European Commission
DG Enterprise & Industry
Unit F2 “Pharmaceuticals”
Legal Proposal on Information to Patients
ulla.narhi@ec.europa.eu
45 Avenue d’Auderghem, Office 10/93
B 1049 Brussels - Belgium

April 7, 2008

Dear Ms Närhi,

Baxter comments to the Commission’s Public Consultation on a legal proposal on information to patients

Baxter welcomes the consultation on a legal proposal aimed at improving patient information throughout the European Union (EU).

Baxter is a global, diversified healthcare company that develops products and therapies to make a meaningful difference in the lives of people with life-threatening conditions such as haemophilia, kidney disease, immune disorders and other chronic and acute conditions. Every day we provide life saving therapy to people with a range of chronic and rare diseases and we make significant investment in the area of rare diseases, such as haemophilia and Primary Immune Deficiencies. Hence we have vast experience and expertise in both existing and developing treatment for rare and chronic diseases and feel qualified to provide feedback. Further information on Baxter is provided in an Annex to this response.

In response to the consultation, Baxter would like to highlight the following issues; detailed feedback is appended to this letter:

- Baxter agrees with the Commission that in a future system, product information provided by companies should, wherever possible, be based on already-approved documents such as the SmPC (Summary of Product Characteristics) and PIL (Patient Information Leaflet); however, where appropriate, information must be made more understandable to be useful for the intended audience.

- Baxter believes that a system based on self-regulatory elements would be best suited to meet the original Commission’s objectives. Self-regulation by the pharmaceutical industry has proven to be highly efficient and valuable, as it offers the opportunity to quickly adapt to changing needs in an un-bureaucratic manner. A similar scheme for health information would include efficient governance structures and robust enforcement procedures.

- We agree with the Commission that Direct to Consumer Advertising (DTC-A) is not an appropriate model for Europe and support the concept of high-quality, objective and non-promotional information to patients from reliable sources, including the manufacturers of these medicines.
- People with rare and chronic diseases require, and are increasingly demanding, information about their disease area and available therapies. This information may be difficult to obtain and answers are sought from a number of sources including the Internet and healthcare professionals. It should be recognised that for some of these people the treatment they are receiving may not have a 'licensed' indication for their specific condition; nonetheless their desire and need for information is real. As a company we are sometimes approached with requests from both health care professionals and patients with queries about non-licensed use; information we are not allowed to share pro-actively. This area therefore raises a challenge, and in the interest of the patient needs attention. The issue could also be considered within this consultation.

Yours sincerely,

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

Baxter submission

Baxter welcomes the European Commission's public consultation on a legal proposal on information to patients as an important opportunity to share its views on this topic. Baxter generally supports our industry's view, which included recommendations for possible ways forward:

- European citizens expect and deserve a modern and comprehensive EU information strategy that will truly benefit them and help to improve public health.
- Access for all EU citizens and patients to non-promotional health and medicines information in their language must be improved. Baxter does not consider US-style Direct-to-Consumer Advertising as an appropriate model for Europe.
- Access to high quality medicines' information from multiple sources is needed, including from the pharmaceutical industry, respecting the highest quality standards. Information should be judged by its actual quality, not the source providing it.
- Availability of, and access to high-quality medicines information in all languages via the Internet must be enhanced, while recognizing the need for non-electronic tools for parts of the population and for improving access to such tools.
- Public Private Partnerships, involving a range of healthcare stakeholders, could be one part of a comprehensive strategy.
- Legislative reform at EU level is needed with the primary goal of giving the same opportunities to all EU citizens, taking into account positive experiences gained at individual Member State level.

Baxter agrees with the Commission that in a future system, product information provided by companies should, wherever possible, be based on already-approved documents such as the SmPC (Summary of Product Characteristics) and PIL (Patient Information Leaflet); however, where appropriate, information must be made more understandable to be useful for the intended audience.

Baxter supports the following categorisation of non-promotional information provision:

- Pro-active information (Push): provided unsolicited to the public, should be limited to general information on diseases, e.g. covering awareness, prevention, etc. but should not mention specific medicines.
- Reference information on diseases and medicines (Pull): sought by patients and citizens as in a library, e.g. through the Internet.
- Reactive Information on medicines: supplied in response to spontaneous enquiries received from patients and citizens.
- Support information: supplied with or subsequent to a prescription for a specific medicine, e.g. to support concordance with the prescribed medicine.

Under this model, the information provided should be based on authorised information (e.g. patient leaflet, summary of product characteristics) and comply with clearly defined

standards for high-quality information. Application of these could be monitored through a European-wide industry “health information” code of conduct, including effective quality

assessment procedures for the information as well as robust enforcement procedures in case of breaches.

As pointed out by the Commission, one of the objectives of the future legal proposal should be “*to avoid any unnecessary bureaucracy, in line with the principles of Better Regulation*”. Baxter believes that a system based on self-regulatory elements would be best suited to meet the original Commission’s objectives for the future proposal and achieve the greatest benefit for public health and each individual patient.

The pharmaceutical industry has a long experience with self-regulation, e.g. in the field of interactions with healthcare professionals. Self-regulation by the pharmaceutical industry has proven to be highly efficient and valuable, as it offers the opportunity to quickly adapt to changing needs in an un-bureaucratic manner.

Self-regulatory schemes with efficient governance and enforcement procedures would be the most practical and beneficial way forward, provided that an adequate legislative frame is put in place allowing the provision of high quality information from multiple sources. We are convinced that this approach would help ensure that information to patients on prevention, diagnosis, treatment and management of diseases meets the highest quality standards and provides the greatest benefits to patients.

Throughout Europe equity of access for people with rare diseases is one of the most pressing issues. The WHO has in 2007 published its 15th List of Essential Medicines to be used globally. The WHO list is intended to provide guidance to individual countries in determining which medicines are considered to be essential and in subsequently prioritizing their healthcare resources. Included in that list are both coagulation factors and immunoglobulins, used for the treatment of people with rare and chronic diseases, such as hemophilia and Primary Immune Deficiencies.

People with rare and chronic diseases require, and are increasingly demanding, information about their disease area and available therapies. This information may be difficult to obtain and answers are sought from a number of sources including the internet and healthcare professionals. It should be recognised that for some of these people the treatment they are receiving may not have a ’licensed’ indication for their specific condition; nonetheless their desire and need for information is real. As a company we are sometimes approached with requests from both health care professionals and patients with queries about non-licensed use; information we are not allowed to share pro-actively. This area therefore raises a challenge, and in the interest of the patient needs attention. The issue could also be considered within this consultation.

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 haemophilia, 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, anaesthesia, 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 range of technology platforms across our organisation to address unmet medical needs.

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

Our vision:

Baxter's vision is to be: recognised 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 commitment 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 specialise in biotechnology, medical devices and pharmaceutical products and therapies.
- We leverage our diverse technology platforms across our organisation to address unmet medical needs and to expand options for physicians and patients (e.g. medical plastics, isolation technology, regenerative technology, peritoneal dialysis 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 sterilisation.
- 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% of our sales are in businesses in which we are the leader in the 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 programmes.
- Increased R&D spending by 24% in 2007 versus 2006, 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 haemophilia.
- 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.