REVIEW

Contemporary Aspects of Marketing in Clinical Trials Including Segments of IT and Technology Transfer

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ABSTRACT

Introduction: The aim of this paper is to present the marketing strategy and the application of management (marketing management) and advertising in order to increase the efficiency of innovative approach in clinical trials that include and involve the use of new technologies and transfer of technologies. **Material and Methods:** This paper has a descriptive character and represents a narrative review of the literature and new model implementation. **Results:** Marketing models are primarily used to improve the inclusion of a larger (and appropriate) number of patients, but they can be credited for the stay and monitoring of patients in the trial. Regulatory mechanisms play an important role in the application of various marketing strategies within clinical trials. The value for the patient as the most important stakeholder is defined in the field of clinical trials according to Kotler's value model for the consumer. **Conclusion:** In order to achieve the best results it is important to adequately examine all the elements of clinical trials and apply this knowledge in creation of a marketing plan that will be made in accordance with the legal regulations defined globally and locally. In this paper, two challenges have been highlighted for the adequate application of marketing tools in the field of clinical trials, namely: defining business elements in order to provide an adequate marketing approach for clinical trials and technology transfer and ensuring uniformity and regulatory affirmation of marketing attitudes in clinical trials in all regions in which they are carried out in accordance with ICH-GCP and valid regulations.

Keywords: marketing, management, IT, clinical trials, advertising, patients.

1. INTRODUCTION

Marketing as a science studies human and social needs. One of the shortest definitions of marketing states that it is a profitable satisfaction of needs (1).

International marketing is the identification of the needs and wishes of consumers, the provision of products and services that will enable the company to have a different marketing advantage, transfer of information about these products and services, their international distribution and exchange through one or a combination of inputs to the foreign market, and it is an international marketing process in which individuals and companies (1):

- Identify the needs and wishes of consumers in different international markets.
- Provide competitive products, services and ideas to satisfy the needs and desires of different consumer groups.
- Transmit information about products and services.
- Deliver products or services using one or more modes of entry to the international market.

The development of science also stimulates the development of the economy, and in this case it also increases the level of health care by always finding new solutions for existing diseases (whether it is medicines, medical devices or therapeutic procedures).

The characteristic of marketing processes in clinical trials is their developed ethical component. Namely, the regulatory authorities have very strictly defined segments that can be subject to marketing activities, which in that way do not violate any of the ethical principles, while on the other hand, they become an advantage for the Orderer of the clinical trials. One of the problems is the lack of synchronization in the approach to the use of marketing in clinical trials, so there are countries that have enabled marketing activities (ad-

vertising) to be implemented, while in other countries this is not the case. Examples are Republic of Serbia and Bosnia and Herzegovina, which under the Law on medicines and medical devices prevents advertising of clinical trials in order to attract and maintain the number of active-participating patients.

2. AIM

The aim of this paper is to present the marketing strategy and the application of management (marketing management) and advertising in order to increase the efficiency of innovative approach in clinical trials that include and involve the use of new technologies and transfer of technologies.

3. MATERIAL AND METHODS

This paper has a descriptive character and represents a narrative review of the literature and new model development.

4. RESULTS

Clinical trial of the medicinal product is a human trial aimed for establishing or confirming the clinical, pharmacological, pharmacodynamic effects of one or more investigational medicinal products, identifying any adverse reaction to one or more investigational medicinal products, in order to investigate the resorption, distribution, metabolism and excretion of one or more investigational medicinal products, as well as determining the safety or effectiveness of the investigational medicinal products.

World Health Organization defines clinical trial as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. There is a large number of regulations, which regulate the procedure of clinical trials and their marketing activities. In some countries, such as the Republic of Serbia and Bosnia and Herzegovina, marketing activities in the field of clinical trials are not allowed.

4.1. Defining specific business elements to enable an adequate marketing approach

Due to the specificity of business in the field of clinical trials, it is necessary to define elements of business in order to provide an adequate marketing approach and make a marketing plan. A clinical trial is one cost-expensive, long, segmented process with uncertain results (it is not known whether the drug will confirm its healing effect and to what extent upon completion of research).

The role of marketing within clinical trials mainly concentrates on the concept of attracting new patients, but also their stay in the study. Such concept must fully comply with the highest ethical standards and applicable international and local regulations.

Also, marketing activities can be activated within the business development sector as through adequate company marketing and promotional activities results are achieved in the form of new projects, partners, vendors etc. In both cases, the greatest share of marketing is within the activities of advertising and promotion.

The specificities of doing business in clinical trials are recognizable because they are actually global projects that are carried out during the product research phase but have the majority of marketing segments of the placement of the finished product. Dichotomy in the conclusion of the differences in forms of business leads to more difficult use of marketing tools whose effectiveness is proven by practice.

The share of this complexity has the use of new technologies which is also necessary to formulate in some processes of marketing activities. From the organizational point of view, it is important for new technologies to have experts who have sufficient knowledge to work on such processes, and such form of "attracting" experts is a special branch of the marketing plan and the creation of a specific marketing strategy for their allocation (1).

Marketing activities related to self-management in patients such as the promotion of negative behavior in terms of obesity, smoking, alcohol abuse, etc. show great significance (2).

