Belgium, land of welcome for clinical research and clinical trials

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Clinical research is the engine of therapeutic advances and of the rapid implementation of recent discoveries in basic research. Belgium has a long tradition of high level basic research and clinical research and of collaboration between the academic world and the pharmaceutical industry.

If we had to name a few we would certainly remember Jules Bordet, who was at the origin of immunology as a full discipline of medicine.
Jean Brachet, one of the founders of experimental embryology and molecular biology, who was the first to discover the key role of RNA.
The Nobel prize Christian de Duve, a pioneer in cellular biology
Walter Fiers, a pioneer as molecular biologist in the genome research, who, with his research team, was able to identify for first time the sequence of a complete gene and the genome of a virus .

And Paul Janssen, a scientist at the crossroads between medicine, pharmacology and chemistry who founded Janssen Farmaceutica, a world famous company, with more than 80 new drugs successfully launched under his leadership, 5 of them being on the list of the "essential medicines" of the World Health Organization. This tradition is more alive than ever.

Belgium is particularly active in biotechnology. It started years ago with the vaccines and the development in the Belgian laboratories of GSK of the first recombinant vaccine grown on yeast, Engerix B, and its registration in 1985 in the prevention of hepatitis B.

It goes on with last year's announcement of a major breakthrough in the fight against malaria by the Belgian GSK plant: "The European Medicines Agency recommends that RTS,S, or "Mosquirix" , should be licensed for use in young children in Africa who are at risk of the mosquito-borne disease."

Just to remember, an estimated 438.000 people died of malaria in 2015, with over 90% of these deaths occurring in sub-Saharan Africa. Mainly, children are affected. Worldwide the number of new episodes of clinical malaria in 2015 is estimated to be around 214 million.

The development of the biotechnology sector in Belgium has created several biotechnology clusters comprising universities, companies and organisations active in the biotechnology industry. Today there are over 140 biotechnology companies operating in Belgium or 7% of all such companies in Europe. Belgian biotechnology companies accounted for 16% of Europe's turnover and almost 10% of R&D expenditure.
Major steps forwards are the consequence of the activity and of the collaboration between universities and industry, to the benefit of the patients.

Belgian biotech companies have well advanced programs. It is the case of Celyad, active in the field of regenerative therapies, in partnership with the Mayo Clinic

and the Dartmouth College. Celyad has developed a technic that must enable doctors to reprogram stem cells of the patient in order to regenerate the cardiac tissue. The Phase III program is ongoing by patients with severe ischemic heart failure

I could give other examples of Belgian successes but my objective is not to list a catalog of achievements. I am looking to the future and I wish to help maintaining and developing the Belgian expertise, competitiveness, reputation and excellence, by providing appropriate tools.
The pact for the future signed in 2015 with the pharmaceutical industry and the initiatives such as regulatory support and scientific advices for start-ups and small and medium enterprises are part of it.
A revision of the legal framework of human body material and ATMP is also ongoing in consultation with the various stakeholders.

Being a fertile ground in research without offering the opportunity to test the fruits of this research would be comparable to a lame duck.
As a consequence, Belgium has become over the years the European country making, with Denmark, the most clinical trials / capita.
More than 600 Clinical trial applications (CTA's) are introduced each year in Belgium, 1/5 being non-commercial studies. The number of commercial Clinical trials has increased by 6% in 2015 compared to 2014 and a total of 1578 studies were ongoing. Some of our research centers are the preferred partner of pharmaceutical companies.

I consider as the uttermost priority to maintain and develop this activity in Belgium given the first to benefit are the patients. Indeed, Clinical trials give them early and free access to new and innovative treatments which would otherwise not be available; the Clinical trials can be the last therapeutic option for patients and they contribute to the better understanding and management of the diseases and the patients.

However, the most difficult when you are a leader is keeping that position. To rest on its laurels leads to tumble. Attention at all times is necessary.
As the Minister of Public Health and Social Affairs, I decided to put up assets on our side and I implemented a proactive policy to create a favorable climate for clinical research. Various initiatives are ongoing aiming to reinforce our strengths and fight our weaknesses.
I already mentioned the pact for the future with the pharmaceutical industry for the patients.

Amongst others, the pact promotes the development and the access to innovative drugs meeting the needs of the patients. It also provides additional funds fostering the conduct of clinical trials and allowing the access to a great number of innovative therapies for more patients.
As you know there is a new EU-directive regulating the conduct of interventional drugs clinical trials. The directive will enter into force in 2018. I consider that new directive as an opportunity allowing us to re-examine and improve our procedures and to reposition Belgium in the clinical trials landscape, making us even more attractive.

Although one of the objectives of the EU-directive is to harmonize the procedures in the different member states, our new law helps to maintain shorter timelines for the assessment and approval of Phase I Clinical trials. Belgium hosts several highly skilled Phase I research centers, used as preferred partners by several pharmaceutical companies.

I want to keep and develop that expertise but the safety of the healthy volunteers must be our uttermost priority. We must keep in mind the recent accident that occurred recently in France and everything has to be done to prevent such occurrences. This requires a strengthening of the expertise, of the protocol's assessment and of the sites inspection. An accreditation of the Phase I units will be organized in order to guarantee the right level of staffing, training, expertise, equipment and procedures. A national database of healthy volunteers will also be set up to reinforce their safety.
Another strength of Belgium is the strong cooperation between the universities and the industry as well as the high level of expertise of our hospitals.

We also address the issue of patient recruitment. Significant efforts are ongoing in collaboration with the various stakeholders.
Networks are one option. By expanding the networks and by allocating dedicated staff helping with recruitment and contacting physicians and other hospitals, the identification of patients is facilitated. Feasibility studies become more reliable. Actions are taken in that direction.
Another national initiative helping the identification of eligible patients is the eHealth data initiative and the possibility of access to anonymized data it will

offer. This will also facilitate the feasibility studies, increase their reliability and foster the recruitment.

Following the implementation of the new clinical trials legislation, information and awareness campaigns about clinical trials, towards the population, patients groups and caregivers, including general practitioners, will be launched along 2017.

Discussions are also ongoing to set up a database allowing patients to identify which studies are performed in Belgium and where, making them aware of potential opportunities.

Finally, I want to mention a last initiative launched this year. As you know clinical studies do not only cover the evaluation of promising novel agents (usually performed by the pharmaceutical industry) but are also important for the development of new therapeutic strategies/ recommendations. This requires the conduct of independent clinical studies and implies very often combinations of treatments, such as surgery, radiotherapy, chemotherapy, immunotherapy, cellular therapy, etc. according to the principle of multidisciplinary.

This also means answering to clinically relevant questions regarding the optimum utilization and appropriate therapeutic sequence of drugs already commercially available, tested in combination with other therapeutic modalities.
These studies are important for patients, for doctors and researchers and for society. They provide a scientific basis for establishing recommendations on the optimal treatment and thus help to ensure the best use of available resources for

health care. Funds have been allocated and a program of such studies has been launched this year in Belgium under the umbrella of the KCE

To conclude I would like to say that I am fully aware how important it is to be number 1 in clinical studies and to be the best place for R & D investment per capita. This is major asset not only for patients, but also for our universities and researchers and for the Belgium economy.
I hope I convinced you we deserve that leader position and that everything is done and will continue to be done to offer the best environment for quality research where partnership between universities, clinical experts, industry and the authorities is a reality.

I thank you for your attention.