



## **Botulinum toxin industry – is it a profitable industry to enter?**

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"This thesis was written as a part of the master program at NHH. Neither the institution, the advisor, nor the censors are - through the approval of this thesis - responsible for neither the theories and methods used, nor results and conclusions drawn in this work."

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## List of abbreviations

ASAPS = American Association of aesthetic plastic surgeries  
BTX = botulinum toxin  
BTX-A ..F = botulinum toxin type A... F  
FDA = Food and Drug Association  
OTC = Over the counter  
R&D =Research and development

**Abstract**

This paper examines the botulinum toxin industry and is it profitable to enter. In particular, the paper aims to define whether the industry structure is attractive because an industry is considered profitable only if it has attractive structure. This has been explored through applying the Porter's five forces framework which provides a good understanding of farces shaping the industry and thus help to define the industry structure. It has been shown that the BTX industry has been characterized by relatively strong rivalry, moderate threat of new entrance, threat of substitutes and the power of buyers and low power of supplies. This structure determines the industry as an attractive one and thus is assumed to be a profitable to enter.

## **Preface**

When choosing the topic for my thesis, my first criterion was to write about an issue that I am interested in. While reading everyday's newspapers, I was amazed by the growing influence and power of the botulinum toxin industry in the cosmetic and medical use worldwide. Botulinum toxin is used in cosmetics to stop aging process and for this reason it became very popular, especially in more affluent societies. In order to learn more about the issue, I did a preliminary research of the market and found an interesting strategy case to be analyzed which triggered my interest further.

Beside the interesting strategic case to evaluate, I chose to focus on this topic also for one more reason. This thesis aims to help a potential new entrant that is considering entering the botulinum toxin market. It is an interesting example of how already dominated; high entry and high growth markets could be evaluated and hence approached by new entrants.

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## **INTRODUCTION**

Botulinum toxin has become widely known and gained a lot of attention in the public, mostly in respect to its use in cosmetics. In cosmetic treatments it is used to correct wrinkles and frown lines. The desire to look beautiful and young among older age groups is increasing along with the public approval of cosmetic treatments rising the awareness and the demand for the cosmetic botulinum toxin treatments. However, the toxin is less known for its multiple therapeutic uses where it has been used to help patients that suffer from strabismus, blepharospasm, dystonia or other movement nerve-related disorders. Its therapeutic use also has been constantly increasing over the past couple of decades and it is assumed that new applications will continue to evolve. Overall, botulinum toxin market is assumed to grow in two digit percent.

The most known botulinum toxin product is Botox® produced by Allergan. Being present for twenty years and having approximately 85% of the market, Botox® achieved such a strong positioning that the whole botulinum toxin industry is often labeled as botox. Except for Allergan, there are a several other market players present: Ipsen, Medytox, Merz Pharmaceuticals, Mentor corporation and Solstice Neuroscience. The rest of the market is split among them.

### **Problem to be addressed**

Given the fact that the botulinum toxin industry is a high growth industry makes it an attractive opportunity to enter. However, the botulinum toxin market, as each pharmaceutical branch, is expected to have high entry barriers such as high R&D investments, high patent cost, long time of clinical testing and regulative approvals of the drug use. Thus, having in mind high entry barriers, attractive growth and one strong player dominating the market, a question arises:

**Botulinum toxin industry – is it a profitable industry to enter?**

According to Porter, “an industry is profitable only if its structure is attractive”.<sup>1</sup> Therefore, the purpose of the paper will be to analyze the structure of the BTX industry. To define the structure of the industry the Porter’s five forces model will be used. Major reason for choosing particularly this model is that it helps in evaluating strength of competition in an industry by looking at five different forces. The model will aim to determine whether the forces are intense and how the five forces shape the botulinum toxin industry. Therefore, the paper will also try to answer following questions:

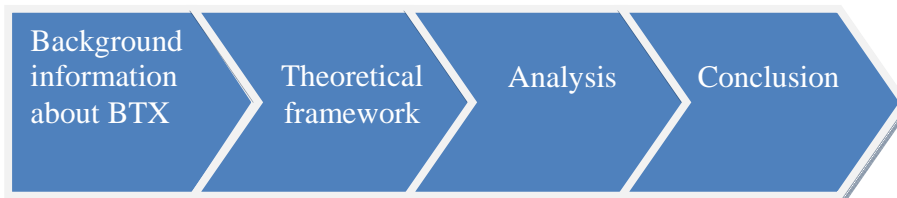
- What are the main threats to a new entrant?
- Where do opportunities for a new entrant lie?

My findings indicate that the industry has an attractive structure and hence should be profitable to enter.

### **The structure of the paper**

The structure of the paper consists of five main chapters. The first chapter will discuss the methods used to obtain data. The second chapter will try to describe what botulinum toxin is and where and how it is used. The third chapter presents the theoretical background for the analysis conducted in the fourth chapter. Therefore, in order to evaluate whether the industry is attractive to enter, the Porter’s five forces framework will be applied. Thereafter, the qualitative analysis of the case will be done in the fourth chapter which is also the most important chapter. The fifth chapter will present the main conclusions drawn from the previous chapter and the recommendations for a new entrant.

**Figure 1. Structure of the thesis**



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<sup>1</sup> Porter, M.E. (2008) The five competitive forces that shape strategy, Harvard Business Review, January, pg. 47

# 1. METHODS USED TO OBTAIN DATA/RESEARCH DESIGN

The purpose of this chapter is to give an overview of the research methods used to obtain data for this thesis. To answer the research questions of the thesis, a qualitative research will be conducted. The qualitative research is suitable for this particular problem because “qualitative is a synonym for any data collection technique or data analysis procedure that generates or use non-numerical data”<sup>2</sup>. The thesis will be built on the case study research strategy since “case study examines a phenomenon in its natural setting, employing multiple methods of data collection to gather information from one or a few entities (people, groups, or organizations.)”<sup>3</sup>. The data collection method used will be a document analysis that will embrace different official and public publications (i.e. secondary data) and desk research. Desk research involves collecting (secondary) data that already exists either from internal sources, publications of governmental and non-governmental institutions, free access data on the internet, in professional newspapers and magazines, in annual reports of companies and commercial databases.<sup>4</sup> The findings will be analyzed through a model acquired from strategic management literature, the Porter’s five forces framework.

Secondary data was collected through several sources. First, the background information was gathered through newspapers and articles. News sources include reputed publications like Reuters, and Medicalnewstoday.com. Second, companies’ annual reports, 10-K reports, press releases and web pages were used to obtain company- and product-specific information. The largest part of secondary data came from this source. The companies whose data was investigated include: Allergan, Ipsen, Medy-tox, Merz Pharmaceuticals, Mentor corporation and Solstice Neuroscience. Third, institutional publications or announcements such as those from FDA, American society for Aesthetic Plastic Surgery

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<sup>2</sup> Saunders, M., Lewis, P., and Thornhill A., (2007). Research methods for business students, 4th edition, Pearson Education Limited, Harlow, UK, Financial Times Prentice Hall, pg. 139

<sup>3</sup> Benbast, I., Goldstein, D.K., Mead, M. (1987) The case research strategy in studies of information systems, MIS quaterly, Vol. 11, No 3

<sup>4</sup> Wikipedia, the free encyclopedia, [http://en.wikipedia.org/wiki/Desk\\_research](http://en.wikipedia.org/wiki/Desk_research); 16.12.2009.



or Dystonia foundation were used to fill in the gaps with regards to the industry dynamics. Additionally, other sources, such as customer forums or social networking sites, were used in order to gather wider perspective of the topic and in order to provide the author with another perspective of discussed topic.

