

Personalized medicine industry model development

Mrak, Marija Kaštelan; Bodiroga Vukobrat, Nada; Sokolić, Danijela

Source / Izvornik: **Management : Journal of Contemporary Management Issues, 2017, 22, 49 - 64**

Journal article, Published version

Rad u časopisu, Objavljena verzija rada (izdavačev PDF)

Permanent link / Trajna poveznica: <https://urn.nsk.hr/urn:nbn:hr:192:480771>

Rights / Prava: [Attribution 4.0 International](#)/[Imenovanje 4.0 međunarodna](#)

Download date / Datum preuzimanja: **2024-07-24**



SVEUČILIŠTE U RIJECI
EKONOMSKI FAKULTET

Repository / Repozitorij:

[Repository of the University of Rijeka, Faculty of
Economics and Business - FECRI Repository](#)



PERSONALIZED MEDICINE INDUSTRY MODEL DEVELOPMENT*

Marija Kaštelan Mrak,** Nada Bodiroga Vukobrat,*** Danijela Sokolić****

Received: 14. 7. 2017

Preliminary communication

Accepted: 9. 10. 2017

UDC 61:005.521

Abstract

Health care is a growing business, but its trajectory patterns are hard to decipher at the moment. This paper provides a short overview of issues important for developing business models for the personalized medicine sector (PM). The paper draws on institutional theory, particularly transaction costs economics (TCE) in an attempt to draft a conceptual framework applicable for identifying relationship patterns among institutional entities, i.e. industry actors in the Personalized Medicine (PM) field. According to the theory, relationships among industry actors are expected to evolve depending on the manifestation of many contextual factors and their developments: investment activity, public

interests, technology development, market structure, regulatory environment, demographic factors, personal preferences, natural factors, etc. In our belief, a descriptive model of an industry should include a broader scope of entities besides directly competing firms. Our rationale is that market actors, in a resource dependent environment, sustain their activity by engaging in (bargaining) relationships with other entities with vested interests in the industry. Basically, we believe that predictions of future industry and particular entities' business model development would be a function of available resources, power relations and regulation.

Keywords: *personalized medicine, business model, incomplete contracts, incentives, business scenarios*

1. INTRODUCTION

Medical science and medical practice have undergone radical development during the past decades. It is likely that amounts invested in research and development (R&D) and in developing industry capacity/

infrastructure, as well as the vested interests of different parties related to the industry will create shifts in the broader health care sector. According to the Forbes contributor Das (2017), specialized in healthcare issues related to transformations and convergence, declining operating margins and R&D

* This study has been supported by the Croatian Science Foundation under the project "Perspectives of maintaining the social state: towards the transformation of social security systems for individuals in personalized medicine", no. IP-2013-11-5709.

** Marija Kaštelan Mrak, Faculty of Economics, University of Rijeka, I. Filipovica 4, 51000 Rijeka, Croatia, Phone: ++ 385 51 355 163; Fax: ++ 385 51 212 268, E-mail: kastelan@efri.hr

*** Nada Bodiroga Vukobrat, Faculty of Law, University of Rijeka, Hahlic 6, 51000 Rijeka, Croatia, Phone: ++ 385 51 359 500; Fax: ++ 385 51 359 593, E-mail: nadab@pravri.hr

**** Danijela Sokolić, Faculty of Economics, University of Rijeka, I. Filipovica 4, 51000 Rijeka, Croatia, Phone: ++ 385 51 355 196; Fax: ++ 385 51 212 268, E-mail: dsokolic@efri.hr

rates of return are forcing pharmaceutical companies to review their traditional mass production business model, *rethink their business strategies* and *enter new markets* such as personalized (or precision) medicine. Personalized medicine (PM), as a term, defines precise treatments designed particularly for narrow group of patients carrying a specific genotype.

The development of PM is expected to induce changes in the broader social, technological, economic and regulatory system. Consequently, professionals and researchers in different fields involved in implementing PM report various challenges; medical professionals emphasize barriers to integrating new medical products and procedures, lack of training for physicians, patients' fear of discrimination, higher costs of treatments, etc. (Najafzadeh et al., 2013; Pavelić et al., 2016). Another group of researchers points out regulatory (legal) concerns related to complexity of intellectual property rights, genetic discrimination, diversity of health insurance systems and health economic policies in various countries, price regulation, etc. (Hamburg and Collins, 2010; Caulfield and Zarzeczny, 2014; Pope, 2013). Jakkal and Rossbach (2013) argue that "*the greatest challenges*" facing the personalized medicine field "*are economic, not scientific*". Business wise, personalized medicine, involving multi-level patient stratification, has the ability of "*optimizing the cost, time and success rate of pharma clinical trials*" by using the new approach and at the same time co-developing drug medical prescription and diagnostics referred as companion diagnostics (R. Das, 2017)^[1].

Moreover, as many personalized medicaments are developed from natural sources (biologic material, as opposed to chemically synthesized pharmaceuticals), they tend to be more expensive to produce

than chemically synthesized drugs. Pharmaceutical representative Shaw^[2] emphasized that those costs, in turn, will have to be recouped by the companies that develop competing products. It is safe to assume that the costs will probably act as "communicating vessels" in search of equilibrium. Thus, part of the financial burden related to the new *business model* will spill over to insurance companies who pay for the treatments, and it will become a growing concern for the patients as they are increasingly forced to bear a bigger share of their medical expenses in the form of increased out-of-pocket charges.

We use the term business model as an expression convenient for extending the idea of organizational design beyond the boundaries of a single business subject. Therefore, the concept of business model is defined through network of entities related in value creation and appropriation. It is perceived as a system of interdependent activities, which span boundaries of a single firm (Zott and Amit, 2009). Morris et al. (2005) imply that the term "business model" is rather vague, yet that it implies strategic consideration (fit, evolution, sustainability), but without discarding operational issues; very much along the idea of value creation so common to economic theory. Precisely, these vague concepts can work well when we try to create a framework for understanding how multiple actors behave/interact in the process of developing PM.

