

JANINA WITKOWSKA\*

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## Corporate Social Responsibility (CSR) of Innovative Pharmaceutical Corporations. The Case of BIOGEN

### Abstract

*The aim of this paper is to discuss the common features and specificity of Corporate Social Responsibility (CSR) practices of innovative transnational corporations (TNCs) acting in the pharmaceutical industry. The innovativeness of pharmaceutical firms is understood here as their ability to make a breakthrough in the treatment of rare, incurable diseases. The examination of the issue leads to the conclusion that the specificity of CSR in this industry is related to the contradiction between the economic and social/ethical aspects of innovation processes in this field. A key issue of CSR in the innovative pharmaceutical industry seems to be the pricing of drugs, especially orphan and ultra-orphan drugs, resulting in patients from less developed countries having limited access to life-saving medicines or those that improve the quality of life. Corporations use their monopolistic position to set extremely high prices. However, without the market/marketing exclusivity offered to pharmaceutical firms by the law, orphan drugs would probably not be developed, produced and commercialized. Traditional CSR practices (corporate philanthropy, community and neighborhood programs, volunteerism etc.) cannot be treated as sufficient 'compensation' for the high prices of medicines. Real, true CSR in the innovative pharmaceutical industry requires either abandoning or reducing extreme monopolistic privileges and offering medicines for rare diseases at lower prices.*

**Keywords:** *Corporate Social Responsibility (CSR), innovative pharmaceutical corporations, orphan drugs, access to drugs, BIOGEN*

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\*Ph.D., Full Professor at the University of Lodz, Institute of Economics, Faculty of Economics and Sociology, Lodz, Poland, e-mail: janwit@uni.lodz.pl

## 1. Introduction

The aim of this paper is to discuss the common features and specificity of CSR practices of innovative transnational corporations (TNCs) acting in the pharmaceutical industry and to evaluate some CSR practices in this field. The detailed research tasks are as follows: to discuss theoretical approaches towards CSR that might constitute the most promising explanation of the behavior of innovative TNCs in the pharmaceutical industry; to define some economic and ethical dilemmas of CSR activities in the pharmaceutical industry; to discuss some limitations in access to innovative medical treatment for patients from less developed countries in the context of CSR practices of pharmaceutical firms; to present a case study of BIOGEN and compare the theoretical findings with the practices of this TNC.

Corporate Social Responsibility (CSR) is defined as the voluntary integration of social and environmental issues into business activities and relations with stakeholders combined with the readiness to sacrifice profit for the sake of certain social interests (Carroll, Shabana 2010, pp. 85–100; Benabou, Tirole 2010, pp. 1–19). In its Europe 2020 Strategy, the EU proposes a new definition of CSR: “*the responsibility of enterprises for their impacts on society*” (EU 2011, p. 6). All these aspects will be taken into consideration while discussing the main issue in the paper.

The innovativeness of pharmaceutical firms is understood here as their ability to make a breakthrough in the treatment of rare, incurable diseases. One of the links between the CSR of the pharmaceutical industry and its innovativeness is its attitude to so-called orphan drug development and the marketing strategy in this field. These drugs are called “orphan drugs” because no one wants to “adopt” or manufacture them because of weak economic incentives and their lack of commercial value (Bruyaka, Zeitzmann, Chalamon, Wokutch, Thakur 2013, p. 117). The concept of an ‘orphan disease’ implies a lack of stewardship; rare diseases have been neglected by society for a long time (Berman 2014, p. 4).

The main theoretical and practical issues that appear here are the contradiction between the economic and social aspects of innovation processes in the pharmaceutical industry and ways to smooth it over. Long-term, costly and risky innovation processes (economic aspect) encounter high expectations of patients related to the accessibility of innovative, life-saving treatments (social aspect). Some questions arise in this context: How could the contradiction between the economic and social aspects of innovation in the pharmaceutical industry be solved in less developed countries? What is the essence of real Corporate Social Responsibility in such a difficult case? What are the drivers of CSR in the field of the orphan drugs market?

Even quite recently, intense disputes went on between CSR proponents and opponents (Friedman 1970; Henderson 2001; Porter, Kramer 2006; Carroll, Shaba-

na 2010). Nowadays, the question of “*whether to do this or not*” has been replaced rather by “*why-, how- and which-* questions” in the course of theoretical and empirical analyses. Business practices in different industries reflect the CSR concept more and more. Tradition and respected ethical norms are decisive for whether enterprises treat social responsibility as a value deeply rooted in their practice or whether they use it mainly for marketing purposes.