In order to better illustrate elements influencing the Porter's five forces of the BTX industry a subjective evaluation was used. The evaluation was conducted based on the information obtained and on author's personal knowledge and interpretation. A scale used in the evaluation was one to five (1-5). One was determined as the low influence, for example; since there are hardly any suppliers, their power is evaluated as one (1). On the other hand, a strong and affluent driver was rated as five (5). Furthermore, if a driver is strong but not heavily expressed, it was evaluated as four (4). For example, all manufacturers clearly emphasize their strong commitment to the industry and hence the element is ranked as five (5). Price competition although existing, is not so strong as competitors also focus to compete on other dimensions and hence is ranked as four (4).

Literature overview was built on the several academic publications. Strategic books such as Hitt, Ireland & Hokisson, Porter and Peng, were used and supplemented with strategic journal articles like Porter, Schofield and Markovitz. Research publication on pharmacy and botulinum toxin like Jankovic, Hamdy et al., Dressler & Saberi were also used to provide the author with more insight of the industry, surrounding challenges, and observations about particular cases.

## 2. PRESENTATION OF BOTULINUM TOXIN

In order to provide a reader with better understanding of the BTX industry some main and basic information defining what botulinum toxin is, how and where is used and also how it works will be given in this section.

Botulinum toxin (BT) is a fermentation product of the anaerobic spore-forming bacterium *Clostridium botulinum*.<sup>5</sup> Botulinum toxin is a neurotoxin known as the most poisonous biological substance.<sup>6</sup> There are seven stereotypes of botulinum neurotoxins: A,B,C1, D,E,F and G.<sup>7</sup> Although all of them inhibit acetylcholine release from nerve terminals, but they considerably differ in their intracellular target proteins, characteristics of action and potencies.<sup>8</sup> For example, application of BTX-A has a duration of 4-6 month, while the BTX-F will create an effect that will last only for 3 weeks.<sup>9</sup> The toxin consists of a complex mixture of proteins containing botulinum neurotoxin and different non-toxin proteins.<sup>10</sup>

The toxin operates through binding to the nerve ending at the point where the nerve joins a muscle. It blocks the release of the chemical acetylcholine (the principal neurotransmitter at the neuromuscular junction) which is required for muscle contraction. The immediate result is weakness and paralysis of the muscle, while over time and the muscle atrophies. The blockage of acetylcholine release is irreversible. The function can

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<sup>5</sup> Hamdy R.C., Montpetit K., Ruck-Gibs J., Thorstad K., Raney E., Aiona M., Platt R., Finley A., Mackenzie W., McCarthy J., Narayanan U., (2007). Safety and efficacy of botox injection in alleviating post-operative pain and improving quality of life in lower extremity limb lengthening and deformity correction, *Trials*, 8:27, [www.trialsjournal.com/content/8/1/27](http://www.trialsjournal.com/content/8/1/27)

<sup>6</sup> MedicineNet, Definition of botulinum toxin, <http://www.medterms.com/script/main/art.asp?articlekey=25769>; 25.08.2008

<sup>7</sup> Hamdy R.C., Montpetit K., Ruck-Gibs J., Thorstad K., Raney E., Aiona M., Platt R., Finley A., Mackenzie W., McCarthy J., Narayanan U., (2007). Safety and efficacy of botox injection in alleviating post-operative pain and improving quality of life in lower extremity limb lengthening and deformity correction, *Trials*, 8:27, [www.trialsjournal.com/content/8/1/27](http://www.trialsjournal.com/content/8/1/27)

<sup>8</sup> Dressler,D., Saberi, F.A., (2005) Botulinum toxin: Mechanisms of Action, *European Neurology*; 53,1, ProQuest Medical Library

<sup>9</sup> Borodic G., Johnson, E., Goodnough, M., Schantz, E., (1996). Botulinum toxin therapy, immunologic resistance and problems with available materials. *Neurology* 46:26-29

<sup>10</sup> Dressler,D., Saberi, F.A., (2005) Botulinum toxin: Mechanisms of Action, *European Neurology*; 53,1, ProQuest Medical Library

be recovered by the development of nerve terminals and the formation of new synaptic contacts, which usually takes 2 to 3 months.<sup>11</sup>

Botulinum toxin, although a poison, it has been used in the medical and cosmetic use for more than two decades. For example, BTX-A has been used as a therapeutic agent since the late 70s and has under medical supervision shown to be a safe drug. Types A and B are the only serotypes used in clinical practice.<sup>12</sup>

The potential for the toxins therapeutic use was recognized as far back as in 1817 by Justin Kerner who recognized that the toxin paralyzed skeletal muscles and parasympathetic function. However, FDA first time approved BTX for its therapeutic use in 1989 which included the use of the toxin as a cure in strabismus, blepharospasm, and other facial nerve disorders. Today, the toxin's clinical applications embrace dystonia and related movement disorders, spasticity and other hypertonic disorders, muscle spasm and other painful disorder including headaches, disorders of autonomic nervous system, nystagmus, palatal myoclonus and stridor.<sup>13</sup> The use of BTX is expanding constantly as new therapeutic applications are being discovered.

More interest in BTX is caused by its cosmetic and dermatological application. The cosmetic use of BTX applies to the correction of wrinkles and frown lines. BTX is used to smooth frown and wrinkle lines of the forehead, glabella and lateral periorbital area. The paralysis of the area under treatment should usually last approximately 4-6 months, eliminating completely the frown and wrinkle lines. Since the botulinum toxin spreads easily, the BTX cosmetic treatment actually aims only at weakening the muscle and not total paralysis.<sup>14</sup>

The adverse effects of using the botulinum toxin can be divided in short and long term complications. Diffusion of the toxin, causing an undesirable spread away from the

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<sup>11</sup> MedicineNet, Definition of botulinum toxin, <http://www.medterms.com/script/main/art.asp?articlekey=25769>; 25.08.2008

<sup>12</sup> Hamdy R.C., Montpetit K., Ruck-Gibs J., Thorstad K., Raney E., Aiona M., Platt R., Finley A., Mackenzie W., McCarthy J., Narayanan U., (2007). Safety and efficacy of botox injection in alleviating post-operative pain and improving quality of life in lower extremity limb lengthening and deformity correction, *Trials*, 8:27, [www.trialsjournal.com/content/8/1/27](http://www.trialsjournal.com/content/8/1/27)

<sup>13</sup> Jankovic, J. (2004) Botulinum toxin in clinical practice, *Journal of Neurology, Neurosurgery & Psychiatry* 2004, 74: 951-957. Downloaded from [jnnp.bmj.com](http://jnnp.bmj.com) on Nov 13<sup>th</sup> 2009

<sup>14</sup> Benedetto, A.V., (1999) The cosmetic uses of botulinum toxin type A, *International journal of dermatology*, 38, 641-655

injection point is considered a short term complication. Immunologic resistance is a major long term complication.<sup>15</sup> The immunologic resistance to BTX occurs after repeated use (medical and cosmetic treatments) and/or where patients received high doses (which is usually the case in medical treatments). The resistance to the BTX therapy is related to the development of neutralizing antibodies. Klein states that the incidence of clinical resistance to the BTX treatment in the cervical dystonia has been approximated to 6,5%. Other complications connected to the use of the BTXs are also ptosis, tearing, vertical deviations and dry eyes.<sup>16</sup> Adverse effects of use of BTX are more serious among medical use than in the cosmetic treatments. This was also confirmed by Cote et al. whose study showed that in the period December 2001 to November 2002, the proportion of reports classified as serious was 33-fold higher for therapeutic than for cosmetic cases.<sup>17</sup> Cote et al. concluded in their study that this may be related to higher doses, complicated underlying diseases, or both.<sup>18</sup>

**Figure 2. Before and after the BTX cosmetic treatment.**



Source: [http://www.baltimore-eyecare.com/the-expert-opinion/uploaded\\_images/botox\\_ba\\_1-755060.gif](http://www.baltimore-eyecare.com/the-expert-opinion/uploaded_images/botox_ba_1-755060.gif) ; 16.12.2009.

