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THESIS BOOKLET

Dávid Dankó

Resource Management in an Industry with Long-term Return – Increasing Efficiency Along the Pharmaceutical Value Chain

Ph.D. dissertation

Supervisor:

László Lázár, Ph.D

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Institute of Management

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Contents

1. Antecedents and choice of subject matter

1.1. Subject matter and antecedents of the research

The present dissertation is an investigation of how efficiency can be increased, and resources optimally managed, in the pharmaceutical industry, in which the core business is capital intensive and is characterized by a high time-to-market and long-term returns. As most pharmaceuticals are not purchased out-of-pocket by patients but are rather provided to them by national health systems or social security schemes, the long-term return is heavily dependent on the actual status of the regulatory and reimbursement environment in the key sub-segments of the global pharmaceutical market.

The present dissertation is an investigation of how efficiency can be increased, and resources optimally managed, in the pharmaceutical industry, in which the core business is capital intensive and is characterized by a high *time-to-market* (TTM) (e.g. Pawar et al. [1994], Smith [2004]) and long-term returns. As most pharmaceuticals are not purchased out-of-pocket by patients but are rather provided to them by national health systems or social security schemes, the long-term return is heavily dependent on the actual status of the regulatory and reimbursement environment in the key sub-segments of the global pharmaceutical market. It is a further objective argument in favour of the pharmaceutical industry that to the best of my knowledge, nobody has investigated the issues of long-term resource management in the pharmaceutical industry in Hungary to date. Even the international literature features only a very few publications that approach the pharmaceutical industry from this perspective.

I intend my dissertation to fit into the series of doctoral dissertations that constitute the results of the academic research conducted at the Institute of Management of the Corvinus University of Budapest, while at the same time reflecting upon the clear shift in my research interests in the past couple of years. The Institute has established two definitive directions of research that the present dissertation is closely related to and whose previous results it can hence make use of while, hopefully, it will also make a contribution to the scientific achievements of the Institute:

- One of those research areas is concerned with the development and Hungarian applications of the toolkits and methods of performance management. Within that field

of research, in addition to the work conducted in the 1990's that had laid the foundations of the field, (e.g. Horváth-Dobák [1993]), I should particularly mention the doctoral theses of Viktória Bodnár and László Lázár (Bodnár [1999], Lázár [2002]) which provide wide-ranging summaries about the fields of controlling and cost mapping and the publications and conference papers that have attempted, in recent years, to resolve the conceptual chaos that characterizes the discipline of controlling (see e.g. Bodnár [2005, 2007], Bodnár-Dankó [2005], Dankó [2005], Harangozó [2007]).

- The other direction of research, which has come to be one of the central fields of research for the Institute, is healthcare management and healthcare controlling, in which recent years have seen several publications and conference papers by Viktória Bodnár, Dávid Dankó, György Drótos, Norbert Kiss, Márk Péter Molnár, Éva Révész, Csilla Varga-Polyák and others. That research has covered the micro-level (institutions), the middle level (networks) and the macro-level (public policy, sectoral level performance management) of the healthcare sector as well. It was within this research stream that a sub-stream focused on pricing and reimbursement as well as market access issues in the pharmaceutical industry. This sub-stream is mostly represented by research and publications by Márk Péter Molnár and myself, not independently from our previous practical experiences.

During the compilation of my dissertation, I endeavoured to build on all the experience I gained during my diploma research project that was initially published as an article (Dankó [2003]), the subsequent assignments as an expert in the pharmaceutical industry, the role I then came to occupy in relation to decision-making and analyses associated with drugs and finally the joint research and projects I conducted with pharmaceutical companies. During the time of writing, I found myself in a somewhat awkward situation: by the time I had defended by draft dissertation, my practical work had moved me closer to the issues of reimbursement policy, i.e. it so happened that my knowledge of the issues that are the subject matter of the present dissertation gained greater clarity and detail not from the perspective of the pharmaceutical industry but from the side of the regulator and payer (the "other side"). As a result, while I would clearly have a comparative advantage if I were submitting a dissertation about reimbursement policy, with my actual subject I can only hope that I was able to augment my experience of the "other side" with the additional research and the closely connected expert work I performed after I stopped working for payer organizations so as to achieve a dissertation that is relevant and valuable.

