Baxter World Trade s.a./n.v.
Bd de la Plaine, 5 Pleinlaan
1050 Brussels - Belgium
Phone : 32 (0)2 650 17 00

Baxter

European Commission
Unit ENTR F/2, Consumer Goods - Pharmaceuticals
Clinical Trials Directive consultation
entr-pharmaceuticals@ec.europa.eu
B-1049 Brussels
Belgium

25 January 2010

Dear Mrs Rocio Salva Roldan,

Baxter comments to the ASSESSMENT OF THE FUNCTIONING OF THE "CLINICAL TRIALS DIRECTIVE" 2001/20/EC - PUBLIC CONSULTATION PAPER

Baxter welcomes the Commission's consultation paper on the assessment of the Clinical Trials directive. We generally support, the EFPIA, EuropaBio and EBE responses. Through our involvement within these trade associations we were able to provide input to the overall industry responses. Still, we would like to highlight some of the issues which are particularly relevant to a diversified company such as Baxter with an expertise in biotechnology, pharmaceutical products and therapies as well as medical devices.

- The introduction of a competent authority assessment of CTAs in some MS where this did not previously exist might result in improved safety or ethics, but it should be borne in mind that clinical trials already, prior to the introduction of the Directive, had to comply with GCP and with the Declaration of Helsinki when they supported applications for marketing authorisation (Directive 91/507/EEC).

- There are many occasions when divergent decisions are adopted in different Member States, and these situations can indeed be extremely disruptive to the conduct of the trial.

- It is true that large resources are needed to track differences in national requirements, coordinate activities, take care of the "chain reaction" resulting from a punctual assessment/decision from one body in one Member State. These activities are not necessarily entirely managed by 'dedicated departments.

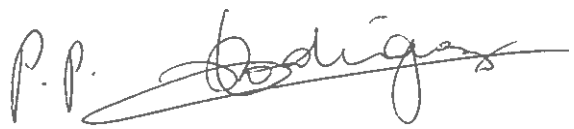
- The 'Voluntary Harmonisation Procedure' (VHP) was launched by the Clinical Trials Facilitation Group (CTFG) as a pilot in early 2009. The VHP initiative allows for regular exchanges between NCA assessors which should logically lead to a convergence of review practices, data- and format expectations. Assessment sharing may be of particular relevance where expertise may not be universally available. For commercial sponsors, the main advantage of the VHP is to be able to process a single list of questions at one point in time.

- Baxter supports the creation of a Community CTA review of trials to be conducted within the EEA as a complement to the present regulatory framework. The key principle being a single CTA dossier submitted centrally, reviewed once and resulting in the granting of a Community clinical trial authorisation - valid throughout the countries of the EEA. Moreover, an electronic-CTA format and structure, which should be based on the e-CTD specification, should be defined and implemented within this new pathway

- The nature of the sponsor (commercial vs non commercial) itself is irrelevant in relation to a possible risk based approach for a number of reasons. The protection of patient rights and safety must be ensured in all settings/cases. Furthermore, even though non-commercial trials may not be conducted to generate data aimed at supporting application for marketing authorisations (for new products, new indications, new dosage forms, new routes of administration, as post-authorisation commitment studies, etc), they are expected to be used to guide medical practice and therefore their scientific integrity is critically important. For example, lack of efficacy of a new dosing scheme is not without risk (including for lack of efficacy), while commercial clinical trials comparing authorised products used strictly within the terms of the marketing authorisations (summary of product characteristics) are low risk.

I thank you in advance for considering our response, which endorses entirely the views of the trade associations: EuropaBio, EFPIA and EBE. I also would like to emphasise that our internal clinical trials experts remain at your disposal should you require additional clarifications regarding this important topic.

Yours sincerely,



Anne-Toni Rodgers
Director Government Affairs & Public Policy - EMEA
Baxter World Trade SA

Annex: About Baxter.

Baxter is a global diversified healthcare company that develops products and therapies to make a meaningful difference in the lives of people with hemophilia, kidney disease, immune disorders and other chronic and acute conditions.

