CROWDSOURCING AS A TOOL FOR RISK MANAGEMENT IN RESEARCH AND DEVELOPMENT ACTIVITY OF PHARMACEUTICAL COMPANIES

„Crowdsourcing", jako narzędzie zarządzania ryzykiem w działalności badawczo-rozwojowej przedsiębiorstwa farmaceutycznego

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STRESZCZENIE

W artykule zdefiniowane zostało pojęcie „crowdsourcing'u". Przedstawiono w nim, że uzyskanie zwrotu środków finansowych zainwestowanych w działalność badawczo-rozwojową przedsiębiorstwa farmaceutycznego jest uzależnione od realizacji odpowiednio ryzyka: 1) inwestycyjnego, 2) organizacyjno-czasowego, 3) braku zapewnienia dostępności produktu, 4) formalno-prawnego, 5) braku dostosowania produktu do praktycznych wymogów systemu ochrony zdrowia, 6) braku skuteczności lub bezpieczeństwa produktu. Następnie przedstawiono „crowdsourcing" jako narzędzie zarządzania i minimalizacji wskazanych powyżej, poszczególnych ryzyk.

ABSTRACT

The article defines the concept of 'crowdsourcing'. It indicates that obtaining a return on funds invested in a pharmaceutical company's research and development activity depends on risks associated with, respectively: 1) investment, 2) organisation and time, 3) failure to provide availability of a product, 4) formal and legal aspects, 5) failure to adjust the product to practical requirements of the healthcare system, 6) lack of safety or efficacy of the product. Subsequently, the author presents crowdsourcing as a tool for management and mitigation of the specific risks indicated above.

Keywords: crowdsourcing, financing, risk, open innovation, the Internet, product, drug, medical device, healthcare, pharmaceutical company

Słowa kluczowe: „crowdsourcing", finansowanie, ryzyko, otwarta innowacja, Internet, produkt, lek, wyrób medyczny, ochrona zdrowia, przedsiębiorstwo farmaceutyczne

'CROWDSOURCING' – DEFINITION AND CLASSIFICATION

The term 'crowdsourcing' [1] is a neologism created from a combination of two English words, i.e. crowd and outsourcing, [2] a word which has already entered the Polish language,[3] or – as pointed out by some authors, the word source[4]. The term 'crowdsourcing' was defined and used for the first time by Jeff Howe, a 'Wired' journalist, in his article entitled: 'The rise of crowdsourcing' published in 2006[5]. He indicated that '*Technological advances in everything from product design software to digital video cameras are breaking down the cost barriers that once separated amateurs from professionals. Hobbyists, part-timers, and dabblers suddenly have a market for their efforts, as smart companies in industries as disparate as pharmaceuticals and television discover ways to tap the latent talent of the crowd. The labor isn't always free, but it costs a lot less than paying traditional employees. It's not outsourcing; it's crowdsourcing.*' [6].

It is also worth indicating that in accordance with the commonly accepted definition: 'crowdsourcing' is 'a process in which an organisation (enterprise, public institution, non-profit organisation) outsources tasks which traditionally are carried out by its employees, to an unidentified, usually very broad group of people in the form of an open call (term constituting a portmanteau of the words: 'crowd' and 'sourcing'). Crowdsourcing makes it possible for all Internet users to participate in tasks which used to be reserved for a narrow group of experts' [7]. On the other hand, B. Malinowski and M. Giełzak define *'crowdsourcing' as 'outsourcing directed at a crowd. This process consists in opening to mass participation of a CROWD* [8] *in tasks which are normally carried out internally or commissioned to experts. Crowdsourcing provides access to essentially unlimited time and intellectual resources, to a dispersed, heterogeneous stream of people in the Crowd who want to participate in a given crowdsourcing initiative. Their contribution, i.e. work, ideas, time, is usually compensated by the crowdsourcing campaign organiser (in an either tangible or intangible manner)'* [9]. Whereas P. Golczyk indicates that the idea of 'crowdsorucing' *is 'using the knowledge and*

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[1] The author intentionally uses the English term in the Polish version of the article in order to popularise it in the Polish language.

[2] Outsourcing – a blend of three words: outside-resource-using.

[3] 'Outsourcing – taking certain functions out from the organisational structure of an entity and transferring them to be carried out by specialised companies' – Słownik Języka Polskiego PWN (PWN Polish Language Dictionary), http://sjp.pwn.pl/sjp/outsourcing;2570186.html, retrieved: 28.01.2017

[4] 'The term crowdsourcing is derived from a combination of two English words: crowd and source – M. Grela, Rynki Predykcyjne jako przykład crowdsourcingu, (Predictive markets as an example of crowdsourcing), Acta Universitatis Nicolai Copernici, Ekonomia XLV No. 2 (2014) 205-217, December 2014, http://apcz.pl/czasopisma/index.php/AUNC_EKON/article/viewFile/5617/5210, retrieved 28.01.2017

[5] J. Howe, 'The rise of crowdsourcing', Wired, 6.01.06, https://www.wired.com/2006/06/crowds/, retrieved 28.01.20176 'Technological advances in everything from product design software to digital video cameras are breaking down the cost barriers that once separated amateurs from professionals. Hobbyists, part-timers, and dabblers suddenly have a market for their efforts, as smart companies in industries as disparate as pharmaceuticals and television discover ways to tap the latent talent of the crowd. The labor isn't always free, but it costs a lot less than paying traditional employees. It's not outsourcing; it's crowdsourcing" - J. Howe, 'The rise of crowdsourcing', Wired, 6.01.06, https://www.wired.com/2006/06/crowds/, retrieved 28.01.2017

[7] Wikipedia, entry: 'Crowdsourcing, source: https://pl.wikipedia.org/wiki/Crowdsourcing, retrieved: 22.10.2016

[8] The Authors B. Malinowski and M. Giełzak use this term to describe a 'digital crowd', 'crowd 2.0', as a crowd which 'is formed spontaneously and includes any demographic group which brings together aware, resourceful and creative Internet users (…), basically anyone who, thanks to the network, along with other people and in cooperation with others is capable of creating a specific value'.