<sup>15</sup> Borodic G., Johnson, E., Goodnough, M., Schantz, E., (1996). Botulinum toxin therapy, immunologic resistance and problems with available materials. *Neurology* 46:26-29

<sup>16</sup> Klein, A.W., (2001) Complications and adverse reactions with the use of botulinum toxin, *Seminars in cutaneous medicine and surgery*, vol 20, No 2: pp 109-120

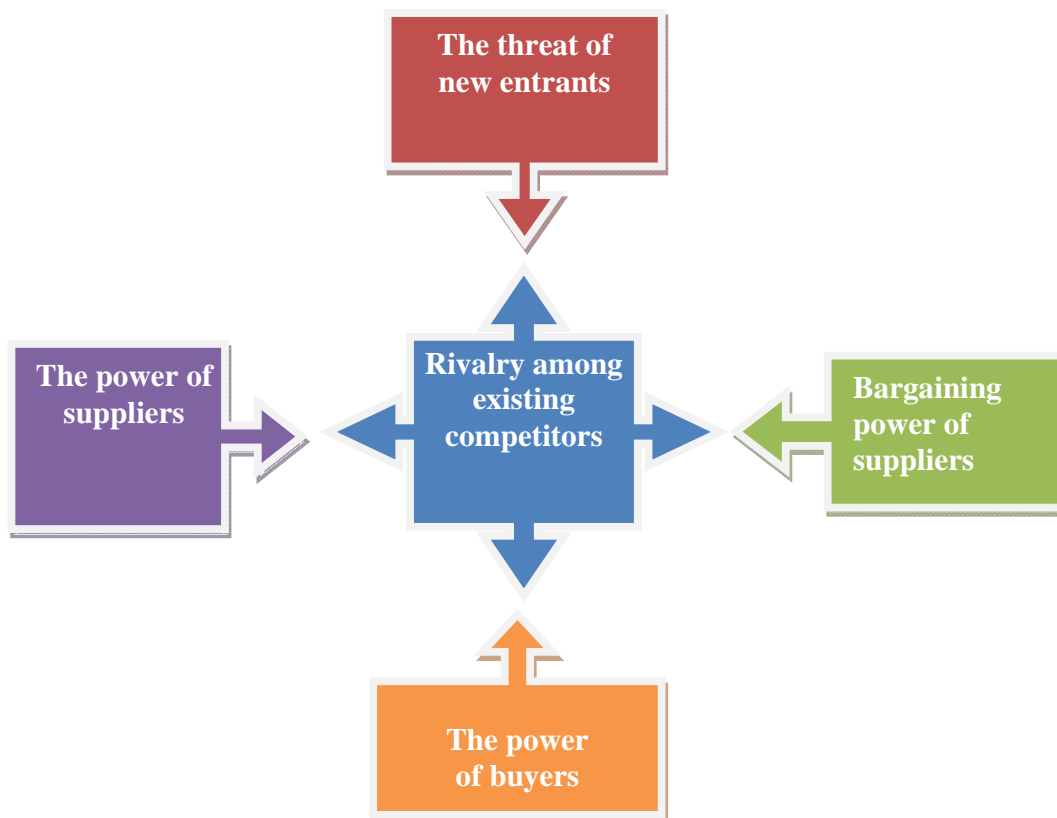
<sup>17</sup> The 217 serious adverse events (AE) reported in therapeutic cases involved a wide spectrum of events and included all 28 reported deaths. Among cosmetic users, no deaths were reported and, of the 36 serious AEs, 30 were included as possible complications in the FDA-approved label.

<sup>18</sup> Coté, T.R., Mohan A.K., Polder J.A., Walton M.K., Braun M.M. (2005) Botulinum toxin type A injections: adverse events reported to the US Food and Drug Administration in therapeutic and cosmetic cases. *Journal of American Academy of Dermatology*. Sep;53(3):407-15

### 3. PORTER'S FIVE FORCES - THEORETICAL FRAMEWORK

One of the most accepted theories on competition and strategy is Porter's five forces analysis. This analysis became widely accepted because it broadens the “old” competition concept. Usually the competition analysis embraces the companies that offer a competitive product or service. However, Porter conjoined four additional forces (threat of new entrants, threat of substitutes, bargaining power of buyers, and bargaining power of suppliers) to the rivalry among existing competitors, stating that all five of them together determine an industry’s attractiveness and competitive position.<sup>19</sup> The stronger the forces are, the more difficult it is to earn returns on investment, making the industry less attractive to new entrants (and vice versa).<sup>20</sup>

**Figure 3. The Porter’s five forces framework**



<sup>19</sup> Porter, Michael E. (2008) *On Competition*, Updated and expanded Edition, A Harvard Business Review Book

<sup>20</sup> Porter, M.E. (2008) The five competitive forces that shape strategy, Harvard Business Review, January

## The threat of new entrants

The threat of a new entrant in an industry is relevant since an entrant seeks to capture market share.<sup>21</sup> Porter determined the threat of a new entrant by the entry barriers and by the incumbents' reaction to the entry. Entry barriers include: economies of scale, product differentiation that is related to customer loyalty, capital requirements, switching costs, access to distribution channels, cost disadvantage independent of scale and government policy.<sup>22</sup> When producing on a large scale, the unit costs decline. This can apply not only to the production but also to the R&D, marketing and other value chain activities. Entering a new industry requires resources not only to finance new facilities, inventories, marketing, R&D and other business activities, but also to gain the access to the distribution channels that existing competitors already have developed.<sup>23</sup> Knowledge, expertise and patent ownership are also forms of entry barriers. Long experience in an industry and knowledge accumulated over the years may pose a high entry barrier, as it can be very difficult for an entrant to copy and gain the necessary experience in a short time.<sup>24</sup> High switching cost will discourage a new entrant. Switching costs are costs that customers bear when they purchase from another producer and in some cases they may be time dependant i.e. lower at the beginning of the customer lifecycle and rising towards the later stages of the cycle. On the other hand, retaliation from incumbents may additionally prevent new entrants. Vigorous retaliation can be expected from a company that holds a great stake of a market<sup>25</sup> but also if the incumbent has resources to fight back and has previously responded vigorously to the newcomers.<sup>26</sup> However, finding a market niche that is not covered by incumbents may be an opportunity for a new entrant. Hitt et

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<sup>21</sup> Porter, M.E. (2008) The five competitive forces that shape strategy, Harvard Business Review, January

<sup>22</sup> Hitt, M., A., Ireland, R., D., and Hoskisson, R., E. (2005) *Strategic Management Competitiveness and Globalization*, Concept and Cases, International Student Edition, 6<sup>th</sup> edition, South-Western, Thomson Corporation

<sup>23</sup> Porter, Michael E. (2008) *On Competition*, Updated and expanded Edition, A Harvard Business Review Book

<sup>24</sup> Peng, M.W. (2006) *Global Strategy*, International student edition, South-Western, Thomson Corporation

<sup>25</sup> Hitt, M., A., Ireland, R., D., and Hoskisson, R., E. (2005) *Strategic Management Competitiveness and Globalization*, Concept and Cases, International Student Edition, 6<sup>th</sup> edition, South-Western, Thomson Corporation

<sup>26</sup> Porter, Michael E. (2008) *On Competition*, Updated and expanded Edition, A Harvard Business Review Book

al. state that small entrepreneurial firms are usually very skilled at finding these opportunities.<sup>27</sup>

Low entry barriers and low retaliation combined with high profit margins will attract new entrants. It is observed that where the threat is high, incumbents should keep the prices down or encourage investment to inhibit potential competitors from entering the industry.<sup>28</sup> Porter claims that it is the threat of an entry not whether the entry actually occurs, that holds down the profitability.