The company operates in three segments: *BioScience* develops biopharmaceuticals, biosurgery products, vaccines and blood collection products and technologies. *Medication Delivery* provides intravenous solutions and specialty products used for fluid replenishment, anesthesia, nutrition, pain management, antibiotic therapy and chemotherapy. *Renal* develops products and services to treat end-stage kidney disease.

Baxter is a different kind of healthcare company, our diversified healthcare model, furthers our ability to innovate and leverage our diverse technology platforms across our organization to address unmet medical needs.

For additional information, please visit www.baxter.com.

Our vision:

Baxter's vision is to be: recognized and trusted worldwide; a preferred partner in improving the quality of and access to healthcare; an innovator in science and technology; the leader in our markets; a high quality investment; a rewarding place to work and develop; and socially responsible members of our communities.

Our culture

The company's culture is grounded in an employee base that has a passion to innovate and drive for solutions, personal accountability for results and integrity, eagerness to learn and continuously improve, uncompromising dedication to quality, relentless focus on rapid and disciplined action and respect for the diverse contributions of all.

Baxter's approximately 45,000 employees in more than 100 countries around the world are connected by their enduring commitment to save and sustain lives. It is this higher purpose that binds us as a company and as global citizens.

Diversified portfolio and expertise

Baxter is a different kind of healthcare company. Our diversified healthcare model furthers our ability to innovate.

- We specialize in biotechnology, medical devices and pharmaceutical products and therapies.
- We leverage our diverse technology platforms across our organization to address unmet medical needs and to expand options for physicians and patients (e.g., medical plastics, isolation technology, regenerative technology, PD solutions).
- Leading cost position and competitive advantage because our businesses share manufacturing, purchasing and supply, distribution, and warehousing (e.g., produce both IV solutions and PD solutions in the same manufacturing plants).

- Our core technical competencies include drug delivery, hardware and software, medical plastics, protein development and manufacturing, separation and purification, and sterilization.
- Dozens of biotech and pharmaceutical companies partner with Baxter because of its formulation and manufacturing capabilities, and global presence.

Global healthcare company

Baxter is truly an international company with a strong global brand and broad geographic reach.

- More than 45,000 employees and 250 facilities worldwide.
- Products are sold in more than 100 countries and manufacturing presence in 27 countries.
- More than 70 percent of our sales are in businesses in which we are the number one leader in the global markets in which we participate.

Innovation in science and technology

We apply science and technology in creative ways to develop products that help save and sustain lives.

- Our heritage has been built on more than 75 years of innovation in healthcare, including a long history of firsts.
  - First manufactured IV solutions.
  - First commercial artificial kidney.
  - First "needleless" IV system.
  - First clotting factor for hemophilia.
  - First portable dialysis therapy.
- Building on our past, we work to bring the next generation of treatments to life.
  - Studying how adult stem cell therapy may help reverse the damage caused by heart disease.
  - Using innovative technology to develop avian flu vaccine.
  - Exploring regenerative tissue therapies that some day may help patients heal faster.
  - Introducing non-PVC-based IV products.
  - Exploring next generation infusion technology to potentially increase patient safety.
  - Focusing on evolving dialysis therapy, including the development of a next generation peritoneal dialysis (PD) cycler, looking at PD solutions to improve outcomes and reduce co-morbidity, and expanding indications for the therapy.
  - Exploring the use of IVIG for the treatment of Alzheimer's and other neurological diseases.

- We are significantly increasing our R&D investments to not only support and grow our current portfolio of marketed products, but are also expanding into adjacent as well as new product opportunities with a balance of short and long-term, incremental and breakthrough as well as in-house and partnered product development programs.
- Increased R&D spending by 15% in 2006 versus 2005, and we are committed to sustained double-digit annual increases over the next five years.

Focused on life-saving and life-sustaining products

We make the most basic and medically necessary healthcare products that are of the greatest priority in both developed and developing countries.

- Clotting factor for people with hemophilia.
- Intravenous solutions for trauma and other acute conditions.
- Dialysis for people with kidney failure.
- Antibody therapy for people with immune deficiencies.
- Products for those who suffer from post-operative bleeding, trauma and cancer.

Sustainability is integral to our business

Sustainability at Baxter is about taking a responsible approach to conducting our business, considering the short and long-term social, economic, and environmental impacts of the work we do and the products and services we make. Part of being a great company means being responsible corporate citizens.