[9] Malinowski B., M. Giełzak. 2015. Crowdfudning, zrealizuj swój pomysł ze wsparciem cyfrowego tłumu (Crowdfunding, make your idea come true with the support of a digital crowd). Wydawnictwo Helion (Helion Publishing House), 272.

experience of a (usually dispersed) crowd (...) the possibility to use such potential on a mass scale was created only after the access to the Internet became relatively common and cheap[10].

M. Grela discussed the following types and forms of crowdsourcing: *'a) solving problems by using a crowd – collective intelligence, wisdom of the crowd, b) using the creative potential of users – crowdcreation, user-generated content, c) crowdvoting (asking the crowd to choose the best solutions), d) crowdfounding, e) microwork, f) inducement prize contests, g) crowdpurchasing, h) implicit crowdsourcing'[11].*

Whereas, according to Sean Moffitt, a 'crowd landscape' is currently made up of 14 key 'segments' which he indicates, and which are presented below as a kind of starting point for further analysis carried out by the author of this article, where those 'segments' can be used in risk management in the research and development activity of a pharmaceutical company. The aforementioned 'segments' include:

1. *'citizen engagement' (also referred to as citizensourcing) – engaging residents, i.e. citizens, to jointly change and manage a city or a state, e.g. WeDundee (http://www.we-dundee.com/) in Scotland, MiMedellin (http://www.mimedellin.org) in Bogota or Open Warsaw, (Otwarta Warszawa, www.otwartawarszawa.pl) in Poland.*

2. *'crowd intelligence' – collective intelligence of a community created based on collaboration, co-creation and engagement of users, e.g. Quora (https://www.quora.com).*

3. *'open innovation' – using resources outside the immediate environment of the company or organisation for the purpose of creating innovative solutions, e.g. Nine Sigma or the Procter & Gamble PG Connect + Develop programme (http://www.pgconnectdevelop.com/).*

4. *'mass collaboration' – independent collaboration of a large number of users concentrated on one project, which is often made up of different modules which can be integrated together, e.g. the Wikipedia encyclopaedia.*

5. *'online communities' – online communities are characterised by a high rate of interactions between community members. They share a common idea, concept, belief, brand or the same interests. The Reddit platform (https://www.reddit.com/) is a prime example of an online community.*

6. *'crowd tasks & creativity' – projects focused on performing tasks, providing services or content, usually by a numerous and dispersed online community, e.g. Amazon Mechanical Turk (www.mturk.com), Crowdspring (www.crowdspring.com).*

7. *'crowd causes' – individuals or charities supporting projects directed at social welfare, geared towards addressing either global or local problems, the solving of which will significantly improve the well-being of people, e.g. XPrize (www.xprize.org)*

8. *'social business' – companies focusing on actual listening, sharing and engaging through open social channels, such as e.g. Dell (http://www.dellchallenge.org).*

9. *'customer co-creation' – cooperation between a company and a group of consumers, directed at working out a common solution.*

10. *'sharing economy' – a concept which resulted in the creation of e.g Uber and Airbnb.*

11. *'non-Equity based crowdfunding' – members of the community financially support a project or venture in exchange for prizes which take the form of the possibility to*

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10 Golczyk P. Marketing Technology. Crowdsourcing definicja (Crowdsourcing - a definition); http://golczyk.com/crowdsourcing-definicja/ retrieved: 28.01.2017

11 Grela M. Rynki Predykcyjne jako przykład crowdsourcingu (Predictive markets as an example of crowdsourcing), Acta Universitatis Nicolai Copernici, Ekonomia XLV No. 2 (2014) 205-217, December 2014 , http://apcz.pl/czasopisma/index.php/AUNC_EKON/article/viewFile/5617/5210, retrieved 28.01.2017

use a service or receive a product. Kick-starter (www.kickstarter.com) is an example of a platform which facilitates participation in such projects.

12. *equity-based crowdfunding – members of the community become shareholders in a project or venture which they support financially, e.g. Crowdcube.*

13. *peer-to-peer lending / commerce – lending/borrowing money within a community without the participation of financial institutions, e.g. the Lending Club (www.lendingclub.com).*

14. *crowdcurrencies – alternative currency systems created by online communities, e.g. Bitcoin'[12].*

The above interpretative and classification approach is very broad as to what can be called 'crowdsourcing', and what might not seem entirely transparent and relevant in the context of analyses presented in this article. Individual indicated 'segments' within the idea of crowdsourcing, despite including cooperation of a 'crowd', differ in terms of what underlies such cooperation and what purposes and results they entail. Furthermore, virtually each of such 'segments' grows and evolves individually within the framework of different communities, in particular those which use Internet-based communication. For that reason, in the opinion of the author of this article, a distinction should be made between crowdfunding (points 11 and 12), peer-to-peer lending as well as crowd currencies (points 13 and 14) and other types of

crowdsourcing. Despite of the fact that those solutions involve cooperation of a 'crowd' and joint creation of values or solutions, the bases for cooperation are different and – in the opinion of the author of this article – should be treated differently. In the case of crowdfunding, such grounds for cooperation consist mainly in obtaining funding for a venture. Crowd currencies can be used to finance settlements and crowdfunding ventures in the Internet, but they can also simply carry value and be used in business transactions. On the other hand, the basis for cooperation in the case of crowdsourcing is obtaining (in particular via the Internet) an idea or desired skills and solutions or co-creating them. The author of this article is of the opinion that between crowdfunding and crowdsourcing there are solutions such as: Social Business and Sharing economy (points 8 and 10). As B. Malinowski and M. Giełzak also pointed out: *'crowdfunding is not necessarily a form of crowdsourcing. Some consider crowdfunding to be a form of crowdsourcing. We treat one as 'a cousin' of the other[13]. Crowdfunding could probably come into being without crowdsourcing and vice versa, but it would be foolish to pretend that their synergy is not simply natural'* [14]. At the same time it is also worth noting that crowdfunding and crowdsourcing can overlap or be used together. I.e. obtaining funds through crowdfunding in order to finance a grant for a research team selected in a contest, which would search for solutions to medical problems.