### Bargaining power of suppliers

Suppliers support a company with the labor, raw materials, equipment, transportation and financial services. These costs influence the company's profitability. If the suppliers are powerful they will charge high prices for their services and hence press profitability out of an industry. A supplier group can embrace power in several ways. Their power is high if the industry is dominated by a few large companies and is more concentrated than the industry to which it sells. Satisfactory substitute products not available to industry firms increase suppliers' power too.<sup>29</sup> Another example is, according to Porter, when firms are not important customers of the supplier group or when suppliers' goods are critical to buyers' success. Porter lists high switching costs of suppliers and highly differentiated services or products offered by the supplier as additional factors that nourish suppliers' power.<sup>30</sup> Contrary, if the bargaining power of suppliers is weak; the company then has more power and therefore may negotiate favorable terms for itself.<sup>31</sup>

In pharmaceutical industry supplier power is also enhanced by strict governmental regulations these suppliers must fulfill in order to be accredited to supply. For example,

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<sup>27</sup> Hitt, M., A., Ireland, R., D., and Hoskisson, R., E. (2005) *Strategic Management Competitiveness and Globalization*, Concept and Cases, International Student Edition, 6<sup>th</sup> edition, South-Western, Thomson Corporation

<sup>28</sup> Porter, Michael E. (2008) *On Competition*, Updated and expanded Edition, A Harvard Business Review Book

<sup>29</sup> Porter, Michael E. (2008) *On Competition*, Updated and expanded Edition, A Harvard Business Review Book

<sup>30</sup> Hitt, M., A., Ireland, R., D., and Hoskisson, R., E. (2005) *Strategic Management Competitiveness and Globalization*, Concept and Cases, International Student Edition, 6<sup>th</sup> edition, South-Western, Thomson Corporation

<sup>31</sup> Peng, M.W. (2006) *Global Strategy*, International student edition, South-Western, Thomson Corporation

in USA the subcontractor is required by FDA to fulfill a variety of legislation.<sup>32</sup> Subcontracting the research and manufacturing activities is especially the case and plays common practice an important role for small and emerging pharmaceutical companies.<sup>33</sup> These do not have developed their own facilities and hence the subcontractors owe a great share of power.

### The power of buyers

Buyers are the customers of the industry. They are considered powerful if they have negotiating leverage relative to the producers and/or if they are price sensitive.

Negotiation leverage is achieved, claims Porter, if there are few buyers, the products offered by industry are standardized, switching among producers bears low costs for customers and if there are possibilities for customers to integrate backward.<sup>34</sup> In addition, customers today are more complex in their demands and are not solely lead by purchasing costs.<sup>35</sup> They evaluate dimensions of quality and the total service/product package. Furthermore, introduction of Internet provided customers with an easier way of obtaining information on products and manufacturers' cost and use it as distribution alternative. This significantly increased buyers' bargaining power in many industries. This phenomenon can be explained by zero switching costs for customers when they decide to purchase from one manufacturer rather than another or from one dealer as opposed to a second or third one.<sup>36</sup>

Buyers' price sensitivity is strengthened if product costs hold significant share of the customer's budget, customers earn low profits, if the quality of buyers' products or services is little affected by the industry's product and if the industry's product has little effect on the buyer's other costs.<sup>37</sup>

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<sup>32</sup> Allergan 10-K report 2007

<sup>33</sup> Van Amum, P., (2008) Outsourcing strategies of emerging pharma, *Pharmaceutical Technology*; 32, 10; ABI/INFORM Global

<sup>34</sup> Porter, M.E. (2008) The five competitive forces that shape strategy, *Harvard Business Review*, January

<sup>35</sup> Schofield, R.A., Breen, L., (2006) Suppliers do you know your customers? *International journal of quality and reliability management*, Vol. 23, No 4,

<sup>36</sup> Hitt, M., A., Ireland, R., D., and Hoskisson, R., E. (2005) *Strategic Management Competitiveness and Globalization*, Concept and Cases, International Student Edition, 6<sup>th</sup> edition, South-Western, Thomson Corporation

<sup>37</sup> Porter, M.E. (2008) The five competitive forces that shape strategy, *Harvard Business Review*, January



Porter also emphasizes the role of intermediate customers as they can gain significant bargaining power if they can influence the purchasing decision of end customers.<sup>38</sup>

These new circumstances are forcing many industries to reconsider their strategies.

### Threat of substitute products

A substitute is a product that performs the same or similar function as an industry product but does so in a different way or by different tools.<sup>39</sup> A substitute will pose a threat if its quality and function are superior to existing products and if they bear low switching costs.<sup>40</sup> Thus, “differentiating a product along dimensions that customers value (like product features, support services, delivery time, etc...) reduces a substitute’s attractiveness”.<sup>41</sup> In pharmaceutical industry, switching from a branded medicine to a generic one is caused by low costs and hence the shift to generics is substantial and rapid. In addition, producers should keep their eyes open in the direction of new technologies and other “out of the focal industry” environment since substitutes may originate from areas that are not directly related to the focal industry.<sup>42</sup>

### Rivalry among existing competitors

All firms within an industry are mutually dependent. Actions taken by one firm motivate reaction from its competitors. In other words, firms actively compete against one another. Competitive rivalry is fueled by competitor’s actions or when a company pursues opportunities to improve its market position.<sup>43</sup> Intense rivalry is witnessed by price wars, high rates of innovation and expensive marketing.<sup>44</sup>

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<sup>38</sup> ibidum

<sup>39</sup> ibidum

<sup>40</sup> Peng, M.W. (2006) *Global Strategy*, International student edition, South-Western, Thomson Corporation

<sup>41</sup> Hitt, M., A., Ireland, R., D., and Hoskisson, R., E. (2005) *Strategic Management Competitiveness and Globalization*, Concept and Cases, International Student Edition, 6<sup>th</sup> edition, South-Western, Thomson Corporation, pg. 57

<sup>42</sup> Porter, M.E. (2008) The five competitive forces that shape strategy, Harvard Business Review, January

<sup>43</sup> Hitt, M., A., Ireland, R., D., and Hoskisson, R., E. (2005) *Strategic Management Competitiveness and Globalization*, Concept and Cases, International Student Edition, 6<sup>th</sup> edition, South-Western, Thomson Corporation

<sup>44</sup> Peng, M.W. (2006) *Global Strategy*, International student edition, South-Western, Thomson Corporation

Porter counted following factors that increase the intensity of rivalry: numerous competitors, slow industry growth, high exit barriers, strong commitment to the business by rivals and lack of literacy of rivals' signals. Furthermore, rivalry pressures profitability if there is a price competition. The price competition is fueled, states Porter, by similarity and low switching costs of competitive products, high fixed and low marginal costs and by product perishability. However, competition on dimensions other than price (for example on product features, customer service, delivery time, brand), elaborates Porter, is less likely to diminish profitability because it actually increases customer's value and can lead to higher prices instead.<sup>45</sup>

## Conclusion

The model of the five forces presents five competitive forces that in Porter's view define the industry structure. The stronger are the forces, the lower is the profit potential of the industry.<sup>46</sup> Hence, the industry structure is an important factor in determining the industry's long-run profit potential and attractiveness.<sup>47</sup> According to Porter, an unattractive industry will have structural flaws, plethora of substitutes, powerful and price-sensitive buyers, strong rivalry and large competitors. On the other hand, an industry is attractive not only because of having a high average return on investment, but also since it is difficult to enter (due to the high entry barriers), suppliers and buyers have only modest bargaining power, substitutes are few and rivalry among competitors is stable.<sup>48</sup>

Below is a summary-table (Table 1.) presenting most of the factors including in which direction (high, low) their effect strengthens each of the force.