## 2. CSR and the pharmaceutical industry – theoretical background

The literature on CSR identifies six key characteristics around which there is a wide consensus. These are:

1. CSR is voluntary and goes beyond activities prescribed by the law.
2. It focuses on integrating or managing externalities which arise when products or services are delivered/rendered by companies.
3. CSR targets various stakeholder groups such as consumers, employees, suppliers, and local communities. The company not only has responsibilities to its shareholders, but it also caters to groups other than businesses.
4. There is a need to integrate social, environmental and economic responsibility with everyday business operations and decision making. It should not, however, conflict with the profitability of the company.
5. CSR must be integrated into normal business practice and in a company’s system of values.
6. CSR goes beyond philanthropy and focuses on “real CSR.” The company should consider how its entire operations, i.e., its core business functions, impact society (Crane, Matten, Spence 2014, pp. 9–12; Bondy, Moon, Matten 2012, p. 283).

The hitherto attempts to explain the specificity of CSR in the pharmaceutical industry are based on general models of CSR or their modifications. The general attitude boils down to the acceptance of the fact that the pharmaceutical industry “*provides cure to a life-threatening disease, but is incapable of providing cure to everyone at affordable prices*” (Nussbaum 2008, p. 67). Nevertheless, the establishment of the relationship between actions and business practices in the pharmaceutical industry and CSR seems to be possible. Some specific positive effects of CSR actions for pharmaceutical companies are distinguished among the general effects of CSR, e.g., building a strong corporate reputation, attracting and retaining a motivated workforce, and reducing regulatory oversight (Nussbaum 2008, pp. 67–76).

According to Freeman’s stakeholder theory, pharmaceutical companies proactively engage in stakeholder management. The list of the major stakeholders

of these companies, apart from typical groups of stakeholders, e.g., stockholders and investors, employees, communities, competitors and the media, also includes special stakeholders, such as patients (consumers), physicians/prescribers (customers), regulatory agencies, legislators, and scientific and patient associations. The following are perceived as the main CSR goals of pharmaceutical companies: reducing their environmental footprint, employee safety, the safe handling of unused medicines, supplier management, material reduction, sustainable workforce, employee and community involvement, and access to medicines (Min, Desmoulin-Lebeault, Esposito 2016, pp. 58–69).

Schwartz and Carroll's three-domain approach to CSR (economic, legal and ethical domains existing simultaneously) combined with the concept of strategic CSR could be used in order to discuss CSR in the pharmaceutical industry (Bruyaka, Zeitzmann, Chalamon, Wokutch, and Thakur 2013, pp. 45–65). These two theoretical approaches are perceived as complementary in explaining CSR activities in orphan drug development. Schwartz and Carroll's model concentrates mainly on a firm's motives for acting in the field of CSR. Strategic CSR is defined as "... any 'responsible' activity regardless of motive that potentially allows a firm to achieve a competitive advantage" (Bruyaka, Zeitzmann, Chalamon, Wokutch, Thakur 2013, p. 46). In terms of Schwartz and Carroll's model, the attitude of pharmaceutical companies to orphan drug development shows that:

- economic motivations are important for these firms, but they are not the only ones,
- incentives provided by orphan drug legislation also create important encouragement for their activities in this field,
- the specificity of doing business in rare diseases requires ethical responsibilities.

The motives of biopharmaceutical firms to develop orphan drugs range from economic reasons ("*develop and commercialize breakthrough innovations*") to dominant ethical motives ("*to save people*"). However, there is also a wide-spread view presented by smaller firms that established pharmaceutical companies are driven primarily by economic interest and opportunism created by orphan drug legislation (Bruyaka, Zeitzmann, Chalamon, Wokutch, Thakur 2013, p. 56).

### **3. The specificity of CSR of the pharmaceutical industry – ethical and economic dilemmas**

The pharmaceutical industry is often criticised for unethical behaviour such as industry-funded ghostwriting, publication bias, prescription data mining, gifts to doctors. It is also criticized for sanctioning excessive prices for life-saving medicines

for those in the developing world (Lőrinczy, Formankova 2015, pp. 2011–2012; Lee, Kohler 2010, p. 642). The empirical questionnaire research results – scarce as they are – also show that ‘...*pharmaceutical companies do not have clearly set procedures for ethical and CSR activities*’ (Lőrinczy, Formankova 2015, p. 2014). Such an attitude was spotted in some of the new EU Member States, i.e., in the Czech Republic and Hungary. Moreover, the differences in ethical behavior between so-called original and generic pharmaceutical companies are observed. While the original companies implement ethical issues to a greater extent, the generic companies “...*still do not have strict rules which would help the employees not to be misled in their work*” (Lőrinczy, Formankova 2015, p. 2014). Although the generic companies usually have Codes of Ethics, they are not respected. At the same time, public pressure on pharmaceutical companies occurs, in general, to implement ethical rules in their strategies and practices.