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[12] Source: crowdsourcingweek.com – indicated as Polish Innovation Portal (Portal Innowacji), 'Crowdsourcing development perspectives' (Perspektywy rozwoju crowdsourcingu), 23.02.2016, http://www.pi.gov.pl/parp/chapter_86197.asp?soid=38D1559667BB40778F1ED6BC89FD705C , retrieved: 28.01.2017

[13] 'Outsourcing directed at a Crowd. This process consists in opening to mass participation of a CROWD130 in tasks which are normally carried out internally or commissioned to experts. Crowdsourcing provides access to essentially unlimited time and intellectual resources, to a dispersed, heterogeneous stream of people in the Crowd who want to participate in a given crowdsourcing initiative. Their contribution, i.e. work, ideas, time, is usually rewarded in some (tangible or intangible) manner by the crowdsourcing campaign organiser' - Malinowski B., M. Giełzak. 2015. Crowdfudning, zrealizuj swój pomysł ze wsparciem cyfrowego tłumu (Crowdfunding, make your idea come true with the support of a digital crowd). Wydawnictwo Helion (Helion Publishing House), 272.

[14] Malinowski B., M. Giełzak. 2015. Crowdfudning, zrealizuj swój pomysł ze wsparciem cyfrowego tłumu (Crowdfunding, make your idea come true with the support of a digital crowd). Wydawnictwo Helion (Helion Publishing House), 9.

In this article, given its subject matter, the author wishes to focus on the following crowdsourcing 'segments'. *'citizen engagement'* (point 1 above), 'crowd intelligence' (point 2 above), *'open innovation'* (point 3 above) *'mass collaboration'* (point 4 above), *'online communities*' (point 5 above) and *'crowd tasks & creativity*' (point 6 above), *'crowd causes'* (point 7 above) and *'customer co-creation'* (point 9 above) – in terms of their analysis and possibilities of using them in management of risk associated with the research and development activity of pharmaceutical companies. Issues concerning 'crowdfunding' have already been analysed by the author in his previous article[15].

'GAMIFICATION' AND 'OPEN INNOVATION'

The author hereof believes that the subject matter of the article also requires the presentation of 'gamification'. *Gamification – a phenomenon consisting in the transfer of mechanisms normally found in computer games into the real world. An organisation which uses gamification lets users i.a. carry our quests, win trophies, raise levels of experience, compete with other participants in the game. In the case of crowdfunding, the campaign alone includes elements of gamification (progress bar, the option of obtaining a title which increases one's prestige within the community by way of buying a prize). Additionally, project originators can also implement other gamification strategies, thanks to which users can be more motivated to engage in campaigns (i.e. location-based games)*[16]. It is the author's view that gamification can serve as a tool for raising effectiveness of crowdsourcing, in particular

through incentivising potential co-workers or business partners to compete for priority in cooperation with the pharmaceutical company in terms of its research and development activity.

In the context of the subject matter of this article, an in-depth clarification of the 'open innovation' phenomenon is pertinent. *Open innovation – a paradigm which assumes that companies can and should make use of external and internal ideas generating innovations. The main idea behind open innovation is that in the world where knowledge is widely dispersed, companies cannot afford to rely solely on their own research. They should also make use of experiences of other enterprises and individuals, as well as make their own resources and research results available for the benefit of the generally understood progress and development*[17]. Open innovation assumes in particular the following principles, pursuant to which '*not all talented people work for us, therefore we have to find and combine knowledge and expertise of talented individuals from outside our company', 'external research and development activity' can create significant value: internal research and development activity needs a part of that value', 'we do not need to come up with research to be able to use it', 'building a better business model is better than being the first one to enter the marke*t; [the latter can be debatable in the context of the subject matter of this article, given the fact that being the first entity to introduce a given product to the pharmaceutical market can be very beneficial to the pharmaceutical company, as it can result i.e. in establishing patent protection or market exclusivity], '*if we make the best of our internal and external ideas, we will win', 'we should benefit from others using our intellectual property and we should acquire intellectual property from*

[15] Mączyński G. 2016. "Crowdfunding as a tool for risk management in research and development activity of pharmaceutical companies".Journal of Health Policy, Insurance and Management – Polityka Zdrowotna, XVII/VII.

[16] Malinowski B., M. Giełzak. 2015. Crowdfudning, zrealizuj swój pomysł ze wsparciem cyfrowego tłumu (Crowdfunding, make your idea come true with the support of a digital crowd). Wydawnictwo Helion (Helion Publishing House), 276.

[17] Source: https://pl.wikipedia.org/wiki/Ekonomia_wsp%C3%B3%C5%82pracy , retrieved: 21.10.2016

other entities whenever it streamlines our business model and contributes to our progress' [18]. It should also be underlined that *'open innovation', as opposed to closed innovation, consists in engaging internal and external company's resources into obtaining innovative ideas. Open innovation has become increasingly popular in recent years. Procter & Gamble, which created the Connect + Develop project in 2001 is considered a pioneer among leading brands. Increased interest in creation of innovative ideas at different stages of the marketing process has been observed among brands in recent years, as illustrated in the graphic below'* [19].

CROWDSOURCING VS. PROSUMERS AND PRESUMERS IN THE HEALTH-CARE MARKET

The article entitled *'Crowdfunding as a tool for risk management in research and development activity of pharmaceutical companies'* [20], discusses in detail the phenomena of prosumers and presumers which constitute a specific evolution of the term 'consumer'. The author wishes to review them in the context of issues associated with crowdsourcing. B. Malinowski and M. Giełzak indicate that *"Prosumer" – a portmanteau of the words "producer" (sometimes: a professional) and "consumer" indicates an evolution of the latter in the direction of being a co-creator rather than just a passive recipient. This term is not a new one (it was created several decades ago by Alvin Toffler, a*

futurist), but it was disseminated more broadly as the Internet developed. Hence today we can talk about prosumption 2.0' [21]. Whereas a 'presumer' is 'a future consumer'. [22]