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<sup>45</sup> Porter, M.E. (2008) The five competitive forces that shape strategy, Harvard Business Review, January

<sup>46</sup> Hitt, M., A., Ireland, R., D., and Hoskisson, R., E. (2005) *Strategic Management Competitiveness and Globalization*, Concept and Cases, International Student Edition, 6<sup>th</sup> edition, South-Western, Thomson Corporation

<sup>47</sup> Porter, M.E. (2008) The five competitive forces that shape strategy, Harvard Business Review, January

<sup>48</sup> Porter, M., E., (1987). From competitive advantage to corporate strategy, Harvard Business Review, May-June

**Table 1. Forces and their factors increasing the competitive structure of an industry**

<b>Forces and their relating factors</b>	<b>Impacts of the factors.</b>
<b>The threat of new entrants</b>	It increases the force/threat/power if the factor is:
Entry barriers	low
Economies of scale	high
Product differentiation	low
Capital requirements	low
Switching costs	low
Access to distribution channels	easy
Market growth	high
Government policy	low
Incumbents' reaction to the new entry	high
A number of companies that hold great stake of the market	low
<b>Bargaining power of suppliers</b>	
Dominance of suppliers in the industry	high
Concentration of suppliers	high
Criticalness of suppliers' goods to the industry buyers	high
Importance of buyers as a customers to suppliers	low
Switching cost of suppliers	high
Suppliers' services' or products' differentiation	high
<b>The power of buyers</b>	
Negotiation leverage:	HIGH
Numerousness of buyers	low
Standardized products	yes
Switching costs	low
Product integration	backward
Customer's demands	high
Price sensitivity	HIGH
A share products hold of the customers' budget	high
Customers' income	low
The power of intermediate customers	HIGH
<b>Threat of substitutes:</b>	
Quality and function of a substitute	high
Switching costs	low
<b>Rivalry among existing competitors:</b>	
Numerousness of competitors	high
Industry growth	low

Exit barriers	high
Commitment to the industry business	high
Price competition:	high
Switching costs	low
Product differentiation	low
Fixed costs	high
Marginal costs	low
Product perishability	high
Competition on other dimensions	low

Porter's five forces framework is considered a static framework because it describes an industry as a constant and externally defined. This can be observed as a limitation. The model assumes that the competition is driven by the industry structure and that companies are constrained by it. In reality, however, competition is a dynamic process and firms continuously influence and alter the industry structure through delivering new technologies, substitute products and distribution channels or engagement in collusive behavior.<sup>49</sup>

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<sup>49</sup> Sudarsanam S. (2003). *Creating value from merger and acquisitions- the challenges*, Prentice Hall-Financial Times

## **4. PORTER'S FIVE FORCES ANALYSIS APPLIED TO BTX INDUSTRY**

In this chapter the Porter's five forces analysis will be applied to the industry of botulinum toxin. Botulinum toxin production is perceived as an industry since "an industry is considered a group of firms that are close substitutes".<sup>50</sup> Botulinum toxin manufacturers compete for the use of toxin in the same or very similar medical and cosmetic treatments.

The chapter will aim to define elements that build Porter's five forces in the BTX industry. Furthermore, the chapter will try to define in which direction and why these elements influence particular force. The final evaluation, the conclusion and recommendation part, will be built upon the findings from this chapter.

The industry analysis will be performed on the global market because BTX is a global phenomenon. In addition, the competitive analysis will be narrowed to the business unit levels where needed, as the manufacturers' activities are diversified and they compete amongst each other only with their botulinum toxin business units.<sup>51</sup>

### **Rivalry among existing competitors**

Botulinum toxin industry, both for cosmetic and therapeutic use, is assumed to be a fruitful one. This argument has been supported by its strong market growth. Mentor Corporation estimates in its Annual report for 2007, that the worldwide market for botulinum toxin products amounts to approximately US\$ 1,4 billion, of which approximately 55% relates to therapeutic uses and 45% to cosmetic use. Furthermore, according to Morgan Stanley's Estimation in 2006, the botulinum market will grow to

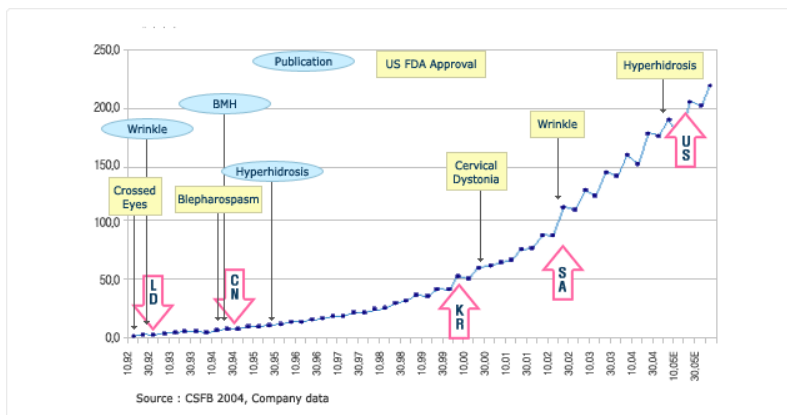
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<sup>50</sup> Hitt, M., A., Ireland, R., D., and Hoskisson, R., E. (2005) *Strategic Management Competitiveness and Globalization*, Concept and Cases, International Student Edition, 6<sup>th</sup> edition, South-Western, Thomson Corporation, pg. 52

<sup>51</sup> Markovitz, Z.N., (1987) Hidden Sector competitor analysis, September/October Planning Review

about US\$ 2 billion by 2010.<sup>52</sup> This represents a market growth of 42,86% in comparison to the 2007. The growth over the coming year is expected to continue this positive trend due to growing consumer awareness, aging baby boomers, consumer desire to withhold a young appearance, consumers' high income, social acceptance of aesthetic practices and by new therapeutic applications.<sup>53, 54</sup> In that manner, it is worth to mention that in the US, quarterly sales of botulinum pharmaceuticals have increased about 20 times compared to 10 years ago. Furthermore, paper presentations and permits for new fields of application have continuously increased every 10 years.<sup>55</sup> Below is a 10 year market growth of botulinum toxin market presented by Medy-tox corporation. The graph illustrates the growth path of botulinum toxin which was slow in the 90s but strongly increased in 2000s.

**Figure 4. A 10 year market growth of BTX**



Source: Medy-Tox' web site, [http://www.medy-tox.co.kr/2008\\_eng/04/sub05.php](http://www.medy-tox.co.kr/2008_eng/04/sub05.php); 17.09.2008.

The botulinum toxin industry is characterized by a diversity of players, some market reports name as much as 19 different players<sup>56</sup>. This analysis will group the manufacturers into two main categories: the branded manufacturers and "generic" manufacturers. Branded manufacturers are established producers, possessing a botulinum toxin branded product. After the preliminary research branded producers are found to be

<sup>52</sup> Medy-Tox' web site, [http://www.medy-tox.co.kr/2008\\_eng/04/sub05.php](http://www.medy-tox.co.kr/2008_eng/04/sub05.php); 17.11.2009.