Following intensified R&D spending, and a change in business strategies, an intricate infrastructure of relationships among various types of interested parties is currently evolving. Differences in technology development trajectories, payback periods, and shifts of financial burdens between stakeholders demand a deeper insight into factors driving the development of emerging business models. At the same time, from the perspective of public authorities concerned

with public health, costs of medical care demonstrate a constant upward trend; and, thus, represent an important issue for public policy design. Both perspectives, market structure (investments and market regulation), and public health, demand theoretical explanations that help understand, predict and shape future developments. In the following pages, we examine information provided by recent reports on the industry and contrast the medical paradigm of traditional and personalized medicine, along with a comparison of the level of technological innovativeness, industry relations, financial and infrastructural aspects between the two approaches.

After providing a short theoretical background, we provide insights into R&D investment activities and trends in health care spending, followed by a descriptive model of the PM industry.

2. THEORETICAL BACKGROUND

Economics is a science interested in understanding the process of value creation and of value distribution. It also examines the correlations between value distribution and value creation over time in expectation that structural differences among alternative structural models will demonstrate impact on levels of value creation and patterns of value distribution. In the 1980s, a role of the State was perceived in terms of the welfare effects of taxation (and consequent social redistributions or state aid) or through direct government enterprising (crowding out effects). Often early uptakes emphasize the disruptive consequences of state action (Pope, 2013). Contemporary economics takes a broader perspective of the role of the State and its administrative measures in shaping the behaviour of market actors

by establishing standards and procedures. Possible as the result of the “rise of the European regulatory state”, and in contrast to deregulatory approaches of the 80s, the State is seen as an agent of promoting public interests through active regulatory measures (Bach and Newman, 2007; Windholz, 2018). To our understanding, envisaging the development of an emerging technological trajectory that overlays an already existing “infrastructure” of multiple and diverse actors will require a more complex conventional organizational model, one that can provide direction for mapping the activities and motives of relevant actors. Such a model would then serve to provide a better understanding of the interactions of actors (especially power relations) that could support adequate policy choices.^[3] According to Ostrom (2010), a complex framework of polycentric governance is needed in order to “*specify the structure of the game and predict outcomes*”.

Transaction Costs Theory (TCE) proposes such organizational arrangements that should be viewed in terms of binary partnerships, suggesting that rules and administrative procedures are set up in order to control risks in long-term cooperation arrangements capable of generating results in high prospective economic outcomes, be those costs or earnings. Organizational measures can include establishing thresholds and reporting procedures for higher transparency, standardizing goods/service or clauses in contract arrangements. TCE has a specific definition of ownership, where ownership (activity internalization) becomes a protective measure; i.e. property rights are seen as a mechanism that mitigates ex post opportunism (Williamson, 1985), including moral hazard and adverse selection.

It is not only the bargaining partners that are interested in lowering transaction costs,

but also society. In fact, government regulation can produce the effect of balancing power relations among specific partners, especially since high transaction costs are more likely in situations involving expressed information asymmetry.

Agency Theory can be employed to study the nature of cost and benefit distribution in binary relationships involving some kind of hierarchical relation. Extending the transaction costs theory to situations where one of the partners exhibits a dominant position over the other, yet cannot control the other's (the inferior partner's) operations and strategic development, governments/regulators are in the position to influence *bargaining relations among partners*, i.e. the distribution of costs and benefits. The dominant rationale of governmental intervention/role of regulators thus becomes the role of balancing incentives.^[4]

Incomplete contracts literature basically expands the logic of devising between-party arrangements as does transaction costs theory, but with more emphasis on "contract clauses" that provide motivation for contracts partners to adhere to contract (Tirole, 1988; Hart, 1995). Characteristics of exchange include duration of the relationship, closeness of the future collaboration, rights and obligations, etc. (Smith & King, 2011).

So, if the role of contracts is providing ex-ante determination of a two party relationship, contract clause will address the characteristics of exchange object, as a way of specifying performance targets that can be monitored. In that aspect, contract theory is consistent with the concept of monitoring in agency theory. The parties' behaviour is not only controlled by specified (identifiable) technical measures. Incentives are not precisely identified, but could be presupposed as being "intrinsic" to a contract party, such as the incentive to preserve good

reputation, which is similar to idea of bonding in agency costs theory. In fact, the idea of contracts promoted by contract theory is that a contracting relation is a complex social construct, where implicit mechanisms can act as strong mechanism for reducing direct transaction costs, assessing predictable risks, but also controlling (at least partly) some of the risks that cannot be anticipated in the ex-ante period. Due to the phenomena of bounded rationality, asymmetric and incomplete information, uncertain future circumstances, opposed interests, and different motives/incentives of contracting /collaborating parties, contracts cannot be observed as complete embodiments of an agreement. Thus, contracts are usually incomplete, and serve to protect one side ex ante investment against other side's ex post opportunism (Bolton & Dewatripont, 2005).

Considering PM, there are at least three obvious economic consequences of this new approach: focusing on smaller patients' groups, instead of on whole/broader populations, imposing variations in time and patient treatment procedures, thus disrupting stable processes, with the consequence of disrupting existing economies of scale. Another important economic phenomenon occurs on industry/market level. Technological innovations require high R&D costs and extensive marketing efforts, promoting the tendency of industry power concentration. The usual economic framework used to establish efficiency of R&D reflects on rate of returns, i.e. time and scope of R&D paybacks, extending focus to spill over effects and allowing policy makers to establish "policy tools" intended for establishing principles of value appropriation and capacity creation, thus achieving best performance in dynamic markets (Martin & Eisenhardt, 2004, pp. 357-382; Mance et al., 2016). In the case of PM, it is important to stress that technology diffusion is as important as technology creation.