In crowdsourcing, a particularly important role is played by prosumers, who in fact invent or co-create various products and services or share their knowledge and ideas to enhance them further. A 'prosumer' in the context of the research and development activity of a pharmaceutical company can be in particular a practitioner, a researcher or even a patient participating in a clinical trial, who consciously wishes to contribute to the progress of R&D works or a different expert who is interested in specific therapeutic solutions. On the other hand, presumers can finance the activity of prosumers which will lead to the creation of a product or service desired by presumers, as well as they can actively encourage decision-makers (e.g. public administration bodies) to cover those products or services with co-financing from public funds. An example of presumers in the context of research and development activity of a pharmaceutical company can include a group of patients who co-finance research on a specific medical technology or, as an e.g. 'association'. apply for that technology to be co-financed from the public funds. As indicated in the earlier article on 'crowdfunding'[23]: *'The role played by both "presumers" and "'prosumers"* [24] *can be fundamental in terms of obtaining marketing authorisation of a product developed in the course of the research and development activity of a pharmaceutical*

[18] Open innovation, source: http://www.openinnovation.eu/open-innovation/, retrieved 22.10.2016, compare H. Chesbrough, (2003), 'Open Innovation: The New Imperative for Creating and Profiting from Technology', Harvard Business School Press.

[19] Polish Innovation Portal (Portal Innowacji), 'Crowdsourcing development perspectives' (Perspektywy rozwoju crowdsourcingu), 23.02.2016,http://www.pi.gov.pl/parp/chapter_86197.asp?soid=38D1559667BB 40778F1ED6BC89 FD705C , retrieved: 28.01.2017

[20] Mączyński G. 2016. "Crowdfunding as a tool for risk management in research and development activity of pharmaceutical companies".Journal of Health Policy, Insurance and Management – Polityka Zdrowotna, XVII/VII.

[21] Malinowski B., M. Giełzak. 2015. Crowdfudning, zrealizuj swój pomysł ze wsparciem cyfrowego tłumu (Crowdfunding, make your idea come true with the support of a digital crowd). Wydawnictwo Helion (Helion Publishing House), 274.

[22] Malinowski B., M. Giełzak. 2015. Crowdfudning, zrealizuj swój pomysł ze wsparciem cyfrowego tłumu (Crowdfunding, make your idea come true with the support of a digital crowd). Wydawnictwo Helion (Helion Publishing House), 274.

company or its coverage – financing from public funds. It is in fact a group of informed and engaged patients and consumers on the one hand, as well as experts on the other hand, who can offer their skills, knowledge or experience as a contribution to the R&D project of a pharmaceutical company. "Presumers" and "prosumers" operate also in the framework of stakeholder groups already existing on the healthcare market, such as patients and patient organisations, representatives of healthcare professionals, public decision-makers, public and private payers. Frequently "presumers" and '"prosumers" are informed representatives of these stakeholder groups.'

EXAMPLES OF CROWDSOURCING PROJECTS IN MEDICINE

Ventures using crowdsourcing have been successfully used in health sciences and for the development of health technologies. Examples can include projects implemented with the use of crowdsourcing, in particular those which can include elements of *open innovation* and which consist in the organisation of challenges/competitions regarding research in medicine and searching for solutions in this regard[25]. One such example would be the challenge (competition) organised by AstraZeneca regarding in vivo measurement of bio-

marker concentration with the use of technologies for on-line monitoring and using it in research on and development of drugs. The project also includes measurement of the concentration as well as effectiveness markers and toxicity of the drug. According to the organiser, such a study can potentially affect the way in which pharmacology and toxicology is monitored in preclinical drug trials [26]. Another example of such a project is the challenge (competition) entitled: '*Whole body imaging and analysis of that image*' organised by AstraZenca. The project originator needs a system allowing for imaging of the whole body and running its analysis for the purpose of skin disorders in clinical trials and is searching for a partner who would deliver or develop the technological solution required for this venture[27].

The author of this article believes that there are also projects in the area of medicine which use e.g. online games which fall into the *crowd tasks & creativity 'segment'. 'Another interesting area in which the use of crowdsourcing yields positive results is medicine. This industry seems to be dominated by experts and the inclusion of amateur Internet users may entail a significant risk. Regardless of this there are several examples where engaging ordinary people in the search for new drugs and identification of severe diseases brought similar effects to experts' conclusions and even surpassed them. The scientists' limited know-*

[23] Mączyński G. 2016. "Crowdfunding as a tool for risk management in research and development activity of pharmaceutical companies".Journal of Health Policy, Insurance and Management – Polityka Zdrowotna, XVII/VII.

[24] Both 'presumers' and 'prosumers', as well as crowdfunding itself, fall within the conceptual and functional framework of the so-called sharing economy. This term is commonly used to describe a new social and economic phenomenon, involving a fundamental change in organisational and distribution models, which is developing in the direction of dispersed networks of interconnected individuals and communities and includes in particular the direct provision of services by people as well as co-creating or co-sharing. Source: https://pl.wikipedia.org/wiki/Ekonomia_wsp%C3%B3%C5%82pracy, retrieved: 30.01.2017 and 'Collaborative economy genesis – czyli jak powstała ekonomia współpracy?' ('Collaborative economy genesis – how did collaborative economy come into being?') Source: http://zgiep.com/collaborative-economy-genesis-czyli-jak-powstala-ekonomia-wspolpracy/, as well as Sokołowski D., S. Starzyński, B. Rok, Ł.Zgiep. 2016. Raport Ekonomia Współpracy w Polsce 2016 ('The Sharing Economy in Poland 2016 Report').

[25] 'IVI Case study' – a challenge with the objective of creating a vaccine against HIV. http://www.ninesigma.com/open-innovation-resources/open-innovation-case-studies/iavi . Access: 28.01.2017

[26] www.innocentive.com; source: https://www.innocentive.com/ar/challenge/9933932 . Access: 23.10.2016

[27] www.innocentive.com , source: https://www.innocentive.com/ar/challenge/9933904 . Access: 23.10.2016

ledge on the structure of proteins causes difficulties in determining what shape a chain of amino acids will take in the process of protein folding. Proteins are composed of long chains of amino acids which form various three-dimensional shapes, similar to origami. Foldit is an online game which consists in individual folding of proteins for the purpose of obtaining the most stable structure. The game itself resembles playing with spatial puzzles. Foldit constitutes a part of a research project conducted by the University of Washington. In the year 2012, the game had approx. 240,000 registered users who contribute to science by playing the game. Configurations which get the largest amount of points are then evaluated by researchers who verify whether they can be used in real life. Thanks to Foldit and the players' commitment, it was possible to analyse the structure of Mason-Pfizer monkey virus (MPMV) which had been analysed by scientists for almost a decade with no significant results'[28].