<sup>53</sup> Global Biotech Forum's web site, [http://www.globalbiotechforum.org/gbf/tech\\_memo\\_file/TM\\_Medy-Tox\\_meditoxin.pdf](http://www.globalbiotechforum.org/gbf/tech_memo_file/TM_Medy-Tox_meditoxin.pdf); 17.09.2008.

<sup>54</sup> Merz GmbH & Co, Annual report 2006/07

<sup>55</sup> Medy-Tox' web site, [http://www.medy-tox.co.kr/2008\\_eng/04/sub05.php](http://www.medy-tox.co.kr/2008_eng/04/sub05.php); last visited 17.09.2008.

<sup>56</sup> Report Linker's web site, <http://www.reportlinker.com/p0119494/World-Botulinum-Toxin-Market.html>; Reuters' web site <http://www.reuters.com/article/pressRelease/idUS72672+18-May-2009+BW20090518> 18.10.2009.

the following companies: Allergan, Ipsen, Medy-tox, Merz Pharmaceuticals, Mentor Corporation and Solstice Neuroscience. “Generic” manufacturers are these that produce botulinum toxin but do not have established botulinum toxin branded products. These would include (for example Chinese, or Hong Kong) manufacturers that sell the toxin OTC<sup>57</sup> through the Internet.

The botulinum toxin market is dominated by Allergan. According to Allergan’s 10-K report for 2007, they owed more than 85% of the total botulinum market share in 2007. This categorizes Allergan as a dominant and powerful market player.<sup>58</sup> The second biggest manufacturer is Ipsen. According to the Ipsen’s registration report for 2007, they claim that they owed 15% of the global market in the 2007.<sup>59</sup> According to the announcements from Allergan and Ipsen, the market in 2007 was divided only among the two of them. In 2008, Allergan possessed approximately 83% and Ipsen 13% of the market. The rest of the manufacturers share the remaining 4%.<sup>60</sup> This means that the overall rivaling forces among BTX manufacturers are not so strong. However, the rivalry among the followers may be enhanced when fighting among themselves to capture the market share. (Table 3.)

**Table 2. Net sales of the most important players and their related market share**

	2007	2008
Total market value** (estimated in US \$ )	1 400 000	1 568 000
Allergan's net sales (US \$)	1 211 800	1 310 900
Ipsen's net sales (US \$, calculated according the ex. rate on the 31.12.*)	205 350	201 625
rest of the market	-17 150	55 475
<b>Market shares</b>	<b>2007</b>	<b>2008</b>
Allergan's net sales (US \$)	86,6 %	83,6 %
Ipsen's net sales (US \$, calculated according the ex. rate on the 31.12. *)	14,7 %	12,9 %
Rest of the market		3,5 %

Source: calculated by author

\* <http://www.xe.com/>

<sup>57</sup> OTC- over the counter= without prescription

<sup>58</sup> Allergan Inc., (2009) Form 10-K for 2008.

<sup>59</sup> Ipsen (2008) Registration document for 2007

<sup>60</sup> This was calculated by author according to the assumption that the BTX market will grow 12% per year. The 12% growth rate resulted from the fact that the market was evaluated to amount to US\$ 1,4 billion in 2007 and should equal US\$ 2 billion by 2010. By assuming the annual growth rate of approximately 12 % the market reaches the estimated US\$ 2 billion by 2010.

Internet supply webpages such as [www.ecplaza.net](http://www.ecplaza.net) or [www.alibaba.com](http://www.alibaba.com) list several (less than 10) “generic” suppliers of BTX. However, since they fall in the remaining 4% of the market share it is assumed that their power is not significant.

Established manufacturers (Allergan plus 5 followers) are aware of the lucrative nature of the botulinum toxin business and therefore maintain strong commitment to it. Botulinum toxin type A is one of the most important Allergan’s products whose sales represented approximately 30%, 31% and 33% of Allergan’s total consolidated product net sales in 2008, 2007 and 2006 respectively. Ipsen’s Dysport is within the four most selling Ipsen’s products (holds 3rd place in 2007) with its share rising from 11% in 2004 to 14% in 2007.<sup>61</sup> Merz Pharmaceuticals also defined aesthetics as its future field of expertise. In line with that goal it will aim to position itself as a complete provider of non-operative aesthetics in which range the botulinum toxin falls.<sup>62</sup> Mentor Corporation states that although the botulinum toxin project does not have a great share in the total net sales of the Mentor Corporation, it is one of their strategic projects: “The increase in research and development spending was primarily to support key strategic product development programs including ... our botulinum toxin project ...”<sup>63</sup> Mentor Corp is developing a next generation botulinum toxin type A product based on proprietary technology that yields a formulation designed to be purer than other commercially available botulinum toxin products.<sup>64</sup> Medy-Tox, a biotech venture company, was established in 2000 with the goal of developing botulinum toxin-based injections. They have two main product lines of which one is Neuronox®, a botulinum toxin type A. Taking into account its efficiency, low risk, and price compared with competitive products, Neuronox® is continually becoming the most welcomed choice of botulinum toxin drug for both doctors and patients in the world. Moreover, the Bank of America Securities research report mentioned Medy-Tox as a leader in the botulinum market.<sup>65</sup> Solstice Neurosciences, Inc. is also a specialty biopharmaceutical company founded in 2004 in the USA. Solstice’s first product, Myobloc®/NeuroBloc® Injectable Solution,

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<sup>61</sup> Allergan Inc., (2009) Form 10-K for 2008.

<sup>62</sup> Merz GmbH & Co. KGaA, (2007) Annual report 2006/2007

<sup>63</sup> Mentor Corporation, (2007) Annual report for 2006

<sup>64</sup> ibidum

<sup>65</sup> Medy-Tox Inc Technology, [http://www.medy-tox.co.kr/2008\\_eng/01/sub02.php](http://www.medy-tox.co.kr/2008_eng/01/sub02.php) ; 17.09.2008.



represents the only botulinum toxin type B currently available to physicians and patients worldwide.<sup>66</sup> It can be concluded that all of the above manufacturers are aware of the botulinum toxin potential and aim at strengthening their position in that segment.

The most differentiated product is Allergan's Botox®. Its differentiation is so strong that the whole botulinum toxin industry is often named after it - botox. A price for cosmetic treatments with botulinum toxin differs according the amount needed to treat a certain area. Botox® costs between \$ 500 and \$ 2000 US and it is expected for a patient to pay this every 4-6 months.<sup>67</sup> However, the average Botox® treatment price, is assumed to range from \$350 to \$500 for each area injected. These costs vary also according to geographic region and depending on the doctor who performs the procedure.<sup>68</sup> Dysport® on the other hand is claimed to be cheaper, ranging from \$360 to \$400 depending on the amount of correction necessary. It is claimed that the Dysport® cost less per unit than Botox®. However, the disadvantage is that more Dysport® units are needed per area compared to Botox®. 75 Dysport® units cost approximately \$300 but they equal 25 units of Botox®.<sup>69</sup> Furthermore, products such as Dysport®, Purtox®, Xeomin® are considered to be more pure and consist fewer antigens that can lead to resistance to the product.<sup>70</sup> Price competition exists among the manufacturers but they are aiming to compete on other product features. These features embrace different ways of customer support like providing them with all necessary information (through Internet and open phone lines) and if needed with financial help(Allergan), assistance programs(Allergan) and most importantly, with better quality of the product i.e. better purity and less antigens (Ipsen, Merz, Mentor Corporation). The competition on other dimensions other then price improves customer value and if companies find the way to serve different customer segments this will weaken the rivalry and lead to positive sum. However, in the BTX market, additional benefits were imposed with the aim not only to acquire new customers but also to convince the opponents' customers to switch. Hence, here the competition on dimensions other than price is assumed to fuel the rivalry.