Areas for CSR in the pharmaceutical industry are perceived to include pricing, patents, research and development (R&D), joint public-private initiatives (JPPIs), and the appropriate use of medicine (Nussbaum 2008, p. 71). The focus of this paper is on the pricing of drugs as a controversial issue connected with accessibility to medicines, especially in the case of orphan and ultra-orphan diseases. Discussing this problem requires that social expectations, economic determinants (costs of R&D and medical trials, risks, market failure) and international trade repercussions be taken into account.

Regarding **social expectations**, pharmaceutical corporations are expected to provide societies with medicines of good quality at fair prices. The pharmaceutical industry is criticised, even blamed, for the fact that prices for life-saving drugs are much too high when considering the poverty of individuals and whole nations. Critics point out that companies put corporate profits before human life. Such views negatively influence the public image of pharmaceutical corporations, which causes serious reputation problems (Leisinger 2005, pp. 577–594). In this context, the question arises if CSR practices, such as corporate philanthropy, community and neighborhood programmes, volunteerism, and donations could be socially accepted as sufficient compensation for the high prices of medicines?

The reactions of pharmaceutical corporations to the above mentioned social expectations could range from a readiness to help out with donations of medicines in cases of acute emergency (for example, Novartis provides free treatment for all leprosy patients in the world) to differential pharmaceutical pricing for patients from developing countries on a case-by-case basis. Some corporations are also involved in strengthening the drug infrastructure, *mHealth* initiatives and targeted R&D in developing countries (Leisinger 2005, pp. 577–594; Droppert, Bennett 2015, pp. 1–8).

As for the **economic determinants** of pricing of medicines, it is worth mentioning that drugs for typical diseases in developing countries, such as tuberculosis, diarrheal diseases, pneumonia, malaria, and measles, are relatively cheap, ef-

fective and off-patent. However, they are not available where they are needed (for example, the lack of access to medicines in the rural regions of sub-Saharan Africa, Leisinger 2005, p. 590). Nevertheless, approximately one-third of the world's population suffers from a lack of access to medicines or vaccines for treatable diseases. This number is higher in Africa and South East Asia, reaching 50%. These data, together with the information that 15% of the world's population consume over 90% of the pharmaceuticals, confirm the existing inequality in access to medicines between developed and developing countries (Lee, Kohler 2010, p. 641).

The situation in the market of innovative drugs – orphan or ultra-orphan drugs – is different as far as the pricing of medicine is concerned. The rare frequency of some diseases, which is defined by law, determines the pricing policies of pharmaceutical companies. In the USA, according to the Orphan Drug Act (Public Law 97–414, as amended), the term “rare disease or condition” means any disease or conditions which affect (A) fewer than 200,000 persons in the country or (B) affect more than 200,000 in the USA and for which there is no reasonable expectation that the cost of developing and making available in the USA a drug for such disease or condition will be recovered from sales in the USA of such drug (Orphan Drug Act, <https://www.fda.gov>). In the EU, a common definition of rare diseases has been accepted in the official documents for the purposes of Community-level policy work. The EU considers diseases to be rare when they affect not more than 5 per 10,000 persons in the integration grouping, i.e., fewer than 1 in 2000 persons (EC 2000, pp. 2–3; EC 2008, p. 2). In the case of a life-threatening, seriously debilitating or serious and chronic condition, a status of rare disease is eligible even when its prevalence is higher than 5 per 10,000 (EC 2000, pp. 2–3). These two definitions above show the similarities in the attitudes of both the USA and the EU towards numerical criteria for rare diseases.

It is estimated that there are about 7000–8000 rare diseases and these numbers might still be underestimated. Rare diseases affect, in aggregate, 25–30 million people in the USA and 6–8% of the population in the EU, i.e., between 27 and 36 million people (Public Health, <https://ec.europa.eu>, Berman 2014, p. 3). There is a lack of information about the situation in this field in developing countries.

Long-term and costly R&D processes, high risks and uncertainty, the costs of medical trials, and the narrow markets have a serious impact on the attitude of pharmaceutical corporations towards orphan drugs and their pricing. The prices of orphan drugs are extremely high. They are less likely to face competition, and they provide a high return on investment: orphan drugs without competition are 2.6 times more expensive than those with competition (MarketLine 2013, p. 12). As illustrations of the problem of the pricing of orphan drugs, data related to the annual costs of the treatment per patient can be used in the case of:

- Cinryze; in this case, the annual cost per patient amounts to USD 487,000.
- Soliris, with an annual cost of USD 486,000 respectively (MarketLine 2013, p. 12).