Moreover, the author believes that the game 'MalariaSpot' constitutes a good example of crowd intelligence[29]. In the game, players are presented with photos, on the basis of which they determine whether specific cells are infected with the malaria virus. In such a case we are faced with a question: would we trust the diagnosis of a shop assistant who, spending his evenings playing the game, carries out a vital analysis and claims that a given cell is infected with malaria? Miguel Luengo-Oroz, a Spanish scientist, proved that in the case of malaria, analyses carried out statistically by 13 random players are qualitatively similar to the analyses carried out by experts. For malaria to be diagnosed, approx. 100 photos of cells need to be evaluated by an expert, which takes around 30 minutes. The MalariaSpot game, which benefits from people's common access to mobile phones, significantly accelerates this tedious process and reduces related costs. In accordance with Luengo-Oroz's estimates published in the book 'Games with Purpose', a mere 3% of the time spent on video games by mankind would be enough to identify all malaria cases in the world.[30]

The CrowdMed platform[31] can serve as an example of both *mass collaboration* and *crowd tasks & creativity*. It is pointed out that *'The reason why this kind of platforms are used is the increased number of cases of rare diseases which are hard to diagnose. CrowdMed invites the collaboration of many people from different areas and offering different experience. These include students, retired doctors, nurses and people who simply are interested in medicine. Thanks to the ranking system, diagnosticians build their reputation within the network and at the same time earn money if their diagnosis is correct. There's no doubt that such solutions will not replace traditional doctor's appointments, but they yield better results than reading descriptions of your symptoms found in search engines and are an effective solution in diagnosing common diseases. IBM has just developed a technology called Watson, which is able to store and process massive amounts of data from a variety of medical sources – systems and databases. It is able to diagnose diseases based on algorithms. It is hard to say whether technology will replace the human factor in medicine, however, the capacity to analyse a large amount of data with precision and consistency will constitute the main advantage of the system'[32].*

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[28] Polish Innovation Portal (Portal Innowacji), 'Crowdsourcing development perspectives' (Perspektywy rozwoju crowdsourcingu) . Access: 23.02.2016, http://www.pi.gov.pl/parp/chapter_86197.asp?soid=38D1559667 BB40778F1ED6BC89FD705C . Access: 28.01.2017

[29] malariaspot.org

[30] Polish Innovation Portal (Portal Innowacji), 'Crowdsourcing development perspectives' (Perspektywy rozwoju crowdsourcingu) . Access: 23.02.2016, http://www.pi.gov.pl/parp/chapter_86197.asp?soid=38D1559667BB 40778F1ED6BC89FD705C . Access: 28.01.2017

[31] crowdmed.com

[32] Polish Innovation Portal (Portal Innowacji), 'Crowdsourcing development perspectives' (Perspektywy rozwoju

Another solution which, up to a point, is associated with crowd intelligence, was a Google service[33] used to predict diseases and to warn against a flu epidemic up to even two weeks before competent public authorities, although this is a non-standard example, as collaboration between individual Internet users was not the direct intention of the venture and the results were based on their individual queries. As indicated in available articles: *'Google Flu Trends uses search tracking technology pioneered by Google Trends and applies it specifically to monitor influenza. The firm's engineers claim to have devised a way of analysing millions of individual searches related to the disease that in tests proved to correlate closely with the actual incidence of influenza.*'[34] The service is now no longer publishing current estimates. The example above demonstrates that analytical tools applied in medicine can be based on crowdsourcing in the way that they use statistical data created by many users and confirm specific behaviour patterns, trends or current epidemiological situation.

RISK IN THE RESEARCH AND DEVELOPMENT ACTIVITY OF A PHARMACEUTICAL COMPANY

R. Holly defines 'risk' as *'the likelihood of an undesirable event taking place, which may, but not necessary will cause a certain damage or loss involving the person whom that event affects'* [35]. Economic literature also includes other definitions of 'risk'[36], inclusive of a negative deviation from the pursued objective. One can also find definitions, where 'risk' is a negative deviation from the intended outcome, regardless of whether this deviation has a positive or negative outcome[37]. For the purpose of various analyses and studies, authors can assume various definitions of that notion[38].

For the purposes of the previous article entitled: *'Crowdfunding as a tool for risk management in research and development activity of pharmaceutical companies'* and the present article, in order to maintain consistency of analysis and allow for the possibility to adequately compare crowdfunding and crowdsourcing, the author understands 'risk' in the following way: *'1) the likelihood of an adverse event taking place and 2) the likelihood of a damage/loss, i.e. acting to the detriment of a certain entity; it always refers to specific events which result*

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crowdsourcingu) . Access: 23.02.2016, http://www.pi.gov.pl/parp/chapter_86197.asp?soid=38D 1559667BB 40778F1ED6BC89FD705C . Access: 28/01/2017.

[33] https://www.google.org/flutrends/about/. Access: 31.01.2017.

[34] http://portalwiedzy.onet.pl/4868,11127,1517609,1,czasopisma.html. Access: 31.01.2017.

[35] Holly R. 2000. Ryzyka polskiego rynku ubezpieczeń ('Risks in the Polish insurance market'). Zeszyty Naukowe. WSUiB, 18(2000): 53 - 54.

[36] Compare 2) G.E. Rejda. 1992. Principles of Risk Management and Insurance (fourth edition), Harper Collins Publishers Inc. 1992 and Hadyniak B., J. Monkiewicz. 2010. Ubezpieczenia w zarządzaniu ryzykiem przedsiębiorstwa tom 1, Podstawy' ('Insurance in company risk management, volume 1– the Basics') Wydawnictwo Poltext (Poltext Publishing House).