In accordance with the above considerations, in my PhD dissertation I shall examine the solutions that companies in the original and generic pharmaceutical industries use in the pharmaceutical value chains in order to improve their organisational efficiency. My basic assumption for conducting that study shall be that in the pharmaceutical industry, the optimisation of resource allocation is implemented partly in the fundamental processes (using *scientific and technological solutions*), partly through *work organisation solutions*, and partly by using *business tools*, and the relevance of the various types of tools varies in the individual value-chain sections as well as between the different strategic models of the pharmaceutical industry. The variation in relevance is the result of differences in potential and implementability. In my research, I shall study *perceived* relevance throughout – the subjective significance that specialists in the pharmaceutical industry attribute to the solutions in question (*see point 2.2 of this thesis booklet*).

1.2. Research questions

In the rest of my dissertation I shall study the following research questions and corresponding summary hypotheses:

Research question	Summary hypothesis
1. What are the solutions available for increasing efficiency in the various sections of the original prescription only (ORX) and generic prescription only (GRX) value chains?	*This research question is aimed at gathering information, so it does not have any corresponding summary hypotheses*
2. What is the relative (perceived) relevance of those solutions along the individual value chains?	H1. In the preclinical phase of the value chains, scientific and technological solutions have the greatest perceived relevance, with work organisation tools in second place and business tools coming last. H2. In the clinical phase of the value chains, the perceived relevance of scientific and technological solutions decreases while that of work organisation solutions and business tools increases. H3. After going to market, business tools assume the dominant role in both value chains.
3. What are the main differences between the resource-management tools used in the original prescription only (ORX) and the generic prescription only (GRX) business models?	H4: In the generic prescription only (GRX) business model, the perceived relevance of business tools lags behind that of scientific and technological solutions and work organisation solutions to a lesser extent than in the original prescription only (ORX) model. H5: Resource management after the product is placed in the market is more significant in the generic prescription only (GRX) business model than in the original prescription only (ORX) model.

Research questions and corresponding summary hypotheses of the dissertation

2. Methodological considerations

2.1. Approach to research

As regards its basic epistemological orientation, my dissertation remains within the framework of *functionalist sociology* (Burrell-Morgan [1979]), i.e. I shall assume that I can *obtain objective knowledge* about my research subject. In relation to that, as an observer I shall remain outside the subject matter of my thesis: I shall attempt to map and interpret reality as an *external observer*.

My dissertation does not have a normative or critical intent, but it does aim to describe, explain and *organize* the phenomena within its subject area as thoroughly as possible. It aims to integrate inasmuch as it wishes to facilitate integration between fields of science that traditionally have little contact and that it identifies with the multidisciplinary approach. The underlying attitude behind the systemic approach and the integrative intent is an admittedly *contingentialist* one (see e.g. Dobák et al. [2006], Kieser [2003]) towards research, characterized by the view that environmental and contextual factors have a fundamental effect on the structural and other operational characteristics of organizations and the coordination tools that they use, including the tools, methods and mechanisms of resource management.

In addition to the systemic approach with contingentialist foundations, I intend the above-mentioned *multidisciplinary perspective* to be perhaps the most important distinguishing feature of the dissertation. As a researcher, I am convinced that people doing theoretical and practical work in the management sciences can improve their chances of reaching new insights, developing innovative solutions and addressing the problems of organizational life in a manner befitting their weight if they have some understanding of the technical and natural scientific background of the core processes. In general, achieving such an understanding is not very difficult, though it does require time and receptivity. I have made the assumption that the target audience of my dissertation does require such an understanding even at the cost of receiving only a more concise and superficial analysis of certain management problems due to considerations of length.