The costs of orphan drugs have been growing consistently. One decade ago, the company GENZYME sold some of the most expensive drugs in the world, costing up to \$200,000 per patient per year for disorders often requiring life-long treatment, and usually, the same price was charged all over the world (Nussbaum 2008, p. 72).

It is obvious that such high costs of the treatment with orphan drugs cannot be covered by patients on their own. They are usually covered by insurance companies (sometimes with a co-payment by patients) or by governments from public budgets. Both forms of financing could be available in developed countries. However, in a crisis, even these countries have negotiated prices or demanded that companies cut prices. It is estimated that around one-third of EU patients have difficulty accessing drugs or do not have access to the drugs they need (Market-Line 2013, pp. 12–13).

The pricing of medicines could also have **international trade repercussions** if drugs at lower prices – although they are conventional or orphan drugs – are offered to patients from developing countries. The trade in such medicines should be controlled to prevent re-exportation or leakage of low-priced drugs to the market of developed countries (Leisinger 2005, p. 587).

#### **4. Regulatory policies towards the promotion of development of innovative orphan drugs**

Taking into account that the development, production and commercialization of orphan drugs encounter serious economic barriers, developed countries introduce specific legislative guarantees/incentives for any company that obtains an orphan drug designation. The above-quoted regulations implemented by the USA and the EU not only define the notion of a rare disease but also guarantee **the market/marketing exclusivity** for producers of medicines for rare diseases. Firms become monopoly providers able to charge monopoly or near-monopoly prices.

In the USA, exclusivity means exclusive marketing rights granted by the FDA upon approval of a drug and they can run concurrently with a patent or not. Orphan Drug Exclusivity lasts seven years. It prevents the FDA from approving any other application for the same drug for the same orphan disease or condition in the 7-year-period (FDA/CEDER SIBA 2015).

In the EU, market exclusivity means that the Community and the Member States shall not accept any application for marketing authorization, or grant such an application for similar medicines for a period of 10 years. This should protect producers from the market competition of similar medicines with similar indications. Nevertheless, this period could be reduced to 6 years if, at the end of the

fifth year, there is evidence available that the medicine is sufficiently profitable not to justify maintaining market exclusivity (EC 2000, pp. 7–8). It is worth noting that marketing authorization is carried out centrally in the EU, which means that a single decision of the European Commission is valid in all EU Member States (EMA 2018).

The market/marketing exclusivity is generally regarded as the most significant incentive offered to develop orphan drugs (IOM Institute of Medicine 2010, pp. 88–87). Other incentives for orphan drug development, production and commercialization include:

- fee reductions or exemption from user fees,
- tax reductions or tax credits,
- grants for clinical trials,
- consultation with staff on acceptable research designs.

The above-quoted instruments are treated as “push” incentives which are intended to subsidize or lower research and other development-related costs. The market/marketing exclusivity and the mechanisms to speed and facilitate the review of drugs are called “pull” incentives (IOM Institute of Medicine 2010, p. 86).

According to the regulations in the USA, 50% of the qualified clinical testing expenses for drugs for rare diseases or conditions could be treated as a credit against the tax imposed for the taxable year. Grants and contracts for the development of drugs for rare diseases and conditions are also foreseen by law (Public Law 97–414, 1983). The FDA provides grants for clinical studies on the safety and/or effectiveness of products for rare diseases that will either result in, or substantially contribute to market approval of these products. Grant funding lasts for 3 to 4 years. At any one time, financial sources are used for 60 to 85 ongoing projects (FDA 2018).

The list of incentives offered by the EU embraces protocol assistance – a form of scientific advice – at a reduced charge for designated orphan medicines, and fee reductions for different regulatory activities related to designated orphan medicines. Companies classified as small and medium enterprises (SMEs) benefit from further incentives which include administrative and procedural assistance. The European Medicines Agency (EMA) does not offer research grants for sponsors of orphan medicines, but funding is available for these purposes from the European Commission and under *Horizon 2020*, the Framework Programme for Research and Innovation (the theme *Personalising Health and Care* which covers *New therapies for rare diseases*) as well as under the transnational programme for rare diseases *E-Rare*. Member States also offer some incentives for designated orphan medicines (EMA 2018).