[37] Compare Zawadzka Z. 2001. Ryzyko bankowe, W: Bankowość. Podręcznik akademicki. (Banking risk, in: Banking. An Academic Handbook), Jaworski W. (edit.), Warsaw: Poltext, 597-628.

[38] Compare Damodaran A. 2009. Ryzyko Strategiczne. Podstawy zarządzania ryzykiem' ('Strategic Risk. Basics of risk management'). Wydawnictwo WaiP (WaiP Publishing House), 2. Compare Soczewko A. 2003. Czy ryzyko ubezpieczeniowe jest podstawowym ryzykiem w działalności zakładów ubezpieczeń? ('Is insurance risk the basic risk in activity of insurance companies?'). Prawo asekuracyjne – a quarterly; 03. See a multiple-author publication: A guide to developing a risk management process, The Association of Insurance and Risk Managers 2001, published online at http://www.rudnicki.com.pl/pub/AIRMIC_Guide_Risk-Management _Process.PDF. Access: 15 December 2009.

[39] Holly R. 2013. Zarządzanie ryzykiem – czyli czym?. (Risk management – i..e. management of what, exactly?).

in the possibility of damage/loss'. Whereas risk management is: *'1) stimulating the likelihood of specific events and 2) impacting the course of events in a way ensuring that its effects do not act to the detriment of the entities whom these effects affect'*[39].

The author has already identified and presented his definition of risk associated with the research and development activity of pharmaceutical companies is his previous article entitled: *'Crowdfunding as a tool for risk management in research and development activity of pharmaceutical companies'*[40]. The adopted proposal refers to the specifics of this research and development activity and the specific operation of a pharmaceutical company and considerations of the healthcare market in which such a company operates. To ensure consistency of analyses in the present article, the author adopted a definition of such activity which is analogous to the one adopted for his article *'Crowdfunding as a tool for risk management (...)*.

The process of inventing, conceptual work and product development, as well as trials and obtaining marketing authorisation – in particular with regard to drugs – is time-consuming and more than ten years can pass[41] before the product can be used by first patients[42] (in the case of a medical device, this process can be shorter than in the case of drugs – this depends on the complexity of the solutions and their intended purpose). In the meantime a competitive company can market a similar product before the company in question, or introduce other therapeutic solutions. Furthermore during that time, organisational or formal and legal conditions in specific healthcare systems can change and thus limit the possibility of introducing the product to the market or force its significant modification. <u>This risk is related to time and organisational issues.</u>

At the same time the cost of conceptual work in the case of creating drugs, conducting trials and obtaining marketing authorisation is very significant (this cost can be lower for medical devices than for drugs, but whether this is the case depends on the specific nature and complexity of the medical device in question). Furthermore, it is often the case that invested funds cannot be recovered if a product – in particular a drug – turns out to be inefficacious or a threat to the health of patients in final stages of clinical trials. <u>This is called investment risk.</u>

The huge costs associated with developing and marketing products – again, usually drugs – need to be 'recovered' through the pharmaceutical company's economic activity and its profits from that activity. If a product is intended for use in a rare or ultra-rare disease, i.e. a small patient population, its cost per single patient can be enormous (if the investment cost is

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[39] Holly R. 2013. Zarządzanie ryzykiem – czyli czym?. (Risk management – i..e. management of what, exactly?).

[40] Mączyński G. 2016. "Crowdfunding as a tool for risk management in research and development activity of pharmaceutical companies".Journal of Health Policy, Insurance and Management – Polityka Zdrowotna, XVII/VII.

[41] Analyses presented in a report by Deloitte Health Economics Group suggest that the longest R&D activity needed to create a new product is typical for pharmaceutical companies and the risk associated with failure to complete this activity and introduce the product on the market at the end of that period is of key importance (obtaining marketing authorisation). The data on the time which passes from the idea to introducing the product to the market are as follows for specific groups of companies: pharmaceutical companies: 10 -12 years See High value, high uncertainty: Measuring risk in biopharmaceutical research and other industries. Investing in the future of health" Deloitte Health Economics Group, Commissioned by Janssen Pharmaceutical NV Belgium 2014 Source: https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-measuring-risk-in-biopharmaceutical-research.pdf (downloaded on: 28.12.2015), p. 13.

[42] For example: 'Average data for Roche indicate that the research and development stage for one of the drug requires 700,874 hours of work, conducting 6,587 experiments and employment of 423 researchers'. K. Kasprzyk 'Jak wygląda cykl życia leku? Od pomysłu do wdrożenia ('What is the life cycle of a drug? From idea to implementation' Source: http://natemat.pl/133827,jak-wyglada-cykl-zycia-leku-od-pomyslu-do-polki-w-aptece, Access: 23.10.2016

proportionally divided by the number of potential recipients) and insupportable without a proper system of reimbursement from public funds. Also in the case of chronic diseases, the cost of the product (in particular a drug) for the patient who needs to use that drug permanently and regularly can also prove to be impossible without additional funding. As a result, if such expensive products are not co-financed, only a small number of patients will be able to use them or they will do so only irregularly; in consequence such products will be virtually unavailable to most patients for financial reasons and will not be bought in amounts ensuring a return on the investments made to develop them. Thus, this is the risk associated with 'failure to provide availability of a product' to patients.

Existing organisational and formal/legal solutions in individual healthcare systems in different countries can vary and be subject to change over time. It is necessary to take these differences into account already in the course of the research and development activity and monitor them constantly, which can also be costly. Failure to take into account legal, formal and organisational conditions in individual countries and to act adequately to those conditions can lead to a situation where a product resulting from a company's R&D activity will not be available in some countries at all or its use or financing in such countries will not be sufficient. In consequence, due to the lack of availability of a product or its lower sales volume, a return of funds invested by a pharmaceutical company in its R&D activity will be lower. This risk is associated with 'formal and legal aspects.'