4.2. Uniformity and regulatory affirmation of marketing approaches in clinical trials

As noted earlier, in some countries (such as Serbia and Bosnia and Herzegovina) there is no legal possibility to advertise or use other marketing strategies that would allow for more efficient implementation of clinical trials. The Ministry of Health and the Regulatory Authority of the United Kingdom has defined very precisely what requirements are placed in front of the advertising team for clinical trials. The most important items are the long periods of analysis, based on which certain statements can be placed in the function of advertising but also prevent the transmission of obscure and altered messages to the recipient of the information. In the world, advertising (and other marketing strategies) has been put into the function of the effectiveness of participation of all participants and stakeholders.

4.3. Proposal of marketing access in clinical trials in conjunction with other industries (based on the customer-perceived value (CPV))

a) Standard marketing approach in other industries

Transaction marketing is part of a larger term called a relationship marketing that aims to develop long-term satisfactory relationships with key stakeholders - customers, suppliers, distributors, all in order to earn and retain their long-term business characteristics (3).

In terms of marketing, the product or offering will be successful if it delivers value and satisfaction to the target buyer. The buyer chooses between different offerings on the basis of which is perceived to deliver the most value. We define value as a ratio between what the customer gets and gives. The customer gets benefits and assumes costs, as shown in this equation:

$$Value = \frac{Benefits}{Costs} = \frac{Functional\ benefits + emotional\ benefits}{Monetary\ costs + time\ costs + energy\ costs + psychic\ costs}$$

Equation 1. Calculation of value according to P. Kotler (3)

Functional benefits are based on a product attribute that provides the customer with functional utility. One of the examples of functional benefit is when you buy a new car, you don't have to buy a new one for next few years.

Regarding emotional benefit - the science of psychology has always dealt with the relationship between the mind or the intellect from one and the emotional structure on the other side. As marketing is a science that responds to the needs of people/users, emotional marketing is also defined

accordingly, but there is an emotional value that the user receives with the purchased product or service. These are two separate segments, but they deal with the same element of humanity - emotion. With regard to the emotional marketing, an important aspect of this area is the brand recognition (4, 5).

Monetary cost encompasses the literal cost incurred by a customer in order to obtain the product or service (including the transfer of certain product, assembly etc.) (3). **Time cost** is the total amount of time that has been invested by a customer during his buying process (3, 4). **Energy cost** refers to the energy spent by the buyer during the entire process of buying the product (3). **Psychic costs** relate to the costs of stress when making purchasing decisions. Psychic costs are purely psychological and should not be confused with other costs which are more tangible such as search costs and switching costs. Search costs relate to the amount of time that a purchaser might spend in searching for perhaps a lower cost option and switching costs relate to the amount of time moving from one provider of education interventions - perhaps an online portfolio - to another (6).

Based on Equation 1, the marketer can increase the value of the customer offering by (a) raising benefits, (b) reducing costs, (c) raising benefits and reducing costs, (d) raising benefits by more than the raise in costs, or (e) lowering benefits by less than the reduction in costs.

b) Proposal of marketing approach in the field of clinical trials

In the field of clinical trials circumstances are specific in comparison to other industries that sell finished products or services. What is consistent is that it is a global business, which has its initiators, its financiers, hence - its budget. But clinical trials do not have a characteristic supplier, because they do not "work" with finished products. However, in clinical trials, services are distributed, not only the tested product. Also, it is certain that particular distributors are involved, but also under the suppliers we can include specific production units of the tested substance (their number, quantity, cooperation are in specific frames because it is a product that is still in the testing phase). Then, in clinical trials, the buyer does not exist as such, but there is an end user of the test product - the patient. Furthermore, the price component of the product must be completely excluded because at the stage of development, a non-final product cannot be sold before it receives all the relevant test certificates and regulatory approval for the post-marketing study. But, the price of the service for some other stakeholders is very precisely defined at this stage of drug testing (Sponsors, contract research organizations, etc.). In clinical trials, the value for the stakeholder - patient is reflected in the benefit/cost ratio as well as in the standard Kotler model (Equation 1). The **functional benefit** of the patient is certainly the cure of the disease, but also the number of visits to the clinic during clinical trials, the quality of treatment, the side effects that the therapy brings with it, etc (3).

Emotional benefit refers to stress that is generated by the expectation of a positive treatment effect. It is important to note that in a large number of clinical trials, placebo is also applied according to the predefined study design and the number of treatment arms, and accordingly, the patient may have up to 50% chance of receiving placebo instead of the expected drug for a particular therapeutic indication. This can negatively affect the emotional benefit in the end. However, the apparent increase in quality of life (in some indications quickly noticeable) will certainly have a positive affect on the emotional benefit and thus increase the overall benefit per patient (3).

The **monetary cost** is excluded in clinical trials because the patient does not pay the treatment and has voluntarily accepted the use of the test substance although there are certain risks as the final results of the trial will not be known until the end (with exception of certain designs of Phase I clinical trials). Accordingly, the value of monetary cost in the Kotler formula can be defined as "0", therefore, it can be excluded.

