fragmentation has resulted in parallel trade, estimated at € 5,200 million in 2009, which benefits intermediaries rather than governments or patients, and deprives the industry of resources to fund R&D.

Several factors explain the relative lack of attractiveness of Europe for pharmaceutical investment. These include market fragmentation, the complexity and inefficiency of the regulatory framework for approval of new medicines and of clinical trials, erosion of the science base and societal attitudes towards new technologies. For example, the European Clinical Trials Directive has added significant administrative and regulatory constraints in some EU countries where there were previously no such measures or where these were set at a lower level, without bringing the intended benefits of a real harmonisation of the requirements to conduct clinical trials across Europe.
**Lundbeck position**

As a European-based innovative pharmaceutical company, Lundbeck is concerned at the declining attractiveness of the EU environment for the industry, which is one of Europe’s leading high technology sectors. European governments need to do more to maintain and enhance its position as a global centre for pharmaceutical R&D and manufacturing in the face of growing competition from the USA and emerging Asian and Latin American economies.

Improving the competitiveness of the industry is especially critical for Lundbeck, as a large part of our worldwide operations are located in Europe, which also accounts for the majority of our global sales. We are particularly affected by the EU environment for pharmaceutical R&D because we are a highly research intensive company, investing some 20% of sales in R&D – well above the industry average – and the bulk of our R&D activity is based in Europe. There is significant potential for EU measures which would assist Lundbeck in its quest to develop new and improved treatments for brain disorders.

Europe’s declining competitiveness has long been recognised. The Innovation Task Force was established by EMEA in 2001 to facilitate the application of innovative technologies and therapies and promote their translation into innovative medicinal products. In June 2002, the G10 group on Innovation and the Provision of Medicines recommended a set of 14 practical ways of improving industry competitiveness in Europe. The Pharmaceutical Forum, established in June 2005, took forward some crucial issues outstanding from the G10 process, in particular Information to Patients, Relative Effectiveness and Pricing and Reimbursement. Some useful progress has been made, in particular the establishment of the Innovative Medicines Initiative, but the short term need to contain health budgets has tended to take precedence over the longer term need to nurture a flourishing European research-based pharmaceutical industry. Further action is urgently needed.

For Lundbeck, the key priorities are

- the review of the Transparency Directive should be used to improve patient access to medicines in Europe and the EU’s competitive environment for pharmaceuticals
- work being done at EU level on Health Technology Assessment (HTA) should focus on governance and collaboration, and lead to increased involvement of stakeholders, including pharmaceutical companies
- EU Commission Vice President Tajani’s initiative on corporate responsibility in the pharmaceutical industry includes a focus on access to medicines in Europe – this provides an opportunity to implement the good pricing and reimbursement principles endorsed by the Pharmaceutical Forum
- European Commission Communication on an Innovation Union aims to improve conditions and financing for research and innovation – this should include new incentives for CNS research and proper rewards for incremental innovation
- The EU’s Innovation Partnership on Healthy Ageing should highlight the value offered by innovative medicines in increasing the years of healthy life enjoyed by EU citizens
- The EU should enhance its attractiveness as a location for pharmaceutical R&D by building on the initial success of the Innovative Medicines Initiative (IMI) through the Horizon 2020 programme, and revising the Clinical Trials Directive to reduce unnecessary delays and bureaucracy
- The EU should further strengthen its own robust framework for the protection of IP rights and use its influence to improve IP protection in emerging markets so that EU companies can receive fair rewards for their investment in R&D.