EURORDIS
ROUND TABLE OF COMPANIES

18th Workshop

EURORDIS Round Table of Companies (ERTC)

Corporate Responsibility in Improving Access to Orphan Medicinal Products

Wednesday 27 February, 2013 (9:00 to 16:30)

Brussels, Belgium
Hotel Le Plaza Brussels, Boulevard Adolphe Max 118 -126

CONCEPT PAPER

Access to medications in a timely and affordable manner is a long-standing issue for patients globally whether affected by cancers, infectious or rare diseases. This problem is more acute in current conditions of economic crises or health budget austerity measures as we observe in the EU since 2008.

There is no unique or simple solution. Key stakeholders working in partnership include patients, industry, regulators, national competent authorities and payers who are forging new concepts and practical measures to address these challenges. The aim is for faster, fair access for patients to treatments, improvement of medical practices based on these treatments and optimisation or reduction of the healthcare budget allocated to innovative treatments for chronic diseases. There are several solutions, some already consensual, and others emerging, but all well identified. These solutions can be implemented separately or in combination towards a new viable economic model for industry rewarding value, a sustainable public health budget model and for equitable approach ensuring that the most vulnerable (the patients) are at the centre of any proposal.

The European Commission published a new policy on Corporate Social Responsibility in October 2011 that states that to fully meet their social responsibility, enterprises "*should have in place a process to integrate social, environmental, ethical and human rights concerns into their business operations and core strategy in close collaboration with their stakeholders*"[1]. The term "corporate social responsibility or CSR" came into common use in the late 1960s and early 1970s after many multinational corporations formed the term stakeholder, meaning those on whom an organisation's activities have an impact[2].

The economic crisis and its social consequences have to some extent damaged consumer confidence and levels of trust in business. They have focused public attention on the social and ethical performance of enterprises. While there are opinions for and against the concept of corporate social responsibility, it cannot be denied that in these times of economic crisis expectations towards the private sector increase. In a study by Giannarakis and Theotokas in 2011[3], it was observed that at the beginning of the economic crisis, companies moved away from socially responsible behaviour due to the cost involved. This move away was higher in the US than in Europe, however participation in CSR was resumed as companies changed their

[1] Communication from the commission to the European Parliament, the council, the European Economic and Social Committee and the committee of the regions: A renewed EU strategy 2011-14 for Corporate Social Responsibility
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0681:FIN:EN:PDF
[2] R Freeman, Strategic management :a stakeholder approach (Pitman 1984) ISBN 978-0-273-01913-8
[3] Giannarakis, G and Theotokas, I (2011) The Effect of the Financial Crisis in Corporate Social Responsibility Performance. *Int. J. Marketing Studies*. 3 (1): 2-10

perception of the idea from a 'threat to an opportunity'. By renewing efforts to promote CSR, the Commission aims to create conditions favourable to sustainable growth, responsible business behaviour and durable employment generation in the medium and long term, while addressing consumers' and patients' needs.

An important challenge – and opportunity - is particularly present this year, which is achieving the goals of the EUROPLAN II project within EUCERD Joint Action. As a community we are faced with the looming deadline of this project that aims to increase the capacity of participants, support EU member states with different geographic and economic concerns and different states of readiness to deliver their National Plan on Rare Diseases via conferences and concrete guidelines. Many different stakeholders play a role in the international and interactive network of stakeholders (including patients, policy makers, academics and industry members) to speed up the elaboration and the implementation of Rare Diseases National Plans/Strategies, through scientific and technical assistance, and workshops.

Two countries have already held their national conferences as part of the EUROPLAN II project, Sweden and Greece, and both reported back on the challenges faced during their respective meetings. Greece in particular felt that no real improvement had been seen since 2010 and that none of the recommendations of the first Conference has been implemented. In addition, the economic crisis has deteriorated the already precarious situation for rare disease patients: lack of registries, no official identification criteria for centres of expertise, no policy for access to orphan medicinal products and increasingly difficult access to those already on the market.

Pharmacies in Greece had been reporting shortages of medicines as some distributors have re-exported comparatively cheap drugs from Greece to other European markets, achieving monetary gains of as much as 600%. Currently, there are fears of drug shortages in certain hospitals as a result of unpaid bills. And concerns that the problem could grow have led to a call for the country to re-evaluate the cost-effectiveness of medicinal products covered by its public health system. Companies members of the European Federation of Pharmaceutical Industries and Associations (EFPIA) offered to cap the total amount that Greece has to pay for its medications in a letter to the Greek ministers of health and finance.

A request was made to pharmaceutical companies, by the representative of the ministry for health, not to re-export the medicinal products thereby leaving citizens without treatment. It seems that this is due to the pricing policy that obliges companies to adopt the lowest price compared to the other EU countries leading to a shortage of medicinal products in Greece, the so-called external reference pricing.

Differential pricing in the context of pharmaceutical products is the strategy of selling the same medicine to different markets at different prices, based on the national GDP and sometimes also on the size of the population. It is an instrument used to improve access to medicines in developing countries, although shortcomings may persist. It seems interesting to launch this debate also inside the EU. In the past, some initiatives were already taken (e.g. Bremen declaration). There are also signals that the pharmaceutical industry is considering to make more use of differential pricing (BMJ 2011, 343, d8049).

The industry has always been a bit nervous about differential pricing, mainly because companies fear that lowly priced products will flow back to high income countries and also because of the practice of external reference pricing, whereby countries calculate a price for a drug on the basis of lower prices elsewhere.

A key point will be to develop an acceptable method to achieve the goal, while respecting the right of the Member States to operate their national health care systems.

The 18th workshop on "Corporate Responsibility in Improving Access to Orphan Medicinal Products" will be divided into three distinct sessions. The morning session will focus on 'Corporate Responsibility and National Measures' and 'Differential Pricing'.

The first part of the morning session, will be opened with an overview by EURORDIS of all consensual or emerging concepts and measures. The Commission will present the outcomes of its policy on Corporate Responsibility and will include speakers from the Commission as well as Industry members involved with the project on a Mechanism of Coordinated Access (MoCA) to Orphan Medicinal Products. This first part will be concluded with a presentation by an EBE-EuropaBio Task Force representative speaking about measures expected by industry in National Plans to improve access to orphan medicinal products.

The second part of the morning will focus on Differential Pricing, with a presentation followed by a panel discussion on the topic. Finally, we will close the morning session with three parallel breakout sessions enabling open and in-depth discussion on i) National Measures, ii) Differential Pricing and iii) Mechanism of Coordinated Access to OMPs.

The afternoon session will begin with feedback from the breakout sessions and then discuss the important issue of how to address the challenges of access to orphan medicinal products in countries most affected by the crisis in Europe. We will hear the industry perspective and follow this with a panel discussion involving the Chair of the Committee for Orphan Medicinal Products, a patient advocate and two representatives of industry.

The workshop will conclude with a wrap-up of the main discussions of the day.