Therefore, the payback of initial R&D investments depends on the pace and scope of market creation. In market creation, efforts are seen to be oriented towards multiple and diverse actors, such as governmental bodies, health care institutions, as well as towards individuals. A third point to be observed concerns social costs of PM creation and diffusion. As national health care systems are dominantly financed from public sources,

3. MAPPING AN INDUSTRY MODEL DEVELOPMENT FOR PERSONALIZED MEDICINE

Considering the broad and diversified scope of activities and actors involved, it is likely that building a *sustainable* model of interactions among actors will require active involvement of public authorities (Sokolic et al., 2014).

Table 1: Contrasting approaches in mapping organizational models

General approach	Process based	Entity based
Dimension best illustrated	Technological flow and Sequencing of activities	Asset ownership Legal and financial aspects
Elementary unit (building block)	Technological units (plants; scale economies) Technical compatibility and proximity of consecutive technological steps	Bundles of resources (scale and scope economies at single entity or network level) Decision making centres (driving actors)
Problem most likely to be observed	Missing links Inadequate capacity to maintain flow	Bargaining positions - Power asymmetries Transfer of resources (distribution effects) Legal and ownership – public/private; crossholdings (vested interests)
Underlying economic reasoning	Optimization of process flow (capacity building and smooth efficient throughput)	Value appropriation
Problem resolution	Planning <i>pace</i> and quantities along the chain Streamlining capacity	Regulation of entity <i>establishment</i> - setting scope of action (presence & size) <i>Regulation at interfaces</i> – interfering with bargaining power

Source: Authors

a policy seeking to promote PM is likely to squeeze out resources of existing institutions and health-care practice. This extends the issue of power relations, i.e. capacity endowment, value creation and value appropriation, also inside existing sub-systems.

There are basically two available approaches in mapping economic activities and value flows. Process based approaches are more technical and often search for capacity balance; they will define production stage processes and eventually specify capacity at each stage in an effort to streamline resource-

es (prevent shortages and enable full capacity utilization) and shorten process time. The second, “Entity based”, approach involves mapping legal entities. These approaches can be motivated by technologically induced savings, such as lower transportation costs that may result from geographic proximity of two warehouses. However, in economic reasoning, mapping sectors by identifying lead actors (size and economic or investment capacity differences among actors, or market concentration at value chain levels) may allow for the estimation of bargaining power and value appropriation. Table 1 points out to the major differences implied by these two approaches.

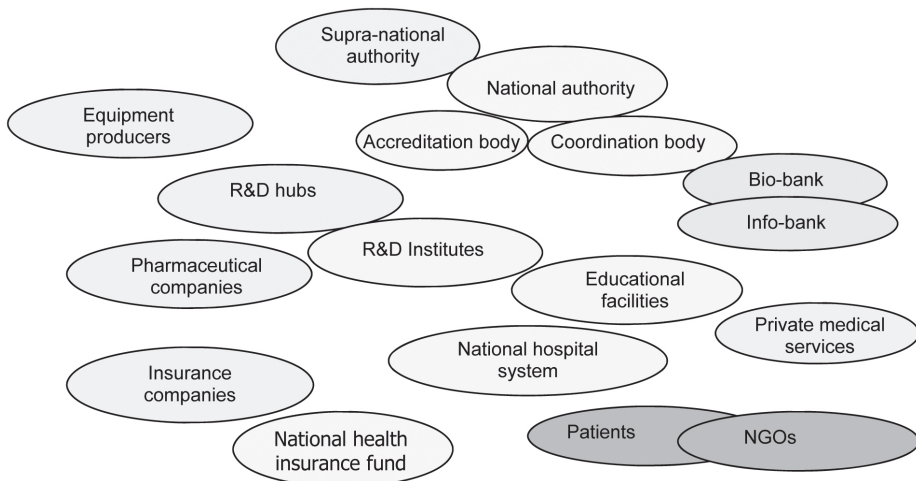
For the purpose of our analysis, we believe the entity approach is better suited for explaining the roles of actors involved. Figure 1 illustrates the main actors in the PM sector in the entity perspective.

The figure is a simplified representation of the entity approach. Model entities were defined according to technological function.

No particular legal entity has been identified at this stage. Shades of gray indicate *status*, which, in this frame, performs the role of functional clusters; i.e. type of *legal structure*. The idea was that different types of organizational entities have different *formation logic* in a sense that they possess various levels of institutional stability, have different strategic goals (for profit, governmental, collective representation-non-profit, etc.), different power of argumentation (information asymmetry), and ownership as source of asset provision and logic of decision-making.

Based on the distinctive features of institution types, we proceeded to identify personal interests that govern actor’s behaviour. Their representatives are listed in Table 2.

In the next section, we present some figures that illustrate the specific PM context at the moment. Particularly, we point some of the reasons why governments are expected to take a more active role in shaping PM future.



Source: Authors

Figure 1: Main actors in personalized medicine industry

Table 2: Comparison of personal interests between traditional and personalized medicine

REGULATION, LEGAL AND ETHICAL ISSUES	Traditional Medicine	Personalized Medicine
- Legal framework	Predictive	Vague
- Ethical issues	Controlled by known procedures	Unknown, vague, under-defined
- Public trust	High	Yet to be acquired
PERSONAL INTEREST VESTED		
- Clinicians	Reputation	Reputation and personal development
- Researchers	Recognition	Recognition and personal motivation for working w/ cutting edge technology
- Patient	Return to pre-symptom state	QALY (Quality Adjusted Life Years)
- Insurance clerks	Volume seeking	Oblivious to customer's situation, dependent of artificial intelligence (AI)
- HC managers	Budgeting	Reputation
- Corporate investors	Profits (ROI)	Profits (ROI)

Source: Authors.