All these instruments have played an important role in the development of R&D in the field of rare diseases and the production of drugs. Some data seem to confirm this observation. Regarding the USA, before 1983, only 38 orphan drugs were developed, while after introducing supporting policy instruments on the basis of the Orphan Drug Act of 1983 more than 220 new orphan drugs were ap-



proved and marketed in the USA, and more than 800 additional drugs were in the research pipeline (Rare Disease Act of 2002, 116, STAT. 1988–1989). In the years 2000–2008, orphan drugs accounted for 22% of the innovative drugs approved by FDA and 31% of the innovative biologics. It is worth noting that 55% of 108 orphan drugs approved from 1984 to 1999 in the USA, and which were still available in 2010, had generic equivalents on the market manufactured by competing companies (IOM Institute of Medicine 2010, pp. 92–93). These data indicate that the processes of distributing innovative medicines occur.

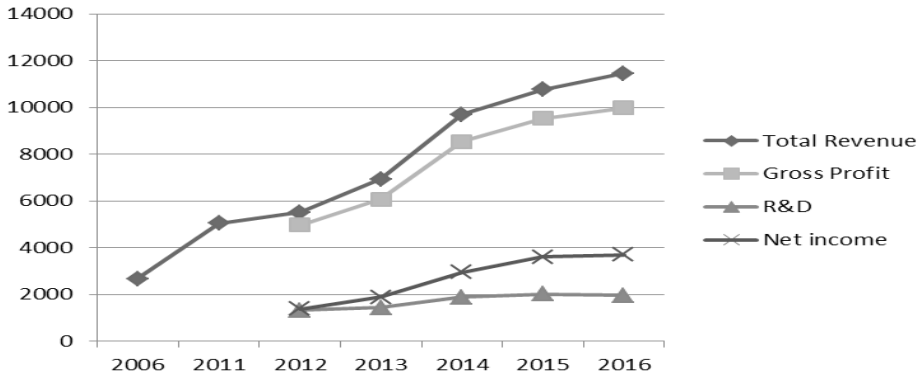
Some data on orphan drug sales also confirm the growing activity of pharmaceutical firms in this field and show promising prospects for the development of the orphan drug market. For example, global orphan drug sales grew to USD 83 billion in 2012, showing an annual growth rate of 7.1% compared to the previous year. In 2012, around 35% of the pharmaceutical industry's new drug offerings were orphan drugs. Orphan drugs are expected to bring in revenues of USD 127 billion by 2018 and will account for almost 16% of total prescription drug sales, compared to 12.9% in 2012 (MarketLine 2013, p. 14).

## 5. A case study – BIOGEN – *some facts*

BIOGEN, formerly known as Biogen Idec, was founded in 1978 by a group of scientists and three venture capitalists in Geneva/Switzerland. Now it is a transnational pharmaceutical corporation introducing onto the market the most innovative drugs for rare diseases (A biotech pioneer, [www.biogen.com](http://www.biogen.com)). BIOGEN focuses on developing, manufacturing and delivering therapies for neurological, autoimmune and hematologic disorders. BIOGEN has introduced leading marketing products for rare diseases, among them AVONEX (interferon beta-1a) approved for the treatment of relapsing forms of multiple sclerosis (MS). AVONEX was among the Top 10 Orphan Drugs in 2012 and is predicted to remain in this group until 2018 (MarketLine 2013, p. 10). In 2016, BIOGEN registered in the USA the first and only one approved drug for the treatment of a rare genetic disease, SMA (*Spinal Muscular Atrophy*), i.e., SPINRAZA. In 2017, its registration was accomplished in the EU. The company continues its innovation efforts, which are confirmed by 14 drug candidates in clinical trials (BIOGEN 2017a).

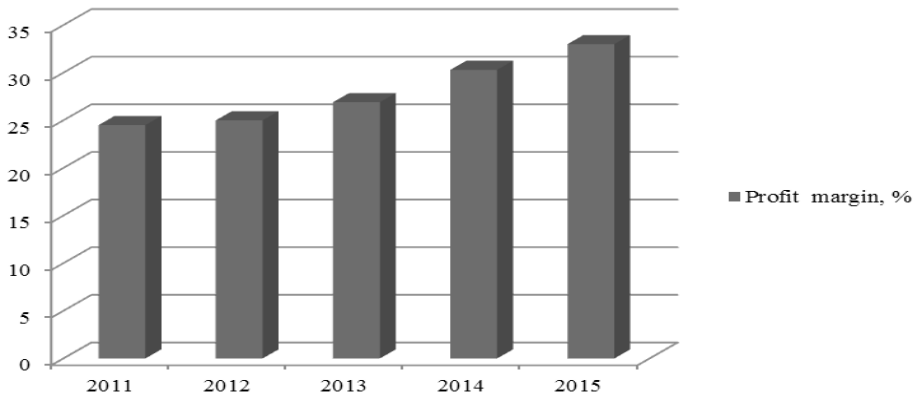
The company operates in the US, Canada, Australia, New Zealand, Japan, Europe, and Central and South America. It has manufacturing facilities located in Research Triangle Park, North Carolina and Cambridge, Massachusetts and Hillerød, Denmark. The major competitors of BIOGEN, Inc. are Abbott Laboratories, Amgen, Inc., Bristol-Myers Squibb, GlaxoSmithKline Plc, Pfizer Inc., Sanofi Genzyme, and Teva Pharmaceutical Industries Limited (MarketLine 2015; p. 29, 34).