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<sup>66</sup> Solstice Neurosciences' web site, <http://www.solsticeneuro.com/company/overview.html>; 11.09.2008.

<sup>67</sup> Botox' web site, [http://www.botox-cosmetic-surgery.com/botox\\_price.htm](http://www.botox-cosmetic-surgery.com/botox_price.htm) ; 05.12.2009.

<sup>68</sup> DocShop web site <http://www.docshop.com/education/dermatology/injectables/botox/cost/> ; 05.12.2009.

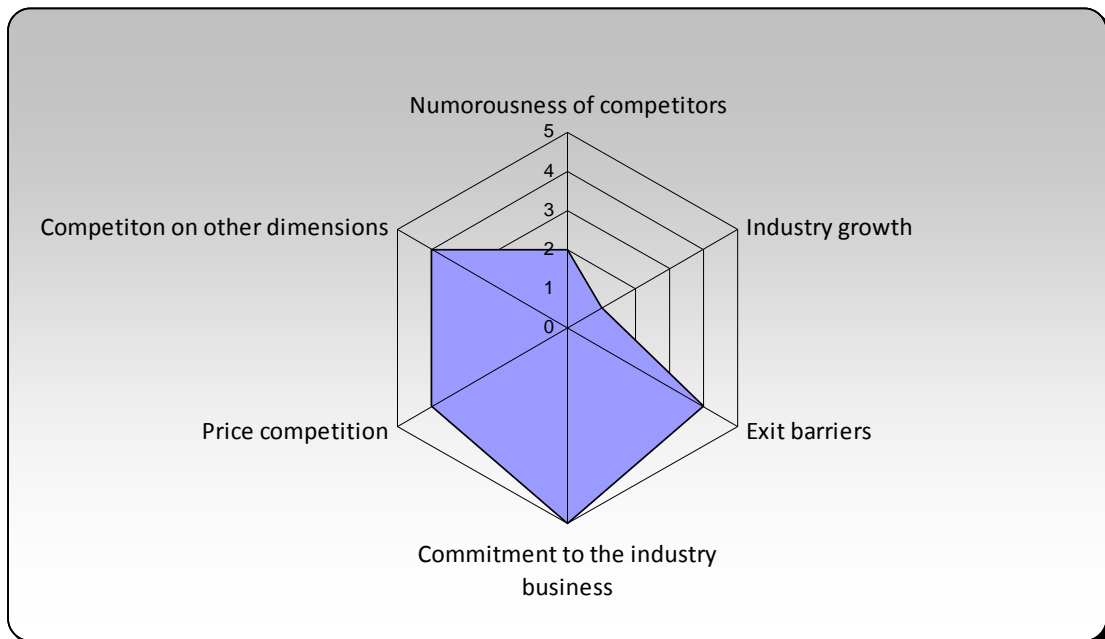
<sup>69</sup> RealSelf's web site <http://www.realself.com/question/how-much-does-dysport-cost>; 05.12. 2009

<sup>70</sup> Lam Facial Plastics' web site <http://lfp-blog.com/questions/lam-facial-plastics/botox-competitors-coming-soon-reloxin-purttox-xeomin/137/>; 05.12.2009.

To conclude, the main forces shaping the rivalry among existing competitors are numerousness of competitors, industry growth, exit barriers, commitment to the industry business, price competition and competition on other dimensions. All of them strengthen the rivalry except the numerousness of competitors and industry growth. Dominance of the single firm and small group of following companies, as well as affluent industry growth weaken the rivalry and encourage entrance.

The graph below shows the forces shaping the rivalry among existing competitors. The graph shows whether a factor has a strong (5) or low (1) impact. Therefore, although the industry growth is strong, that factor weakens the rivalry and therefore is here marked as a weak driver (estimated to equal 1).

**Figure 5. Rivalry among existing competitors**



## The power of substitutes

Substitute solutions greatly differ for BTX use in the cosmetic and therapeutic treatments. Botulinum toxin used for therapeutic treatments, have few, or in some cases no substitutes at all.<sup>71</sup> For example, botulinum toxin is held to be best treatment for cervical dystonia<sup>72,73</sup>, as is the case for Blepharospasm (excessive blinking)<sup>74</sup>. If botulinum toxin treatment does not help Blepharospasm patients then surgery is an option. On the other hand, treating hyperhidrosis for example provides patients with two main substitutes: antidepressants and anxiolytics. The power of substitutes for therapeutic use is dependable upon substitutes that are available for that particular therapeutic problem.

Use of botulinum toxin in (cosmetic) treatments has several advantages: it is a non surgical, low-time consuming, painfree and easy procedure. Furthermore, its effect arise relatively fast after the procedure, within 24-48 hours after receiving Botox®, wrinkles are gone and the effect can last up to 4 months<sup>75</sup>. In addition, the procedures poses little to no risk. The cosmetic treatment's characteristics have therefore been difficult to beat by any other substitute. Alternatives to BTX cosmetic treatments that have usually been mentioned are: serum (injection-free alternative made from biological ingredients), collagen (as a substance in the anti-aging creams or as wrinkle fillers), restylane (the latest substitute for BTX treatment, is hyaluronic acid derivative used to produce fullness in the skin), snipping the muscle (a surgical process), conventional surgeries and REX (makes use of radiofrequency energy, which is targeted at the motor neurons to weaken them so that they are unable to connect to the muscle that causes frowning).<sup>76</sup> The cosmetic substitutes can be grouped into following: surgical solutions, creams, new alternative solutions like fillers or REX. Customers will always prefer non surgical

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<sup>71</sup> Schantz E.J., Johnson E.A., (1992). Properties and use of botulinum toxin and other microbial neurotoxins in medicine, Microbiological review, American society for Microbiology, March issue

<sup>72</sup> Dystonia Foundation web site, [http://www.dystonia-foundation.org/pages/more\\_info/46.php](http://www.dystonia-foundation.org/pages/more_info/46.php); 005.12.2009.

<sup>73</sup> Brashear A., (2009). Botulinum toxin type A in the treatment of patients with cervical dystonia, Biologics: Targets 6 Therapy No. 3

<sup>74</sup> Blepharospasm Research Foundation web site, <http://www.blepharospasm.org/med-therapy.html>; 05.12.2009.

<sup>75</sup> Botox' web site, [http://www.botoxcosmetic.com/how\\_botox\\_works/injection\\_process.aspx](http://www.botoxcosmetic.com/how_botox_works/injection_process.aspx); 28.10.2009.

<sup>76</sup> Buzzle's web site, <http://www.buzzle.com/articles/alternatives-for-botox.html>; 06.12.2009

treatments to surgical and fast solutions to slow and long term processes like cream use. Therefore, fillers/ hyaluronic acid or REX can be considered as potentially the strongest BTX substitutes.

Hyaluronic acid is “a viscous slippery substance that lubricates the joints, maintains the shape of the eyeballs, and is a key component of connective tissue.”<sup>77</sup> The most known HA brands are Perlane®/Restylane® produced by Medici and Juvederm® by Allergan. There are also brands like Aquamid, Bio-Alcamid, Dermalive, Evolence, ProCytch, Inamed Aesthetics, Radiesse and Teosyal.<sup>78</sup> The use of hyaluronic acid as a injectable dermal filler is relatively new (approved by FDA in 2003) and still unknown to potential customers. However, according to the ASAPS, hyaluronic acid<sup>79</sup> is the first follower of the botulinum toxin cosmetic treatments in the category of the nonsurgical cosmetic procedures and this trend has been occurring in the same pattern for past several years. For example in the 2007, there were more than 2,7 million BTX injection in the USA and more than 1,4 million hyaluronic acid procedures. The ratio is 2:1 in favor of BTX however states that hyaluronic acid is aggressively treating the BTX injections.