4. RATIONALE FOR GOVERNMENT'S INVOLVEMENT IN SUPPORTING PERSONALIZED MEDICINE

The impact of State in shaping actors' behaviour is to be carefully considered. It occurs either through efforts in mitigating possible inefficient power imbalances (regulating markets), or as an agent in providing maximum public welfare. The rationale for closer government's involvement in PM development is very much related to long-term trend in health care (HC) financing. As total HC expenditures rise (Figure 2), technologies promising cost efficiency attract the interest of policy makers.

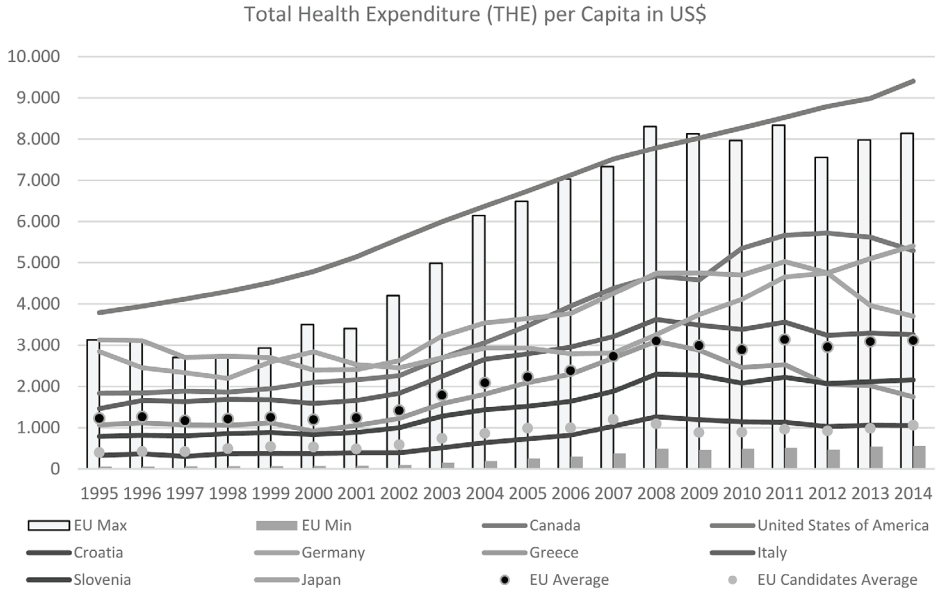
The role of the State, and one of the reasons why state investments lead beyond private sector investments, is to facilitate

the emergence of an infrastructural and institutional environment that will promote value creation and speed up development and dissemination. Available measures of government intervention are twofold:

1. *Supplementing private investments*, wherever public interest exists, on those stages of the value chain (or at the nodes in a polycentric governance model);

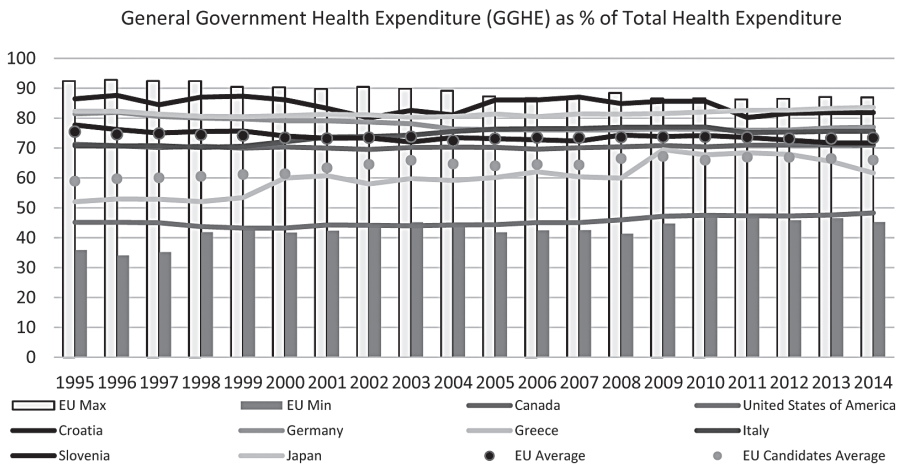
2. *Providing administrative measures in shaping the behaviour* of market actors by licensing institutions, products and procedures, and establishing standards.

General government health expenditure dominates in total HC expenditures in most developed countries. As can be seen from Figure 5, EU has as much as 75% of total health spending financed by public funds.



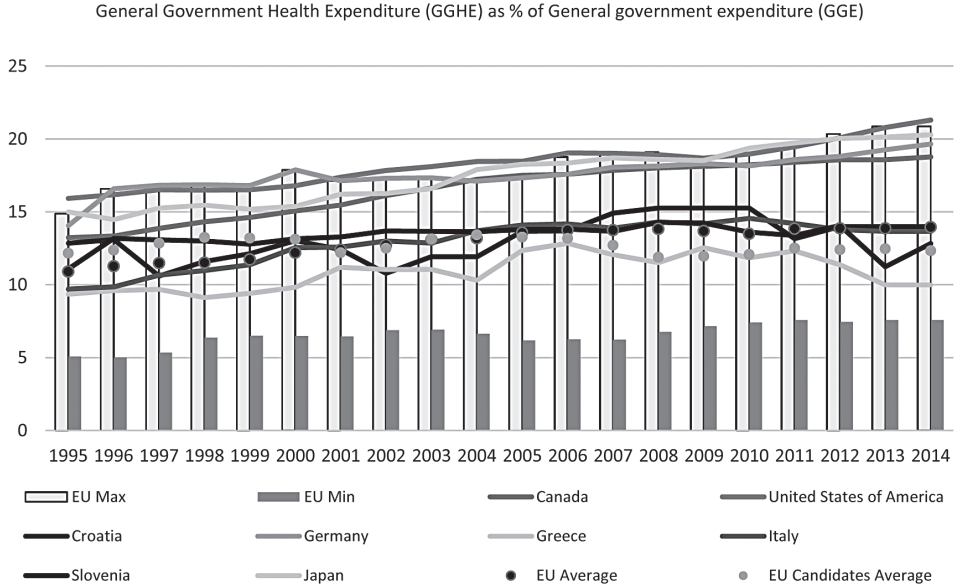
Source: World Health Organization (WHO), 2017.