2.2. Methodology

In line with the research approach, the *methods of analysis* were as follows:

- The chapters outlining the basics of resource management and the general description of the pharmaceutical industry are based on a detailed and extensive *review of the literature* that covered the major periodicals in the management sciences, pharmaceutical research, technology and chemical technology. Secondly, the literature review also included the specialist books on the subject that are available to me, largely about general issues of management, innovation and production organization in the pharmaceutical industry. The review of the literature was already a part my draft dissertation, but, in accordance with the suggestions of my reviewers, I have made the parts summarising theory somewhat simpler.
- Based on the detailed literature review, the experience of the previous research efforts and background interviews conducted with pharmaceutical specialists, I performed *independent scientific work* to arrive at the analytical framework of the draft dissertation, which, firstly, attempts to integrate the theory of resource management with the operational characteristics of the pharmaceutical industry, secondly, it alludes at the logic of the empirical research section of the dissertation and thirdly, it renders the research questions of the empirical study more specific.
- The reviewers of my draft dissertation had several critical comments to offer concerning the planned methodology of the empirical study. Accepting their advice and suggestions I performed a radical reconsideration of the research methodology: I attempted to find international sources of information; I also decided not to use questionnaires with questions requiring descriptive responses, as the conceptual complexity of the theme would have made my questions difficult to comprehend for my research subjects representing various professions and levels of decision-making, and I decided to use only in-depth interviews instead. I also used secondary sources in relation to areas and questions to which my interview subjects themselves were unable to provide information directly, but were able to point me to case studies in the literature that I felt were relevant. Furthemore, I also relied on personal communications I received from the executives of international pharmaceutical companies when my work or my attendance of conferences afforded opportunities to talk to them; I emphasise that those conversations were not

scientific in character and they cannot be considered to be parts of my research, but they are highly significant for the subject of my research.

The analytical model for the empirical study is based on a detailed description of the process of developing, manufacturing and marketing of medicines, which, in effect, is the *value chain* of the pharmaceutical industry. The value chain is the totality of 'paths' that the products of pharmaceutical companies travel along during their life-cycles, and during which they consume various resources. The analytical model has been set up in a way that a separate specific value chain belongs to each strategy model. The following strategy models have been investigated:

- Original prescription-only (ORX) segment (and value chain)
- Generic prescription-only (GRX) segment (and value chain)
- OTC segment (and value chain, with respect to first market entry)

Resource management can be provided using various solutions in the individual phases of the value chains. I conjecture that it is helpful to distinguish the *scientific and technological solutions* associated with basic process technologies, the *work organisation solutions* that aim to improve coordination and communication within the organisation and the so-called *business tools*, which consist of performance management and marketing techniques.

The relevance of the individual resource management tools as perceived by the decision-makers who use them varies between the individual strategic models. By *perceived relevance* we mean the opinions of managers concerning the closeness of the connection between use of a particular tool and the achievement of strategic advantage. I shall consider a particular resource management tool to be relevant if, in the opinion of the managers who use it (or those supervising its use), it is of critical importance for achieving strategic competitive advantage for pharmaceutical companies. At a high level of abstraction we can assume that in any strategy model, the perceived relevance of a resource management tool is dependent on the following factors:

- its intrinsic *potential*, i.e., more specifically the relative resource-intensity of the section of the value chain in which it is used (relative to other sections of the value chain); the extent

to which it will be able to *influence* the resources (in scope or depth) consumed in the section concerned; and the *strategic advantage* that the company may gain through this;

- the practical utility of its *implementation*, i.e. the level of organizational adaptation that it requires, the methodological and IT background it needs, and the degree of support it can expect from the organization on the basis of socio-cultural characteristics.

3. Results

3.1. Results for the original prescription-only (ORX) strategic model

The value chain of original prescription-only manufacturers is very long, covering up to two decades. The value chain consists of several phases with radically different characteristics, and efficiency is increased by different sets of resource-management tools in the various phases. The range of resource-management techniques is extremely wide: it includes technological and scientific, work organisation and business tools.

