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Note

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Public Consultation on the Concept paper on the Revision of the EU Clinical Trials Directive.

Position Paper Belgium

Since 1995 the Pharma in Belgium sector has seen a continuous growth. In 2009 the total value of manufacturing of medicines was 5.4 billion €, representing an annual growth of 6.8 %. Today Belgium has 31 biopharmaceutical companies where medicines are developed and/or manufactured. Not only major companies but a considerable number of SMEs ensure this strong presence for the pharmaceutical sector in Belgium. In 2009 alone the sector invested more than 500 million Euros in R&D and manufacturing infrastructure. This represents a yearly increase of 5.3% as compared to the 2.9% increase recorded in the global processing industry.

The pharmaceutical sector invests yearly 1.8 billion € in R&D in Belgium. This represents a tripling of the R&D investments over the past decade. Today the sector is the biggest private investor in R&D in Belgium, responsible for no less than 40% of the private investments in R&D. The biopharmaceutical research industry in Belgium provides more than half the private contribution for meeting the Lisbon criteria and it creates a substantial part of the added value for our economy.

Additionally, the Pharma sector employs to date around 29,000 mainly highly qualified people, of which almost 5,000 active in R&D. This represents a doubling of R&D personnel since 1995. Despite the structural difficulties (increasingly complex and expensive R&D, shortening of patent life, increasingly strict safety standards, limited patient access, expiring patents, etc.) resulting in mergers and re-organisations over the past year, the sector continues to recruit highly educated personnel: 65% of the sector's employees have a higher education.

Belgium, with its **extensive and high quality network of academics, university and non-university hospitals, (bio) pharmaceutical companies, spin-offs, biotech companies, and SMEs active in the pharmaceutical sector** is a dedicated host country for the biopharmaceutical research industry in Europe. These bio- pharmaceutical companies **are** at large **responsible for a major part of the clinical research activities performed in Belgium.** This not only involves corporate headquarters located in Belgium but also the subsidiaries of international companies, who are playing a very major role mainly in clinical research.

These activities represent a considerable contribution to the improvement of our public health and they support largely our knowledge economy.

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invest in health

In terms of number of clinical trials, Belgium is among the European leaders, after Germany, France, Italy, the United Kingdom and Spain. Approximately 9% of all clinical trials conducted in Europe are taking place in Belgium (EudraCT data base). About half of all clinical trials are phase I/II trials. This is a more than a respectable figure given the relatively limited number of research centres. If the same comparison is made on the basis of the number of patients participating in trials, Belgium is of course ranking lower, due to its relatively limited patient population. However, when these figures are expressed in per capita terms, Belgium emerges as Europe's clear number one. This is a situation that needs to be maintained.

Major strengths are the generally recognised quality of the research and an authorisation procedure that respects very short deadlines, allowing Belgium very often to be the first country to recruit patients in a multinational clinical trial.

However over the recent years a new trend developed. The emerging countries are attracting a growing number of large-scale clinical trials as they have access to large patient populations required to run these trials. Additionally, the costs of running clinical trials are still lower in these countries: i.e.; the cost of conducting a clinical trial in India is still half the costs of running the trial in the United States. The shift to the "rest of the world" has increased markedly in recent years and the trend looks set to continue, ultimately leading to a drop in clinical research activities in EU and US.

This trend noted at EU level also affects the Belgian situation and it is essential for the future of clinical research to stay vigilant and ensure that Belgium can keep its position in the global environment. Creating a regulatory framework that favours the conduct of clinical trials at EU level should by all means be reinforced to keep clinical research in Europe. While attempting to enhance the environment in Europe, consideration should also be given to processes which ensure that smaller countries like Belgium take actively part in the clinical development activities. For smaller countries, with high expertise but maybe lower patient potentials, other arguments may play a role and therefore it is very important to consider timelines and harmonized assessment approaches on the agenda.

pharma.be consolidated the input received from its members regarding the different aspects related to the planned revision of the Clinical trial directive keeping in mind the strengths of a country like Belgium.