The **time cost** for the patient is of great importance. Examples that clearly show this are the number of patient visits– the response will be significantly greater if the patient needs to come on visits less frequently. Also the response depends on e.g. the number of injections that patient has to receive (it is not the same if the patient has to be administered with 1 or with 10 injections). Additionally, the number of procedures that the patient needs to pass has a great affect, and also the degree of their invasiveness (it is not the same whether the patient will perform gastroscopy once every two years or once in 3 months), etc. The **energy cost** is difficult to calculate, but it should not be too influential for the patient. The patient should be in a hospital in which he or she is normally treated, with the medical team in charge. The length of the trip to the hospital is individual characteristic, but again - it should not be too affective. The final result is under question while the trial is in progress, but the patient can see a benefit in certain indications that could be characterized as completed in some cases shortly after administration of the drug. If the treatment is unsuccessful, then the energy cost would have a negative sign. Accordingly, it is suggested that, in case of a positive effect of the drug (proven by the medical team on the control examinations), the coefficient "+1" is defined, whereas in the negative (or unsuccessful treatment of the test substance) the prefix of the coefficient would be "-" , therefore it would be recorded as "-1". A similar approach is also proposed for psychic cost, so if there is a positive effect on the quality of life (the assumption is that the patient's stress decreases), it defines the coefficient "+1", while in the event of a negative action on the quality of life it defines a coefficient with a negative sign -"-1" (3).

In accordance with the above, if the variable parameters of the Kotler formula would have been defined as (3):

- **N1–functional benefit**
- **N2–emotional benefit**
- **N3–monetary cost**
- **N4–time cost**
- **N5–energy cost–coefficient +/-1 (depending on the effect of treatment on the patient)**
- **N6–psychic cost–coefficient +/-1 (depending on the effect of treatment on the patient),**

$$Value = \frac{Benefits}{Costs} = \frac{N1 + N2}{N4 \times (+/-1) \times (+/-1)}$$

Equation 2. Calculation of value in a clinical trial

The formula of value and satisfaction in a clinical trial (observed in relation to a patient as a user and stakeholder) would be defined as:

If the value of N1 + N2> 0, it is possible to calculate the value. If the N1 + N2 = 0, the whole fraction is equal to 0. If the N1 + N2 <0, then the solution would have a negative sign.

The overall sign of the fraction depends on the sign of N5 and N6, and the numerator and therefore the ratio of benefit and cost, or the observed value.

4.4. The role of marketing

The successful execution of a clinical trial means the project is finished on time, on budget, and has a high level of quality (7). These objectives should be clearly defined before initiating any project. In clinical trials, human and technology transfers represent a significant aspect. Through a training process carried out in institutions where clinical trials are conducted, doctors, as well as interdisciplinary teams, become acquainted with the technology and know-how of the use of a particular medicine, its effect, the operation of a particular therapeutic procedure or medical device. Through this path, they become involved in the latest international research that represent the top of medical scientific activity (8, 9). Later, researchers are trying to implement the standards and protocols they learned during clinical trials on regular work in their hospitals. In industrialized countries there is control over international technology transfer or costs for such transfers, and this is the case where international technology sales can cause major social costs/impacts, while attitudes in developing countries are different as they are mainly buyers rather than sellers of high technologies (they want to ensure that import technology meets their needs–smaller scope and labor-intensive technology) (10). Organizations of sites that focus on performing clinical trials significantly outperform those that mix trial activity with the provision of traditional patient care.

The patient is in focus of the clinical trial and therefore is the most important stakeholder. The overall marketing strategy is defined on the basis of the patient's value (as suggested in the previous text). At the center of the marketing strategy developed to increase the number of recruited patients - is patient and patients needs.

On the other hand, it is important to keep the patient within the clinical trial by clarifying certain preferences that would represent a benefit for the patient, or using a value analysis for the user according to the Kotler formula. In the media, on the websites oriented to medicine and pharmacy, legal regulations, patient associations, and others, you can find information on the performance of clinical trials, their development, success, length of duration, indication, etc. Patient representation is a very important area that has recently been taken over by non-governmental organizations such as European Patients' Academy (EUPATI), who are actively working on providing additional information to patients and their increased awareness of newly-initiated clinical trials that would help them to find an adequate drug.

5. CONCLUSION

This paper confirms the importance of marketing for clinical trials, but also defines a marketing approach based on Kotler's value model for users. An adapted model like this can be applied to marketing directed to all stakeholders, of which the patients are most important. The transfer of technology and the importance of using an adequate marketing strategy for the IT domain is defined. In order to achieve the best results it is important to adequately examine all the elements of clinical trials and apply this knowledge in the creation of a marketing plan that will be made in accordance with the legal regulations defined globally and locally. In this paper, two challenges have been highlighted for the adequate application of marketing tools in the field of clinical trials, namely: defining business elements in order to provide an adequate marketing approach and ensuring uniformity and regulatory affirmation of marketing attitudes in clinical trials in all regions in which they are carried out in accordance with ICH-GCP and valid regulations. Aspects of marketing management are defined in this paper as well as their use within clinical trials.

• **Conflict of interest:** none declared.

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