The above-mentioned differences in organisational, formal and legal aspects in individual countries and their variability over time are also associated with the pharmaceutical company's need to prepare and maintain a diversified infrastructure for distributing or promoting the product. A pharmaceutical company's risk in research and development activity

in this regard will be associated with the need of flexibility in introducing changes in distribution structures as well as promotional and marketing actions to ensure availability of the product in the market. Should such a risk come into being, we might face a situation where, despite the fact that the product is formally available on the market, it is practically not applied, thus – in consequence – due to lower sales of the product, the return on the funds invested in its development and introduction to the market will also be lower. This risk is the 'failure to adjust the product to practical requirements of the healthcare system.'

The risk associated with research and development activity of a pharmaceutical company is associated with lack of efficacy or safety of the product. The greater the number and severity of adverse effects caused by the product, the greater the chances that the product fails to obtain marketing authorisation or its authorisation is suspended. Furthermore, the less evidence confirming the efficacy or safety of the product, the fewer patients will potentially be treated with it, or the less likely it is for the product to receive financing from the public funds. This, in consequence, will result in failure to ensure the product's availability on the market, its low sales volume and failure to retrieve the funds invested in the research and development process. This risk is associated with 'lack of safety or efficacy of the product.'

To sum up this part of the article, the author wishes to indicate that obtaining a return on funds invested in a research and development activity of a pharmaceutical company can depend in particular on whether one of the following types of risk comes into being: 1) organisation and time, 2) investment, 3) failure to provide availability of a product, 4) formal and legal aspects, 5) failure to adjust the product to practical requirements of the healthcare system, 6) lack of safety or efficacy of the product. The author of this article wishes to underline that risk considerations in research and development activities of a pharmaceutical

company have been presented in a general and directional manner. The author's intention was mostly to present risks which might lead to a pharmaceutical company's failure to obtain a return on funds invested in research and development activity. As a result the company does not earn and fails to gain competitive advantage.

BENEFITS AND RISKS ASSOCIATED WITH CROWDSOURCING – GENERAL REMARKS

Furthermore, M.Grela also indicates that an important aspect of crowdsourcing is also motivation to participate in a specific venture, and individual participants can also be motivated by different factors, in particular: *'a) an opportunity to earn money, b) developing their own skills, c) networking with professionals from the industry, d) building their portfolio for future work, e) resolving difficult problems, f) building social relationships, g) pursuing their own interests h) entertainment.'* Wikipedia, which can be thought of as a source of publicly available information, lists the following benefits of crowdsourcing: *'1) Problems can be solved at a relatively low cost, usually very quickly; 2) You pay depending on the outcome, sometimes compensation is not paid out at all; 3) The organisation reaches a wider range of talents, not only those who are available in the same organization; 4) By listening to communities, organisations gain a first-hand insight to the needs and desires of customers; 5) The community gets the feeling that it co-creates the brand, and thus the contribution results in*

a sense of ownership.'[43] The aforementioned M. Grela indicates that the basic advantages of crowdsourcing include: *'1. The possibility of obtaining a desirable result cheaper than with other solutions. 2. The possibility of obtaining a different perspective on the problem at hand and making use of creativeness of a large group of people. 3. Lack of necessity to ensure continuous monitoring of the group fulfilling the task. 4. A very good marketing tool. 5. The possibility to single out talented employees. 6. The possibility of reducing the cost-consuming R&D department*[44].

It is also pointed out in various publications that *'Crowdsourcing allows you to reach a plenitude of knowledge, creativity and potential which lies in resources outside our organisation. This potential can consist in our consumers, experts dispersed all over the world, students or mothers on maternity leave. Thanks to making use of this potential, the brand certainly loses nothing and can increase its chances for obtaining competitive advantage.'* [45] *'Crowdsourcing makes it possible to obtain ideas, content or broadly understood solutions to problems faster, cheaper and currently also in better quality than by way of traditional models. Brands from various industries, e.g. IBM, P&G, Coca-Cola, Roche, Doritos, Lego, Dell, Samsung, Toyota have reached for crowdsourcing on many occasions while creating an advertisement content which recipients could relate to, perfecting and creating new products or searching for advanced innovative solutions'.*[46]

At the same time M. Grela lists the following disadvantages of crowdsourcing: *'1. Ma-*

43 Wikipedia, entry: 'crowdsourcing', https://pl.wikipedia.org/wiki/Crowdsourcing, retrieved: 28.01.2017

44 Grela M. 2014. Rynki Predykcyjne jako przykład crowdsourcingu (Predictive markets as an example of crowdsourcing), Acta Universitatis Nicolai Copernici, Ekonomia XLV No. 2 (2014) 205-217, December 2014 , http://apcz.pl/czasopisma/index.php/AUNC_EKON/article/viewFile/5617/5210, retrieved 28.01.2017

45 Polish Innovation Portal (Portal Innowacji), 'Crowdsourcing development perspectives' (Perspektywy rozwoju crowdsourcingu). Access: 23.02.2016, http://www.pi.gov.pl/parp/chapter_86197.asp?soid=38D1559667BB40778F1ED6BC89FD705C . Access: 28.01.2017

46 Polish Innovation Portal (Portal Innowacji), 'Crowdsourcing development perspectives' (Perspektywy rozwoju crowdsourcingu). Access: 23.02.2016, http://www.pi.gov.pl/parp/chapter_86197.asp?soid=38D1559667BB40778F1ED6BC89FD705C . Access: 28.01.2017.

king it easier for the competition to obtain information about the company. 2. The possibility of plagiarism carried out by some members of the crowd. 3. The possibility of discouraging employees against effective actions. 4. The possibility of obtaining negative effects'.[47] *'As crowdsourcing is becoming increasingly important in so many business and social areas, the risk associated with lack of regulations is also becoming more and more pertinent. Risks associated with social exploitation resulting from the offering of inconsiderable compensation for huge work outlays and with copyrights create potential risks for both the participants and the organisers of crowdsourcing projects.'*[48]

'It is hard to imagine that crowdsourcing could completely replace traditional models of creating advertisements, financing models and R&D processes. However, the facts are that open innovation, co-creation and other crowdsourcing models constitute a challenge for traditional business models, change the status quo and the functioning of organisations in many areas. They can constitute both an alternative and an interesting complement to the traditional models. In many cases it turns out that only a combination of traditional and crowdsourcing models yields a truly sustainable solution, where advertisement concepts can be created in a crowdsourcing model and prepared by production houses, and ideas for solutions can be proposed by consumers, after which the product division can evaluate such ideas and the possibilities for their implementation by the company. Crowdsourcing is an interesting proposal enhancing the ideation and creation process'.[49]