The competition between original pharmaceutical manufacturers takes place in the field of innovation. Their profit is derived from innovation – in Schumpeter's terms, new technological processes and, most of all, product innovation (Antalóczy [1997], Roberts [1999]). The most important source of competitive advantage for them is how fast they are able to place a new product in the market. The sooner the preparation reaches patients, the more time they have left of the period of patent protection (exclusive market access) to generate revenue, so the more profit they are able to make. That profit provides the foundation for developing subsequent products; in that sense, continuous innovation is its own precondition. Despite the fact that the company's innovate in competition with each other, the greatest enemy is *time* itself. Original manufacturers must defeat time – and the outcome of that battle also decides the outcome of the fight against each other. It is estimated that each day saved in the development process may result in additional revenue of up to one million dollars (Sweeny [2002]), and the reverse is also true: delays in development can result in tremendous losses of revenue not to mention the additional costs of development and licensing.

So, in the original prescription only model, the main tasks of resource management are to accelerate the development process, to prevent avoidable costs and to eliminate superfluous activities. As a result, the most important resource-management tools are those covering several phases, i.e. the longitudinal ones.

Thus the essence of efficiency improvement (resource management) conducted by original pharmaceutical manufacturers is the prevention of costs and risks, even at the cost of greater up-front investment. All activities, phases of work, processes and assignments of tasks should be eliminated whose later time requirement does or may result in additional costs. This is rarely possible to do using business tools, so in the phases of the value chain prior to the marketing of the drug, scientific and technological solutions and work organisation solutions appear to be more important. Due to the nature of the work tasks to be performed, the business tools widely documented in the management literature (e.g. controlling tools) have limited relevance, as in the original pharmaceutical industry most of those are simply not worth using because they are not capable of producing true competitive advantage. The medical and official requirements applicable to medicines, the biochemical properties of drug molecules, the characteristics of the technology of organic chemistry and the areas with high administrative burdens – e.g. quality management and environmental protection – are all unavoidable, which do not favour the use and acceptance of classical process development or the "textbook" varieties of costing and systems of indicators. Business tools in themselves are therefore unlikely to achieve substantial improvements of efficiency in the original pharmaceutical industry. As a general rule, their significance increases after the drug is placed in the market, when they serve as the basis for portfolio decision, *make-or-buy* decisions and capacity decisions.

However, there are some exceptions: of the methodologies that are taught (among other places) at university courses in economics, project management and other methodologies that can be used within the framework of strategic pricing (e.g. net present value calculation) have markedly high relevance, but in practice those are also extended using industry-specific characteristics which, according to the traditional functional classification, belong among marketing tools, public relations tools and IT solutions.

The implication is that resource management in original pharmaceutics is an interdisciplinary activity. It covers several aspects of clinical pharmacology, pharmacological technology,

project management, marketing, public relations, controlling and information technologies. The question is: what is the significance of such a diverse activity relative to other strategic activities? Based on my in-depth interviews with pharmaceutical industry specialists I have formed the impression that for them, resource management is the totality of efforts made to increase efficiency and reduce risks. In that sense, they understand the role of resource management clearly, but many of my interviewees added that its significance does not match that of influencing the market in a proactive manner or continually renewing the product portfolio.

Original pharmaceutical companies aim to develop their processes and to develop their internal efficiency, too, but they do so in a much less spectacular fashion than those in other industries, as taking such measures only result in competitive advantages for them if they have an innovative and market-ready basic product. It may also play a role that original companies are large, inflexible and tend to avoid risks, while they are permeated by everyday rituals of operation (Desjardins [1997]). In their case, success is the result of innovation, innovation requires capital strength and capital strength is indirectly a function of size. But there is a trade-off between size and flexibility: for a pharmaceutical company to be large and stable in the long-term, it needs standardised operating processes, and standardised processes reduce flexibility (Allen [1997]). It is no accident that original pharmaceutical manufacturers outsource the research and development tasks requiring flexibility and the taking of higher risks – their sluggishness and their internal coordination mechanisms do not bode well for the success of those activities. Regulatory factors such as the strict GMP regulations also contribute to that effect.