Graphs 1 and 2 present key financial information on the economic activities of BIOGEN, including some data on total revenue, gross profit, R&D expenditure, net income, profit margin, and profit per employee.



**Graph 1. BIOGEN – Financial overview, 2006–2016, USD, Million**

Source: MarketLine and own elaboration.



**Graph 2. BIOGEN – Profit margin, 2011–2015, %**

Source: MarketLine and own elaboration.

An analysis of the financial data related to BIOGEN allows us to summarize the following:

- Total revenue of the corporation grew twofold between 2012–2016, reaching USD 11.5 Billion.
- R&D expenditures amounted to almost USD 2 Billion in 2016 (about 20% of annual revenues has been reinvested back into R&D over the past decade).
- Net income grew to the level of USD 3.7 Billion in 2016.
- The profit margin increased from 24.5% in 2011 to 33.0% in 2015.
- Total employment amounted to 7400 people worldwide in 2016.

- Profit per employee almost doubled in the same period.
- Payouts to members of the Executive Board ranged from USD 4 to 18 million annually (MarketLine 2015; BIOGEN 2016, 2017a).

The above-quoted data confirm the good financial condition of the company and indicate its prosperous future. Although it is difficult to judge what the impact of incentives offered by the state has been on its financial/market situation, one can suppose that the state policy towards orphan drug development has given the company strong and positive motives.

As for revenues by geography, developed countries remain the largest geographical market for BIOGEN's products. The USA was the leading market for products offered by BIOGEN in 2015. It accounted for 73.9% of its total revenues. Europe took second place with 14.2% (excluding Germany), then Germany with 6.2%, Asia – 1.9% and others – 3.7% respectively. The high geographical concentration of revenues is treated as a weakness in BIOGEN's SWOT analysis (MarketLine 2015, pp. 28–29). However, a widening of the market for innovative/orphan drugs in other parts of the world economy seems to be limited by the high prices of the drugs.

## 6. The CSR practices of BIOGEN

BIOGEN is a socially responsible transnational corporation engaged in all general and specific areas of CSR which are also typical of other firms' activities in this field, i.e.:

- Protection of the environment, including driving responsibility across the value chain; (BIOGEN has been a carbon neutral company since 2014 and introduced a *Zero waste to landfill* strategy).
- Stakeholder engagement (including investors, patients, patient groups, health-care professionals, employees).
- Social performance (i.e. community giving in the form of grants, the Matching Gifts Programme, Volunteer Hours).
- Diversity & Inclusion (Women and Minorities).
- Employee development; Health & Safety at Work.
- The establishment of the BIOGEN Foundation (providing access to hands-on science education, teacher development in science, college readiness and support, and basic social needs – combatting child hunger, poverty and social mobility) (BIOGEN 2016, 2017a, 2017b.).

It is worth pointing out that in 2014, BIOGEN (at that time BIOGEN Idec) was named the Global Biotechnology Industry Leader on the Dow Jones Sustainability World Index (DJSI World), (Regional Business News 09/23/2014).

All these CSR activities of BIOGEN confirm that the idea of traditional social responsibility is a value deeply rooted in the practice of the company. This TNC carries out all conventional activities which are treated as a core of CSR in the light of theoretical findings, as well as some industry-specific activities. Table 1 presents a comparison between the main theoretical characteristics of CSR, pharmaceutical industry-specific CSR and BIOGEN's CSR practices. Nevertheless, the high pricing of medicines for rare diseases remains a controversial issue. This situation is common in the pharmaceutical industry. The case of BIOGEN illustrates this problem.

Regarding its **pricing policy**, BIOGEN informs that the company strives to achieve an appropriate balance among three key principles:

- The clinical value of the product.
- The impact of the therapy on the health care system, including the financial implications on payers and patients.
- Stakeholder returns.

The company is aware of the need to remove barriers to access the medicines. A justification for its pricing policy could be, among others, the fact it spent about 20% of its revenues on R&D in the last decade, and provided over USD 1.1 Billion in patient financial assistance in 2016 (BIOGEN 2017a).