Figure 2: Total Health Expenditure (THE) per Capita in US\$



Source: World Health Organization (WHO), 2017.

Figure 3: General Government Health Expenditure (GGHE) as % of Total Health Expenditure



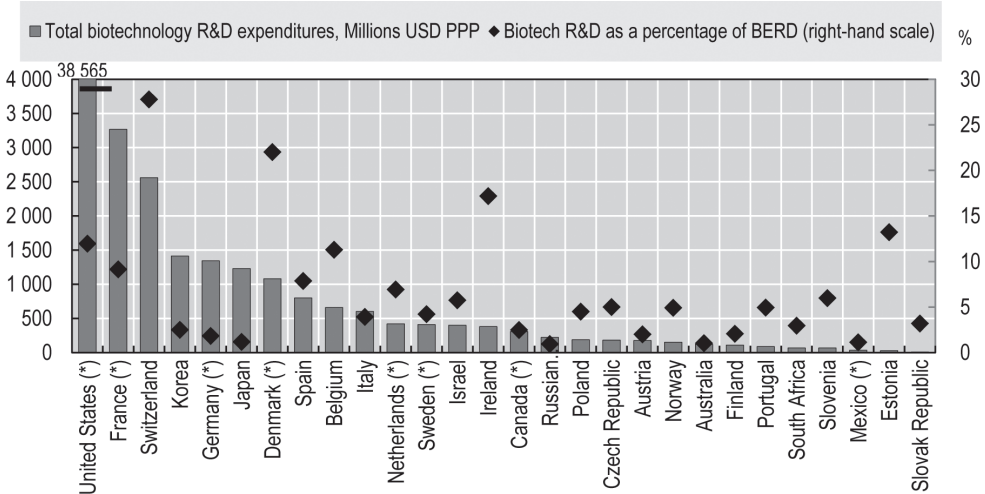
Source: World Health Organization (WHO), 2017

Figure 4: General Government Health Expenditure (GGHE) as % of General government expenditure (GGE)

This proportion has been stable for the past two decades. During this same period, the EU average proportion of HC spending in total government expenditure has risen by more than 2%, from 11% in 1995 to 14% in 2014. The total HC expenditure in GDP for EU27 has gone from 7% to 9%. The figures indicate that health care provision is a very important financial burden on society as a whole (Figure 3).

PM technology does not promise to decrease this burden. Instead, expects the personalized treatments to yield drop of total treatment costs and better the health status of individual patients (studies by medical professionals have been conducted on cancer patients), thus, lessening the need for HC interventions. On the other hand, having in view high cost of developing and implementing new treatments, as well as the ag-

ing of the world population, it is not likely that health care costs will go down. This fact encourages the study of regulation mechanisms, since medicine is already very much “under the jurisdiction” of the State. The immediate question raised is about “spillages” that may be happening at the private-public interfaces. However, a more important issue may soon become whether power asymmetries might be misdirecting resources. In the next section we are trying to explain our concerns. The refinement and upgrading of our descriptive industry model may help the State (regulator) in understanding value formation, spotting critical relationships, identifying resource pools and better mediating processes and relationships through an effective and efficient policy.



Source: OECD, Key Biotechnology Indicators, <http://oe.cd/kbi>; and OECD, Main Science and Technology Indicators Database, www.oecd.org/sti/msti.htm, October 2016.

Figure 5: Biotech R&D investments in the business sector

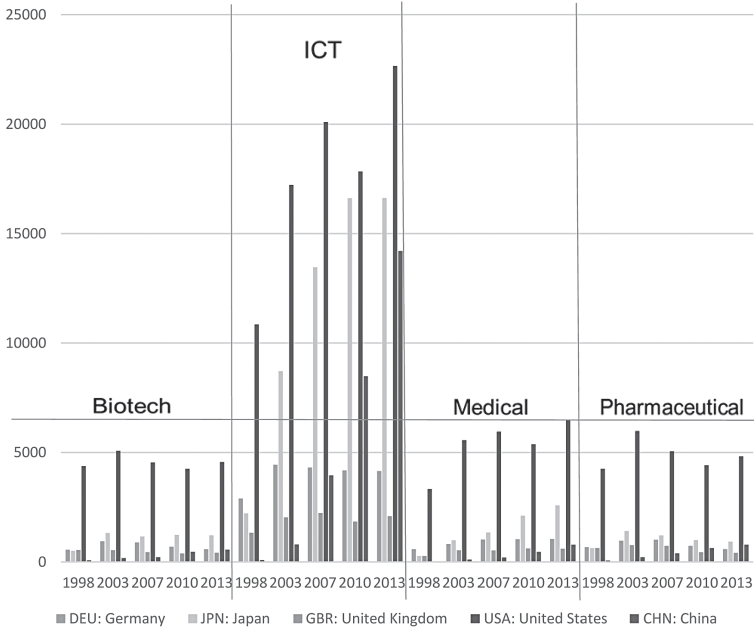
5. CRITICAL POINTS FOR FURTHER PERSONALIZED MEDICINE DEVELOPMENT

As noted before, investment activity is one of the main indicators of industry dynamics. Technological innovation in PM can undoubtedly be described as a market disruptive technology (Kastelan Mrak & Bodiřoga Vukobrat, 2016). As such, PM, as well as the broader health care sector, provide an arena for private investors seeking investment opportunities. Many market analysts and global consulting companies, such as The Blackrock Investment Institute, describe HC industry in 2017 reports as innovative, yet risky and highly impacted by regulation (and current public policy issues). Current investment activity is likely to generate future power relations in extents that surpass business profit considerations, but affect transnational power/market structure. Trends in investors' markets and stakeholders' considerations have been recently researched by Milne et al. (2015) and analysed

by market specialists and financial advisors, such as Deloitte and the already mentioned Blackrock Investment Institute.