In summary, based on my research:

- **In the original prescription only strategic model, the significance of resource management using business tools is low, with the exception of project management and the methodologies used for strategic pricing.**
- **However, scientific and technological solutions and work organisation solutions do play an important role in improving organisational efficiency, although their significance in promoting business success still remains below tools such as continuous product innovation (*pipeline*) and the proactive influencing of the market.**
- **In the original strategic model, the focus of increasing efficiency is on preventing costs and risks in a forward-looking and interdisciplinary manner.**

The resource management solutions used in the original prescription only model are shown in the following table which was compiled as a summary of the results of my research:

Value chain phase	Category	Type	Solution	Potential	Implementability	Perceived relevance
Discovery and synthesis	Longitudinal tools	Scientific and technological solutions	Combinatorial chemistry and screening methods	Very great	Medium	Very great
		Work organisation methods	Acceleration of work process	Minor	Medium	Minor
			More efficient work organisation			
			Better raw material management			
	Cross-section tools	Computer assisted drug research (scientific and technological solution)	Structure-driven drug design	Great	Not possible to assess in general	Great
			Targeted design			
			Virtual screening			
		Pharmacogenomics (scientific and technological solution)		Medium	Not possible to assess in general	Medium
	Reduction of capacity costs	Rationalisation (work organisation solution)	Across-the-board rationalisation	Variable / Great	Medium	Medium / Great
			Differentiated rationalisation	Variable / Great	Difficult	Medium / Great
		Outsourcing (work organisation solution)	Full outsourcing	Medium / Great	Uncertain	Medium / Great
			Partial outsourcing			
Preclinical trials	Frontloading	Scientific and technological solutions	In silico testing	Very great	Difficult	Great
			Trial design			
			Parallel trials			
			Acceleration of carcinogenicity trials			
		Work organisation methods	Acceleration of work process	Medium	Medium	Medium
			More efficient work organisation			
			Better raw materials management			
	Outsourcing preclinical trials (work organisation solution)		Full outsourcing	Medium	Not possible to assess in general	Medium
			Partial outsourcing			
	Prevention going beyond preclinical phase	Process chemistry (scientific and technological solution)		Great	Not possible to assess in general	Great
Clinical trials	Close cooperation with regulatory authorities (work organisation solution)			Great	Partly depends on external stakeholders, partly requires a change of attitudes, hence difficult	Great
	Structured selection of patients (work organisation solution, with some scientific and technological elements)			Very great		Very great
	Careful selection of trial configuration and locations (work organisation solution)			Very great		Very great
	Phase 0 and *proof of concept* trials (work organisation solution, with some scientific and technological elements)			Very great		Very great
	Limited registration			Very great		Very great
	Use of data management and communication technology (work organisation solution)			Great	Variable	Great
	Strategic pricing (business tool)			*See tools covering several phases of the value chain*		
	Project management (business tool)			*See tools covering several phases of the value chain*		
Licensing and registration	Consultations with regulatory and financing authorities (work organisation solution)			Medium	Depends on external stakeholders	Medium
Production	Optimisation of activities associated	Optimisation of procurement process (work organisation solution)		Medium	Good	Medium

Value chain phase	Category	Type	Solution	Potential	Implementability	Perceived relevance
	with procurement and inbound logistics	Maintaining high quality of supply (work organisation solution)				
		Achieving optimal stock levels (work organisation solution)				
	Optimisation of production capacities	Outsourcing	Outsourcing active ingredient production (work organisation solution)	Medium	Generally good	Medium
			Outsourcing packaging (work organisation solution)	Medium	Good	Medium
		In-plant rationalisation (work organisation solution)		Minor	Medium / Difficult	Minor / medium
		Concentration of production capacities (work organisation solution)		Minor	Medium / Difficult	Minor / medium
	Streamlining of support infrastructure	Process management (business tool)		Medium	Variable	Medium
	Other business tools			Medium	Variable	Medium
Marketing and sales	Increasing the efficiency of product promotion and sales	Product segmentation(business tool)		Medium	Good	Medium
		Reducing promotional costs (work organisation solution)	Outsourcing the work of medical sales reps	Medium for the time being	Variable	Medium for the time being
			Reorganisation of medical sales rep network			
			Alternative sales channels			
	Controlling the costs of postmarketing tests	Structured selection of patients (work organisation solution, with scientific and technological elements)		[Minor or medium]	Depends on external stakeholders	[Minor or medium]
		Data management and communication technologies			Variable	
	Improving the efficiency of outbound logistics	Optimisation of the distribution process (work organisation solution)		Medium	Good	Medium
		Optimisation of product inventories (work organisation solution)				
		Management of distribution centres (work organisation solution)				
		Streamlining account management and customer relations (work organisation solution)				
Tools covering several phases of the value chain	Project management (business tool)			Very great	Variable	Very great
	Strategic pricing (business tool)			Very great	Variable	Very great
	Benchmarking (business tool)			Minor	Poor	Minor