Nevertheless, some ethical dilemmas related to the selectivity of this assistance have not disappeared. Someone decides indirectly "*Who will live who will not have a chance?*" Also, the argument that high prices enable them to earn money for further R&D cannot be convincing for patients and organizations from less developed countries. Future new cutting-edge solutions would be not available for them either. In this context, some doubt arises that perhaps real, true CSR requires abandoning or at least reducing monopolistic privileges and offering medicines for rare diseases at lower prices.

These dilemmas could be illustrated by the first-ever medicines for SMA (*Spinal Muscular Atrophy*) – the newly registered SPINRAZA (nusinersen). SMA is a rare disease, affecting about 35,000 patients worldwide, mainly children, so it is treated as a small addressable market size. The drug will cost USD 125,000 per injection, amounting to USD 750,000 for the first year and USD 375,000 each year after that (Weintraub 2017). After the registration of SPINRAZA in the European Union, the issue of the price was intensively discussed, and it is expected that the price of the medicine will be up to EUR 270,000 for the three-dose-maintenance per individual per year (SMA Europe 2017). It is worth noting that this therapy is lifelong. This extremely costly therapy arouses heated discussions, even in the USA. The drug is out of the reach of individual patients, not only those from less developed countries, unless governments pay for it. Predictions related to worldwide sales of SPINRAZA are promising. It is estimated that it will amount to over USD 2.3 billion by the early 2020s (Weintraub 2017). Intensive marketing

and BIOGEN's involvement in multiple community engagement initiatives may boost future revenues for SPINRAZA (Market Realist 2017).

Finally, the role of other organizations in the breakthrough in the treatment of SMA should be pointed out. *Cure SMA* is a non-profit organization dedicated to the treatment and cure of SMA, funding groundbreaking research in this field and providing support to families that suffer from SMA. Since its founding in 1984, *Cure SMA* has invested USD 70 Million in research on the treatment of SMA. In 2003–2006, *Cure SMA* provided over USD 500,000 in seed grants to fund the therapeutic approach that led to SPINRAZA. The critical intellectual property was generated by Cold Spring Harbor Laboratory (CSHL) and the University of Massachusetts Medical School at the preclinical phase of development of SPINRAZA. In 2010, IONIS (then ISIS Pharmaceuticals) licensed the intellectual property to begin the development of SPINRAZA (*Cure SMA* 2018).

In January 2012, IONIS entered into a collaborative agreement with BIOGEN for the development and commercialization of the drug. BIOGEN received worldwide rights for commercialization of the drug in August 2016. IONIS has received a payment of USD 320 Million from BIOGEN for the development of SPINRAZA, including a USD 60 Million milestone payment and a further USD 90 Million based on regulatory approvals in Europe and Japan. IONIS will also receive tiered royalties on the drug's sales up to 1% (Drugdevelopment–technology.com 2017). This means that financial obligations of BIOGEN towards the innovator will decrease future profits of the company coming from the global sale of SPINRAZA.

However, the question whether the extremely high price of SPINRAZA is economically and ethically justified remains unanswerable.

## 7. Conclusions

1. The innovative pharmaceutical industry is involved in CSR practices which could be discussed on the grounds of main CSR models or a combination of them.
2. The specificity of CSR in this industry is related to the contradiction and the conflict between the economic and social/ethical aspects of innovation processes in this field. The essence of this contradiction is the limited access of patients from less developed countries to life-saving medicines or those that improve the quality of life.
3. A key issue of CSR in the innovative pharmaceutical industry seems to be the pricing of drugs, especially orphan and ultra-orphan drugs. Corporations use their monopolistic position to set extremely high prices. However, with-

out the market/marketing exclusivity offered to pharmaceutical firms by the law, orphan drugs would not be probably developed, produced and commercialized.

4. Traditional CSR practices in the pharmaceutical industry (corporate philanthropy, community and neighborhood programmes, volunteerism etc.) do not seem to be sufficient “compensation” for the high prices of the medicines.
5. The case study of the pharmaceutical company BIOGEN shows that the pharmaceutical company is aware of the need to remove barriers to access the medicines. Nevertheless, financial assistance for patients and free drug programmes offered to some patients are inevitably connected with their selectivity.
6. Real, true CSR in the innovative pharmaceutical industry requires either abandoning or at least reducing monopolistic privileges and offering medicines for rare diseases at lower prices. Pharmaceutical corporations should take into consideration the differences in GDP per capita between developed and developing countries.
7. Stronger co-operation between different groups of stakeholders in different countries would be necessary in order to use financial resources in a more efficient way; societies and individuals would be able to offer to support patients with rare diseases and their families.