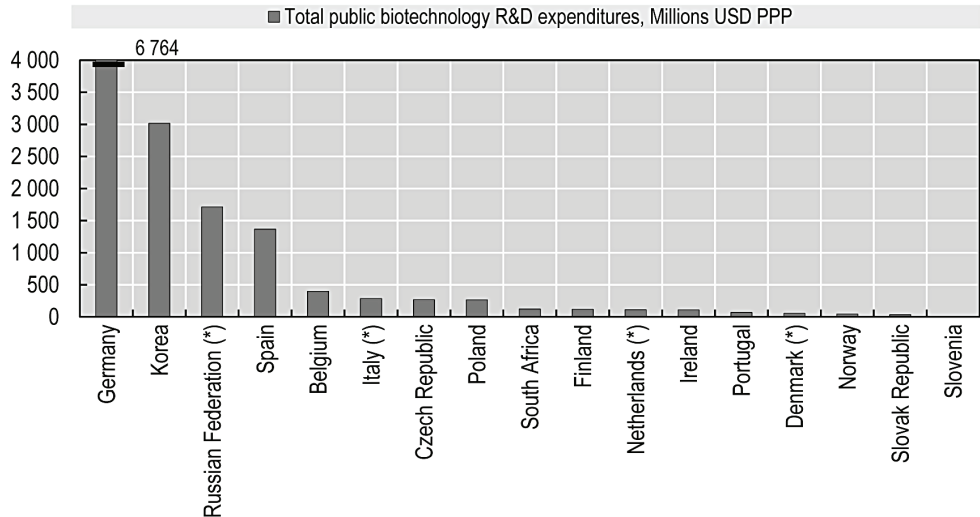
Key Biotechnology Indicators (OECD, October 2016) show investments in Biotech R&D to be the highest in the US at 38.6 billion USD (ppp) in the business sector compared to France, at US 3.3 billion, as a country with the second highest investment (Figure 5).

However, it is not only the development of genetically based diagnostic and treatment procedures that are revolutionizing health care, or biotech as a related field. To be considered are also the R&D activities in the related industries. The impact of ICT development and digitization has been noticed and estimated as crucial for PM development and implementation (HC digital transformation in Chilukuri & Van Kuiken, 2017, biobanking in Hewitt, 2011; Olson et al., 2014; Fleming et al., 2015).



Source: OECD statistics (2017), <http://www.oecd.org/sti/inno/keybiotechnologyindicators.htm>

Figure 6: R&D activity by number of patents per industry and country



Source: OECD, Key Biotechnology Indicators, <http://oe.cd/kbi>; and OECD, Main Science and Technology Indicators Database, www.oecd.org/sti/msti.htm, October 2016.

Figure 7: Total public R&D in biotech

Journal of Contemporary Management Issues

Table 3: Comparison of the business logic of traditional and personalized medicine

	TRADITIONAL MEDICINE	PERSONALIZED MEDICINE
MEDICAL PARADIGM	Segmented	Holistic
- Process activating entity	Patient	Provider of funding
- Patient assessment and treatment	On call /per case	Life-long schemes
- Point of initiating of patient treatment	Ex post (upon symptom)	Preventive (before symptom)
LEVEL OF TECHNOLOGICAL INOVATIVNESS		
- Continuity in relation to past medical practices	High	Low
- Average time to market for a product/ process/ treatment	Longer	Short (crucial)
- R&D payback horizon	Longer	Short and variable
- Patent protection duration (years)	Longer (5-20)	Shorter (> 5)
- Incidence of cutting-edge innovation	Rare	Common
INDUSTRY ATTRIBUTES		
- Level of importance of pipeline	Medium	High
- Critical process stage (bottleneck)	Production and distribution	R&D
- Scale (size of the population)	Large cohorts of non-differentiated patients	Stratified genotype populations (small)
- Inter-industrial relations (at production stages)	Specialized (distinction among production stages apparent)	Integrated (distinction among production stages less apparent)
- Intra-industrial relations (market concentration)	Concentrated	Dispersed/specialized
FINANCIAL ISSUES		
- Costing patterns	Administrative pricing, budgeting	Open-ended, treatment based
- Dominant R&D funding sources	Public	Corporate/Public (depending on institutional setting)
- Price setting principle (policy)	Standardized	Treatment based
- Sources for financing patient treatments	Public	Insurance funds (mostly private)
- Readiness of private insurances to extend coverage	Depends on market trends (market leader following)	Volatile (depending on “patient” profit/ QALY prospects)
- Ability to objectively asses customer risk	Lower	Likely very high
IT INFRASTRUCTURE		
- Information infrastructure	Physical and digital archive	Big data
- Data availability	Complex	Even more complex

Source: Authors

In comparison to the Biotech, the Medical and the Pharmaceutical sectors, the number of patents in ICT over the period 1998-2013 (data for 2013 being the last available) have approximately tripled the number of patents in the industries directly related to Health Care. Figure 6 also indicates the outstanding difference between countries, where the US significantly outperforms leading European countries.

It is also interesting to compare public investments by region. Growing HC expenditures make PM attractive to governments due to promised efficiency gains in terms of costs per quality-adjusted-life-years (QALY), with the size of investments undertaken by public and private investors growing. In that respect, Germany at 6.8 billion USD (ppp) more than twice exceeds Korea's investment, as the second largest country in public investments in biotech R&D (Figure 3).