Overview of resource-management solutions used in the value chain of original prescription-only drugs

3.2. Results for the generic prescription-only (GRX) strategic model

Various resource-management tools correspond to the various phases of the value chain in the generic prescription-only strategic model, as well. The value chain has fewer phases than that of originators, largely due to the lack of a clinical development phase and the relative simplicity of licensing. As a result, the tools used for improving efficiency also exhibit less variety.

Although marketing-driven product markets are quite common, price is the definitive factor in the competition between generic manufacturers. Their competition against time is less crucial, although they do have to take the expiry of the exclusive market access of the originators in mind. As a result, with generic manufacturers the performance of production, marketing and sales is at least as important if not more important than that of compound development and licensing.

In the development and licensing phases, generic manufacturers are also characterised by cost prevention, but its significance is lower relative to the original prescription only strategic model. On the other hand, as they operate in a competitive rather than a monopoly market, they are under much greater pressure to operate their production and sales in an efficient manner. Price competition forces them to exploit all the reserve capacities in the operation of their organisations and to be flexible. As a result, the operation of generic firms in the period after drugs are placed in the market appears to be much tighter and ‘leaner’. Increasing efficiency is a continuous endeavour that is a part of everyday work, whose focus is not so much on the longitudinal tools of influencing costs but on optimising operating processes.

In the interest of maintaining cost-effectiveness and flexibility, the companies using the generic prescription only model tend to use the solutions for efficiency improvement that are to be found in the pages of management textbooks to a greater extent. Work organisation methods and business tools are more suitable for the optimisation of operating processes. Accordingly, the resource management of the generic prescription only model is also interdisciplinary in character, but there is an observable shift of emphasis towards the use of business tools. According to the results of the interviews, work organisation solutions and business tools are in general use, and the gap between the significance of scientific and

technological solutions and other methods is not as great as in the original prescription only model.

Presumably, the importance of achieving organisational efficiency is proportional to the intensity of price competition in the market of active ingredients that are no longer under patent protection. In markets where brand-based drug ordering is dominant, doctors think in terms of brand names rather than active ingredients, and marketing, as a factor of success, may be more important than improving efficiency. In those markets, however, where competition of substitutable drugs is really efficient, and/or where the financing authority uses administrative means to enforce drug prices that are near the marginal cost, the role of resource management increases exponentially.

Actually, according to the specialists I have questioned, the duality of increasing efficiency and influencing the markets is characteristic of the generic prescription only strategic model as well: while functional resource management is vitally important, it is not worth much if marketing work and product portfolio management are weak. So in this respect there is no striking difference between original and generic pharmaceutical companies.