USING CROWDSOURCING IN RISK MANAGEMENT IN RESEARCH AND DEVELOPMENT ACTIVITY OF PHARMACEUTICAL COMPANIES

Crowdsourcing can be used by a pharmaceutical company to obtain new, diverse ideas or solutions, as well as intellectual property rights on the market and outside the previously used 'internal' structures, which can allow for mitigating the risk associated with the excessive time needed to carry out a research and development activity (solutions from the 'open innovation' segment). The use of 'gamicifaction' in crowdsourcing can allow for engaging other (co-operating) entities in a pharmaceutical company's research and development activity, in particular by way of providing support, suggesting solutions or ideas in exchange for a specific prize, e.g. a grant (solutions from the *'crowd tasks & creativity'* segment can be particularly useful in such situations). Crowdsourcing can therefore be a tool for managing and minimising the risk associated with organisation and time described above.

Crowdsourcing can also help select scientific or business partners for the pharmaceutical company's research and development activity. Furthermore, crowdsourcing can be used to recruit research or expert teams or individual scientists or researchers, which can contribute to both a more effective use of funds within the framework of the R&D activity and to reducing both the costs of that activity and the time before a product is ready for marketing. Crowdsourcing solutions can also allow for a

[47] Grela M. 2014. Rynki Predykcyjne jako przykład crowdsourcingu (Predictive markets as an example of crowdsourcing), Acta Universitatis Nicolai Copernici, Ekonomia XLV No. 2 (2014) 205-217, December 2014 , http://apcz.pl/czasopisma/index.php/AUNC_EKON/article/viewFile/5617/5210 . Access: 28.01.2017.

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[49] Polish Innovation Portal (Portal Innowacji), 'Crowdsourcing development perspectives' (Perspektywy rozwoju crowdsourcingu). Access: 23.02.2016, http://www.pi.gov.pl/parp/chapter_86197.asp?soid=38D1559667BB40778F1ED6BC89FD705C . Access: 28/01/2017.

more effective use of risk-sharing schemes concluded between the pharmaceutical company and partners selected with the use of crowdsourcing methods. Crowdsourcing can also allow for a better use of own resources by the pharmaceutical company conducting the R&D activity. One example of such an activity is a pharmaceutical company making a patented solution available for use by other entities to develop new products, with the assumption that the pharmaceutical company would profit from such products. In the opinion of the author of this article, the above solutions lead to the use of the 'open innovation' by the pharmaceutical company conducting the R&D activity. As a consequence this can contribute to dispersing of risk associated with financing of the pharmaceutical company's research and development activity and faster R&D progress and as a result, risk mitigation. Hence crowdsourcing can be considered a solution for managing and mitigating 'investment risk'.

Furthermore, crowdsourcing makes it possible to obtain feedback from consumers, in particular regarding practical advice on how to improve an existing solution (one can consider using solutions from the following segments: crowd intelligence, mass collaboration and online communities. Thanks to the use of IT technologies and the Internet, crowdsourcing offers pharmaceutical companies running a research and development activity access to an unlimited number of individuals with different ideas or solutions. This, on the other hand, allows for a better adjustment of a product to the market needs and the consumers' financial capacity. Furthermore, crowdsourcing makes it possible for a pharmaceutical company to obtain various scientific or business data, information about potential recipients of the product as well as information about the epidemiology of disorders which their product would address. Crowdsourcing can in this regard serve as a tool for managing and minimising the risk associated with 'failure to provide availability of a product'.

Crowdsourcing solutions can be used to invite presumers (future consumers) to cooperation, even if for the purpose of drawing their attention to the research and development project, as well as prosumers, whose knowledge and experience could support the company's research and development activity (solutions from two segments: customer co-creation and open innovation can be particularly pertinent here). The groups of people referred to in the previous sentence can in particular include researchers conducting clinical trials or participants of such trials. This can contribute to the reduction of R&D costs and increasing the product's safety and quality (more high-quality trials), as well as to a better adjustment of the product to formal and legal requirements in a given healthcare system. Crowdsourcing can in this regard serve as a tool for managing and minimising the risk associated with failure to adjust the product to practical requirements of the healthcare system and the risk associated with lack of safety or efficacy of the product.

Using crowdsourcing in order to engage local partners in cooperation within the framework of a specific healthcare system, acquire prosumers' knowledge and experience, as well as learn the needs of presumers (future consumers) makes it also possible to minimise the risk associated with failure to reach a certain group of patients and payers or failure to respond to changing legal, formal and organisational conditions (solutions from the 'crowd causes' and 'citizen engagement' segments can prove to be particularly useful in these situations). This can serve as a tool to manage and minimise the risk associated with formal and legal aspects.

SUMMARY

Crowdsourcing can be applied in the research and development activity of a pharmaceutical company and can in particular be used for risk management associated with such activity or building value by that company. The use of

crowdsourcing can contribute in particular to the reduction of the risk associated with investing resources in research and development activity or the risk associated with the excessive time needed to conduct such activity. By referring to the definition and the idea of crowdsourcing one can indicate that it can also serve as a tool to search for expertise, solutions and even co-workers or business partners in the field of research and development activities conducted by a pharmaceutical company.

At the same time one should point out that crowdsourcing solutions used in a rushed, unconsidered manner can prove to be harmful to the pharmaceutical company itself and to the research and development activity it conducts. They can result in particular in the competition learning the direction or advancement stage of the pharmaceutical company's research and development efforts.

In the opinion of the author of the article, the use of crowdsourcing by pharmaceutical companies in the scope of their R&D activity should become more frequent. Particularly due to the fact that it can constitute a financial and organisational alternative or a substantial supplement to the company's internal R&D works. Crowdsourcing can also result in better designs of future products of research and development activities and this in consequence can lead to better returns on the investments made on such activity. At the same time it is worth underlining that crowdsourcing and the tools used within its framework also change and evolve over time and thus need to be reviewed and updated.

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