The above figures indicate that the present situation is very diverse, when comparing countries and public health financing models. Nevertheless, we have still attempted to systemize comparative differences between the traditional medicine and personalized medicine paradigm. Our view of the differences between the two paradigms (Table 3) rests on the distinctive patterns pointed out in Tables 1 (Contrasting approaches in mapping industry models), Table 2 (Comparison of personal interests between traditional and personalized medicine) and Figure 1 (Main actors in personalized medicine industry).

A constant and rapid technological development, which results from intensive R&D investments, is reflected in market segmentation. Markets are becoming more and more fragmented, to the point (in the future) of becoming truly personalized: one person - one specific trajectory of life-long treatment. This implies personalized health care costs, a perspective that puts the state and commercial insurance funds at a crossroad,

challenging the regulators to decide on how much of personally "generated" health care expenses should be "socialized".

Apart from this social and political consideration, economists focus also on the differences between the two medical paradigms that can be expected in terms of market creation. Such factors include: market structure, financing capacity (available resources and their distribution), value creation and appropriation cycles (payback horizons), scale issues, and other factors we deemed interesting for investors and public authorities trying to shape industry development. Almost in all of the listed categories, we estimate that PM disrupts the common logic of established business model (based on clear flow, balanced capacity, and scale economies of standardized products and treatment). A higher variability implied by treatments designed upon personal (small cohorts') specifics adds a great deal of volatility to the costs and effects of medical treatment that becomes very case specific and therefore more complicated to plan in market share/payback effects (return on investment for corporate investors) and in budgetary terms (public financing models).

On the other hand, personal genetic testing increases the possibility of planning future/life-long risks and medical procedures; the implication being one "form" of predictiveness is replaced by another. Big data, as ICT infrastructural precondition for PM, also allows for the capture of life-style data, which is to some extent already being collected (for marketing purposes), but may be applied for "calculating" health risks in combination to genetic data.

6. CONCLUSION

From the perspective of developing market trends in pharmaceutical industry, biotechnology, life sciences and other sectors related to personalized medicine field, major

investments in the basic science have been made, rendering the industry very dynamic. Technology developments in personalized medicine have enabled the development of new diagnostic tests and diagnostic procedures, as well as drugs and treatment methods and protocols. It is likely that amounts invested in the system (increasing of available resources), as well as the identity of investors (and relative power relations) will create shifts in the broader health care sector. As such, the PM industry represents an exciting arena for investors, researchers and policy makers.

This paper elaborates a segment of a broader research on determining value of a next generation medical system. Even though available data on personalized medicine is fragmented because of the many different angles that researchers take when trying to predict future developments, by combining different sources of information, and by developing a theory based industry model, we point to some considerations we find relevant for understanding personalized medicine development. Any evidence and highlights may in fact be treated as “circumstantial”, yet other authors seem to confirm the disruptiveness of personalized medicine as a new medical paradigm. Based on important industry features and trends, our

descriptive model identified main industry actors. Their systematization in terms of purpose or formation logic (public-private), and extent of possible active impact on industry development, guided us in creating a list of relevant features that compare the business logic of traditional and personalized medicine. Therefore, the contribution of this paper lies primarily in identifying points of consideration for public authorities-policy makers if they wish to promote faster PM development.

The data indicate that R&D in personalized medicine and ICT innovation are still the driving forces for maintaining future growth. However, if regulation (state action) was to make the sector less volatile, investment activity would continue at a high level. A possible consideration to be addressed by future research is identifying main beneficiaries and value pockets. After obtaining these insights, we feel more confident about continuing our research in understanding of incentives of main groups of stakeholders specified in our industry model.

For further research, an analysis of national health care system is suggested to identify business model alternatives and perspectives on personalized medicine implementation.

References

1. Bach, D., Newman A. L. (2007). The European Regulatory State and Global Public Policy: Micro-institutions, Macro-influence, *Journal of European Public Policy*, 14 (6), 827-846.
2. Bolton, P., Dewatripont, M. (2005). *Contract Theory*, MIT Press
3. Caulfield, T., Zarzeczny, A. (2014). Defining medical necessity in an age of personalised medicine: A view from Canada, *Bioessays* 36, 813–817.
4. Chilukuri S., Van Kuiken, S. (2017). Four keys to successful digital transformations in healthcare, <http://www.mckinsey.com/business-functions/digital-mckinsey/our-insights/four-keys-to-successful-digital-transformations-in-healthcare>
5. Das, R. (2017). Drug Industry Bets Big on Precision Medicine: Five Trends Shaping Care Delivery, *Forbes Magazine Online*, <https://www.forbes.com/sites/reenitadas/2017/03/08/drug-development-industry-bets-big-on-precision-medicine-5-top-trends-shaping->