In summary, based on my research:

- **In the price-driven generic prescription only strategic model, resource management is strongly focussed on the efficiency and flexibility of operating processes.**
- **As daily operating processes are in the focus of attention, the significance of work organisation solutions and in particular that of business tools is greater than in the original prescription only strategic model.**
- **Appropriate resource management is a necessary, but not sufficient condition of business success in the generic prescription only strategic model. It does appear to be a lot more important than in the case of original pharmaceutical manufacturers, which operate in monopoly markets.**

The table below presents the tools of resource management used in the generic prescription-only business model:

Value chain phase	Category / type	Solution	Potential	Implementability	Perceived relevance
Compound development	Patent research management	Structuring of patent research (work organisation solution)	Medium	Good	Medium
	Production technology management	Process chemistry (scientific and technological solution)	Medium / Great	Variable	Medium
		Outsourcing of production technology (work organisation solution)	Great	Variable	Medium / Great
Preclinical and clinical trials, licensing	Close cooperation with the regulatory authorities (work organisation solution)		Medium	Depends on external stakeholders	Medium
	Structured selection of patients (work organisation solution)				
	Selection of trial locations (work organisation solution)				
Production	Procurement management	Just-in-time production management (work organisation solution)	Great	Difficult	Great
		Quality norms and supplier selection criteria (business tool)	Great	Good / variable	Great
		Customer audits (business tool)	Medium / Great	Good / variable	Medium / Great
		Modernisation of warehousing and transportation (work organisation solution)	Medium	Variable	Medium
	Production cost management	Determination of optimal batch size (work organisation solution with scientific and technological elements)	Great	Good / variable	Great
		Homogeneous plants (work organisation solution with scientific and technological elements)	Great	Medium / Difficult	Great
		Optimal selection of control points (work organisation solution)	Medium	Good	Medium
		Outsourcing (work organisation solution)	Very great	Variable	Great
	Optimisation of packaging	Optimisation of packaging (scientific and technological solution)	Minor	Good	Minor / Medium
		Outsourcing (work organisation solution)	Medium	Variable	Medium
	Optimisation of supporting processes	Process management (work organisation solution supported by business tools)	Medium	Variable	Medium
Marketing and sales	Product management	Coverage and returns calculation methodologies (business tools)	Medium	Good	Medium
	Product promotion management	Streamlining of medical sales rep networks (work organisation solution)	Medium / great	Variable	Medium
		Outsourcing of doctor visits, “contract reps” (work organisation solution)	Medium / great	Variable	Medium / great
		Alternative sales channels (work organisation solution)	Medium / great	Variable	Medium / great
	Improving the efficiency of outbound logistics	Optimisation of the distribution process (work organisation solution)	Medium / great	Good	Medium / great
		Optimisation of the stock level of finished product (work organisation solution)	Medium / great	Good	Medium / great
		Management of distribution centres (work organisation solution)	Medium / great	Good	Medium / great
Tools covering several phases of the value chain	Project management (business tool)		Very great	Variable	Very great
	Strategic pricing (business tool)		Nagy	Variable	Great
	Benchmarking (business tool)		Minor	Poor	Minor

Overview of the resource-management solutions used in the value chain of generic prescription-only drugs

4. Summary of conclusions

In summary, some of the hypotheses I formulated for my research were fully supported by the results of the qualitative study, while some of them were only partially validated and hence required amendment. In my opinion, none of the hypotheses have proven completely false. Reviewing them one by one:

- Hypothesis H1 – "*In the preclinical phase of the value chains, scientific and technological solutions have the greatest perceived relevance, with work organisation tools in second place and business tools coming last*" – seems to have been substantiated in both of the strategic models I examined, although to differing degrees and in particular with different robustness:
    - The empirical results indicate that in the original prescription only (ORX) model, in the preclinical phase the most relevant techniques are the scientific and technological solutions of combinatorial chemistry (including screening methods), computer assisted drug discovery, process chemistry and frontloading. The significance of work organisation solutions as a whole is lower, although some particular techniques do have high perceived relevance, while business tools play practically no role at all. So the hypothesis can be considered proven in the original prescription-only business model.
    - The situation is not so clear in the generic prescription only (GRX) model. Here, the significance of the preclinical phase as a whole is smaller, so the various resource-management solutions are not so strongly "polarised" into relevant and irrelevant groups, either. According to the results of the interviews, process chemistry, which uses scientific and technological solutions, plays a more important role than work organisation solutions, but on that basis, the hypothesis is only partially supported by the evidence in the generic prescription only model. Further interviews may be required to achieve a firmer result.
- Hypothesis H2, namely that "*In the clinical phase of the value chains, the perceived relevance of scientific and technological solutions decreases while that of work organisation solutions and business tools increases."* seems to be substantiated rather than falsified:
    - In the original prescription only (ORX) model, work organisation methods clearly become important in the clinical phase, with scientific and technological solutions

occurring embedded in them. Among business tools, strategic pricing and project management are exceptionally important in that phase, which supports the hypothesis.