**Table 1. Main theoretical characteristics of CSR, pharmaceutical industry-specific CSR and BIOGEN's CSR practices**

Main characteristics of CSR – theoretical findings	Pharmaceutical industry-specific CSR areas and practices	The CSR practices of BIOGEN	
		Conventional practices	Industry-specific practices
<ul style="list-style-type: none"> <li>• Voluntary character of CSR practices.</li> <li>• Focus on integrating or managing the externalities which arise when products or services are delivered/rendered by companies.</li> <li>• Orientation of CSR practices on stakeholders and other social groups.</li> <li>• Integration of social, environmental and economic responsibility with everyday business operations and decision making.</li> <li>• Integration of CSR into normal business practices and a company's system of values.</li> <li>• Concentration on "real CSR"- going beyond philanthropy.</li> </ul>	<ul style="list-style-type: none"> <li>• Pricing of medicines.</li> <li>• Patenting of new medicines.</li> <li>• Research and development (R&amp;D).</li> <li>• Joint public-private initiatives (JPPIs),</li> <li>• Appropriate use of medicines.</li> <li>• Proactive engagement in stakeholder management (including special stakeholders such as patients (consumers), physicians/prescribers (customers), regulatory agencies, legislators, scientific and patient associations.</li> <li>• Safe handling of unused medicines.</li> <li>• Increased access to medicines for different social groups.</li> <li>• Donations of medicines in emergency situations.</li> </ul>	<ul style="list-style-type: none"> <li>• Protection of the environment, including driving responsibility across the value chain.</li> <li>• Stakeholder engagement.</li> <li>• Social activities (community giving – grants, Matching Gifts Programme, Volunteer Hours)</li> <li>• Activities in the field of "Diversity &amp; Inclusion".</li> <li>• Employee development.</li> <li>• Health &amp; Safety at work</li> </ul>	<ul style="list-style-type: none"> <li>• Proactive engagement in stakeholder management (patients, patient groups, healthcare professionals).</li> <li>• Investigational access to medicines for patients (clinical trials, expanded access programs (EAPs) to patients who are unable to participate in clinical trials, single-patient access or emergency use).</li> <li>• Affordability access (financial assistance to patients who are otherwise unable to access BIOGEN's medications).</li> <li>• Education of physicians and demonstration of product efficacy and value.</li> <li>• R&amp;D expenditure in the field of rare diseases.</li> <li>• Grants for middle and high school students made through the BIOGEN Foundation and the Community Lab.</li> </ul>

Source: Own elaboration on the basis of the references used in the paper.

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## Streszczenie

### **SPOŁECZNA ODPOWIEDZIALNOŚĆ (CSR) INNOWACYJNYCH KORPORACJI FARMACEUTYCZNYCH. STUDIUM PRZYPADKU BIOGEN**

*Celem artykułu jest dyskusja nad ogólnymi cechami społecznej odpowiedzialności przedsiębiorstw (CSR) i specyfiką praktyk podejmowanych w tym zakresie przez innowacyjne korporacje transnarodowe, działające w przemyśle farmaceutycznym. Innowacyjność firm farmaceutycznych rozumiana jest tu jako ich zdolność do dokonywania przełomu w leczeniu rzadkich, nieuleczalnych chorób. Analiza tego problemu prowadzi do wniosku, że specyfika CSR w tym przemyśle jest związana ze sprzecznością, jaka ujawnia się między ekonomicznymi i społecznymi/etycznymi aspektami procesów innowacyjnych. Kluczową kwestią społecznej odpowiedzialności przedsiębiorstw w innowacyjnym przemyśle farmaceutycznym wydaje się być wycena leków, a w szczególności tzw. leków na choroby sieroce i ultra-sieroce, a co za tym idzie ograniczony dostęp pacjentów z mniej rozwiniętych krajów do leków ratujących życie bądź poprawiających jakość ich życia. Korporacje wykorzystują swoją monopolistyczną pozycję do ustanawiania ekstremalnie wysokich cen tych leków. Jednak bez przyznanej im prawnie rynkowej wyłączności, leki na choroby sieroce nie powstałyby i nie zostały wprowadzone na rynek. Tradycyjne praktyki CSR (filantropia, programy na rzecz społeczności lokalnych, wolontariat itp.) nie mogą być traktowane jako wystarczająca „kompensata” za wysokie ceny leków. Rzeczywista, prawdziwa społeczna odpowiedzialność w innowacyjnym przemyśle farmaceutycznym wymaga rezygnacji z monopolistycznych przywilejów bądź ich zmniejszenia i zaoferowanie leków na rzadkie choroby po niższych cenach.*

**Słowa kluczowe:** społeczna odpowiedzialność przedsiębiorstw (CSR), innowacyjne korporacje farmaceutyczne, leki sieroce, dostęp do leków, BIOGEN