- future-care-delivery/&refURL=https://www.forbes.com/forbes/welcome/?toURL=https://www.forbes.com/sites/reenitadas/2017/03/08/drug-development-industry-bets-big-on-precision-medicine-5-top-trends-shaping-future-care-delivery
6. Fleming, J. et al. (2015), Attitudes of the general public towards the disclosure of individual research results and incidental findings from biobank genomic research in Australia, *Internal Medicine Journal*, 45 (12), 1274-1279.
 7. Hamburg, M. A., Collins, F. S. (2010). The path to personalized medicine, *The New England Journal of Medicine*, 363 (4), 301-4.
 8. Hart, O. (1995). *Firms, Contracts and Financial Structure*, Clarendon Press
 9. Hewitt, R.E. (2011). Biobanking: the foundation of personalized medicine, *Current Opinion in Oncology*, 23(1), 112-9.
 10. Jakka1, S., Rossbach, M. (2013). An economic perspective on personalized medicine, *HUGO Journal*, 7(1), 1-6, <http://www.thehugojournal.com/content/7/1/1>
 11. Kaštelan Mrak, M., Bodiroga Vukobrat, N. (2016). Examining the Role of the Legal Framework for predicting Developmental Paths for Personalized Medicine, *Book of Papers from the 5th International M-Sphere Conference for Multidisciplinary in Business and Science*, <http://www.m-sphere.com.hr/book-of-papers>
 12. Mance, D., Mance, D., Vitezić, D. (2016). Incremental cost-effectiveness pharmacoeconomic assessment of hepatitis C virus therapy: an approach for less wealthy members of the common market, *Croatian Medical Journal*, 57(6), pp. 582-590.
 13. Martin, J.A., Eisenhardt, K. M. (2004). Coping With Decline In Dynamic Markets: Corporate Entrepreneurship And The Recombinative Organizational Form, in Joel A.C. Baum, Anita M. McGahan (Eds.) *Business Strategy over the Industry Lifecycle (Advances in Strategic Management, Volume 21)* Emerald Group Publishing Limited, 357 - 382
 14. Milne, C. P., Cohen J.P., Chakravarthy, R. (2015). Market watch: Where is personalized medicine in industry heading?, *Nature Reviews Drug Discovery* 14, 812–813
 15. Morris, M. H., Schindehutte, M., Allen, J. (2005). The entrepreneur's business model: toward a unified perspective, *Journal of Business Research* 58 (2005), 726–735.
 16. Najafzadeh M., Davis J. C., Joshi P., Marra C. (2013). Barriers for integrating personalized medicine into clinical practice: A qualitative analysis, *American Journal of Medical Genetics, Part A*, 161A, 758–763.
 17. Olson J. E., Bielinski S. J., Ryu E., Winkler E. M., Takahashi P. Y., Pathak J., Cerhan J. R. (2014). Biobanks and personalized medicine, *Clinical Genetics* 86, 50–55.
 18. Ostrom, E. (2010), Beyond Markets and States: Polycentric Governance of Complex Economic Systems, *American Economic Review*, 100, 1-33 <http://www.aeaweb.org/articles.php?doi=10.1257/aer.100.3.1>
 19. Pavelić, K., Kraljević Pavelić, S., Sedić M. (2016). Personalized Medicine: The path to New Medicine, in Bodiroga Vukobrat et al. (Eds.) (2016), *Personalized Medicine: A New Medical and Social Challenge*, Springer
 20. Pope, C. M. (2013). *Key Points Legislating Low Prices: Cutting Costs or Care?*, Background, The Heritage Foundation - Leadership for America, No. 2834

21. Smith, D.G., King, B.G. (2011),. Contracts as Organizations, *Arizona Law Review*, 51 (1), http://digitalcommons.law.byu.edu/faculty_scholarship/43
22. Sokolić, D., Kaštelan Mrak, M., Katunar, J. (2014). Understanding the role of context in shaping the development of business systems, *Scientific Journal of Maritime Research*, 28, 137-144
23. Tirole, J. (1988). *The Theory of Industrial Organization*, MIT.
24. Williamson, O. E. (1985), *Markets and Hierarchies: Analysis and Antitrust Implications*, The Free Press.
25. Windholz, E.L. (2018), *Governing through Regulation: Public Policy, Regulation and the Law*, Routledge Critical Studies in Public Management, Taylor and Francis, London.
26. Zot, Ch. And Amit, R. (2010), Business Model Design: An Activity System Perspective, *Long Range Planning*, 43 (2-3), 216-226

RAZVOJ MODELA INDUSTRIJE PERSONALIZIRANE MEDICINE

Sažetak

Zdravstvena industrija je brzo rastući sektor, ali smjerove njezina razvoja je trenutno teško predvidjeti. U ovom se radu iznosi kratki pregled čimbenika, značajnih za razvoj poslovnih modela u području personalizirane medicine. Rad se zasniva na doprinosima institucionalne teorije, a posebno ekonomike transakcijskih troškova te pokušava razviti konceptualni model, koji bi se mogao primijeniti na utvrđivanje odnosa između organizacija, odnosno industrijskih aktera u području personalizirane medicine. U skladu s teorijskim određenjima, odnosi između industrijskih aktera bi se trebali razvijati u skladu s manifestacijama brojnih faktora konteksta i njihovog razvoja, a što uključuje: investicijsku

aktivnost, javni interes, razvoj tehnologije, tržišnu strukturu, regulatorno okruženje, demografske čimbenike, osobne preferencije, prirodne čimbenike, itd. Autori vjeruju da bi deskriptivni industrijski model trebao obuhvaćati veći broj organizacija, osim direktnih konkurenata, i to na temelju uvjerenja da tržišni akteri, u okruženju koje ovisi o resursima, održavaju svoje aktivnosti kroz angažman u održavanju odnosa s drugim organizacijama, koje imaju skrivene interese. Stoga autori smatraju da će predviđanje budućeg industrijskog razvoja i razvoja poslovnih modela konkretnih poduzeća ovisiti o raspoloživim resursima, odnosima moći i regulaciji.

Ključne riječi: *personalizirana medicina, poslovni model, nepotpuni ugovori, poticaji, poslovni scenariji*

¹ Highlights added by authors.

² Winfred Shaw is senior director of the Precision Medicine Center for Excellence at Quintiles, a company that provides services and solutions to biopharmaceutical companies (in Mangan, D. (2015), Personalized medicine: Better results, but at what cost?, CNBC interview, <http://www.cnbc.com/2015/12/04/personalized-medicine-better-results-but-at-what-cost.html>, accessed on April 17th 2017).

³ The conceptual model would help in defining critical regulation points and advice choice of regulatory instruments, ultimately affecting the distribution incentives, that is of costs and benefits fits into a dynamic development model.

⁴ Controlling original balance of power created by unregulated markets.