  - In the generic prescription only (GRX) model, the hypothesis can be formally accepted on the basis of the overall view furnished by the interviews: the role of work organisation solutions does become more important in this model, too, while scientific and technological solutions barely play a role at all in that phase. However, when interpreting the results it must be borne in mind that in the case of equivalent generics, the clinical phase is severely limited, so the results primarily have explanatory power in the cases involving non-bioequivalent or biosimilar drugs.

- According to hypothesis H3: "*After going to market, business tools assume the dominant role in both value chains.*" This was only partially substantiated. It would be more apt to reformulate the hypothesis as follows:
  - After going to market, the perceived relevance of work organisation models does not decrease in the original prescription only (ORX) business model, while that of business tools increases, but even so, in relation to the entire ORX value chain, the significance of efficiency-increasing measures taken in the phases after access to market falls behind that of the scientific and technological solutions and work organisation solutions applied prior to access to market.
  - In the generic prescription only (GRX) business model, the role of business tools is more significant overall, but they cannot be said to have a definitive role relative to work organisation solutions, the more likely situation is that they only play a supplementary and supporting role.
- Hypothesis H4: "*In the generic prescription only (GRX) business model, the perceived relevance of business tools lags behind that of scientific and technological solutions and work organisation solutions to a lesser extent than in the original prescription only (ORX) model.*" seems to be clearly correct. The reason for that is presumably that in the price-driven generic markets, the efficiency of daily operation needs to have special attention devoted to it, while the path dependence that characterises the original prescription model is not so dominant there. Still, it must be emphasised that strategic pricing – as a business tool – has greater perceived relevance in the ORX than in the GRX model, which can be regarded as an exception that proves the rule. In fact, overall, strategic pricing seems to be a technique that needs to be treated separately in all significant respects.

- Finally, hypothesis H5, which states that "*Resource management after the product is placed in the market is more significant in the generic prescription only (GRX) business model than in the original prescription only (ORX) model.*" can also be said to have been substantiated on the basis of the above. Still, the results of the research suggest that the truth of the hypothesis is already inherent in the previous hypotheses, so it is somewhat questionable whether this can be considered an independent hypothesis.

The results of the present study suggest that the significance of resource management is increasing in the pharmaceutical industry, and in this traditionally technology-driven industry, the work organisation solutions and business tools that are based on the characteristics of the market are coming to the fore. To a great extent, market constraints in the original prescription only and generic prescription only business models that I have examined are represented by the requirements of the financers, with the competition between substitutable preparations being an added element in the case of generics. All of that makes it probable and necessary that in the future, we shall have to deal more intensely with resource management – the optimal allocation of available resources and the improvement of efficiency – in the pharmaceutical industry.

My research was suitable for demonstrating the specific techniques that can be used along the original prescription only and the generic prescription only value chains in order to improve the efficiency of the allocation of resources within organisations. In that respect, I trust that the survey I conducted – despite the limitations of the methodology based on the 14 in-depth interviews and secondary sources that came to light during the research – approximated a comprehensive view and identified and classified the available techniques correctly. It is obvious, however, that this approach – which examined two segments of the pharmaceutical industry each of which is quite massive, and did so along the entire length of the value chains – is not suitable for an in-depth analysis of the limits and characteristics of application of the individual techniques. It is also clear that the interpretation and evaluation of relevance was not an easily comprehended task for the specialists I questioned, particularly within the framework of one-hour interviews and with the added complication that the terminology that was easily comprehensible and trivial for me (management jargon) required interpretation for them.

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