The Relaxed Expressions (REX) procedure is the newest substitute method for BTX cosmetic procedure. Its results are already visible after one hour and last for 16-18 months. The price of the REX is about \$1500 per procedure.<sup>80</sup> The procedure although new represents a sever threat to BTX since it is non toxin based, results are shown fast, long lasting and the price is highly competitive to the BTX treatment.

BTX use cases immunologic reactions in patients. After many treatments antibodies are created in the body and there is an absence of reaction to the treatment. It has been shown that BTX-A treatments in such cases can be substituted by treatments with other

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<sup>77</sup> MedicineNet's web site, <http://www.medterms.com/script/main/art.asp?articlekey=25768>; 18.10.2009.

<sup>78</sup> Linda Briggs' web site, <http://www.lindabriggs.co.uk/fillers.htm>; 18.10.2009. Emedicine's web site <http://emedicine.medscape.com/article/1125066-overview>; 10.12.2009; About's web site, [http://plasticsurgery.about.com/od/minimallyinvasive/a/dermal\\_fillers.htm](http://plasticsurgery.about.com/od/minimallyinvasive/a/dermal_fillers.htm) 10.12.2009

<sup>79</sup> Hyaluronic acid is “a viscous slippery substance that lubricates the joints, maintains the shape of the eyeballs, and is a key component of connective tissue.”; MedicineNet's web site, <http://www.medterms.com/script/main/art.asp?articlekey=25768>; 18.10.2009.

<sup>80</sup> Youtube's web site [http://www.youtube.com/watch?v=xZtJ\\_9rNp3U](http://www.youtube.com/watch?v=xZtJ_9rNp3U); 07.12.2009.

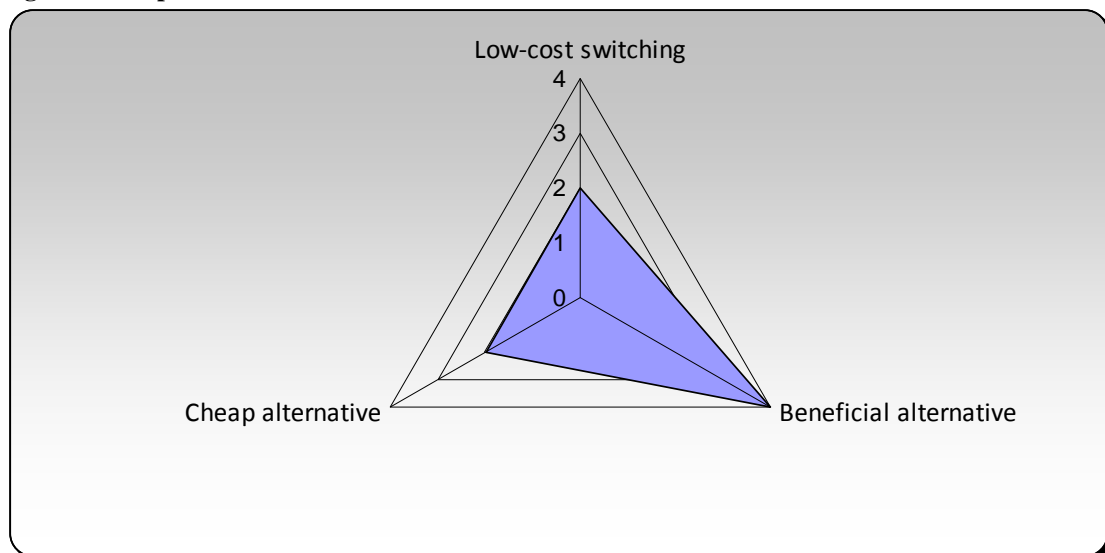
botulinum serotypes like BTX-F or BTX-B. However, the benefits of these treatments have shorter (BTX-F 1 month) duration compared to the BTX-A treatments<sup>81</sup>

Some other toxins have been shown to produce a similar effect to BTX. These are tetanus toxin, saxitoxin and tetrodotoxin. However, their effects and production are not still 100% explored.<sup>82</sup> However, as the applications of BTX will increase the interest for its substitutes will also increase. Therefore, these toxins will also present a considerable threat to BTX in the future.

To conclude, the power of substitutes is different for cosmetic and therapeutic use. While in therapeutic use often there is no better alternative and hence the power of substitute is low, in cosmetics the power is stronger. There are substitutes that are cheap alternatives such as creams, or beneficial substitutes that overcome the problem of the immunologic reactions such as HA, REX or other toxins. The later presents the most threat to the BTX products. In addition, it is assumed that as more research will be done on the beneficial substitutes, their power will grow.

Overall, it can be concluded that the treat of botulinum toxin substitutes is moderate with the tendency to become more serious in the future.

**Figure 6. The power of substitutes in cosmetic use of BTX**



<sup>81</sup> Brin, M.F., (1997) Botulinum toxin: Chemistry, Pharmacology, Toxicity and Immunology, Muscle & Nerve Supplement 6

<sup>82</sup> Schantz E.J., Johnson E.A., (1992). Properties and use of botulinum toxin and other microbial neurotoxins in medicine, Microbiological review, American society for Microbiology, March issue

## The power of buyers

When discussing the power of buyer a distinction should be made between buyers and end user. End users are customers that use botulinum toxin for cosmetic treatments to soften the gabbellar facial lines or for therapeutic treatments to fight diseases like various muscle disorders or strabismus. Intermediate customers or also called buyers refer to doctors, hospitals or clinics. For both of these groups, the demand for botulinum toxin medicines is high and strong. Increased demand to preserve younger appearance, aging of baby boomers, as well as increased presence of the producers on the market and therefore increased customer awareness of the products leads to a growing demand for botulinum toxin as a cosmetic treatment and while decreasing buyers' power. Medical customers also have a low power as their treatment usually depends on the BTX treatments for which there are currently few or hardly any substitutes are available. This is illustrated by the example of cervical dystonia mentioned previously, where botulinum toxin injections are considered to be the most effective treatment.<sup>83</sup>

Increasing advertising of the BTX products in recent years has strengthened customers' awareness and consequently enhanced demand. BTX products have mainly been used in Western countries. However, the Internet helped to spread the news about the benefits of BTX and the products have become known and hence desirable all over the world as well as in low income countries such as China, India, Russia or Brazil. The emerging markets are densely populated and desperate to follow the Western countries trends and therefore present another source of demand pressure.

Most cosmetic customers are high income customers and the BTX products do not hold a great share of their budget. On the other hand, medical customers are not necessarily wealthy, and the procedure could hold a significant share of their budget. However, in most cases medical procedures are covered by insurance. Therefore, the customers are assumed not to be price-sensitive which decreases their power.

The bargaining power of suppliers strongly increases in the case of adverse effects of the drug use (especially in the case of death). Customers' complaints and law suits may cause companies to loose their goodwill and established image and lead governments to impose

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<sup>83</sup> Dystonia Foundation web site, [http://www.dystonia-foundation.org/pages/cervical\\_dystonia\\_more\\_info/46.php](http://www.dystonia-foundation.org/pages/cervical_dystonia_more_info/46.php); 18.10.2009.

even more strict regulations. These actions can significantly influence the producers' market positioning and production costs as well as customers purchasing desire. One of the examples is a recent case in the USA, where due to the adverse effects, FDA announced changes to safety labeling of the botulinum toxin for the following brands; Botox®, Myobloc® and Dysport®.<sup>84</sup> In addition, the negative publicity on adverse cases strongly influences customers' choices and therefore increases their power.

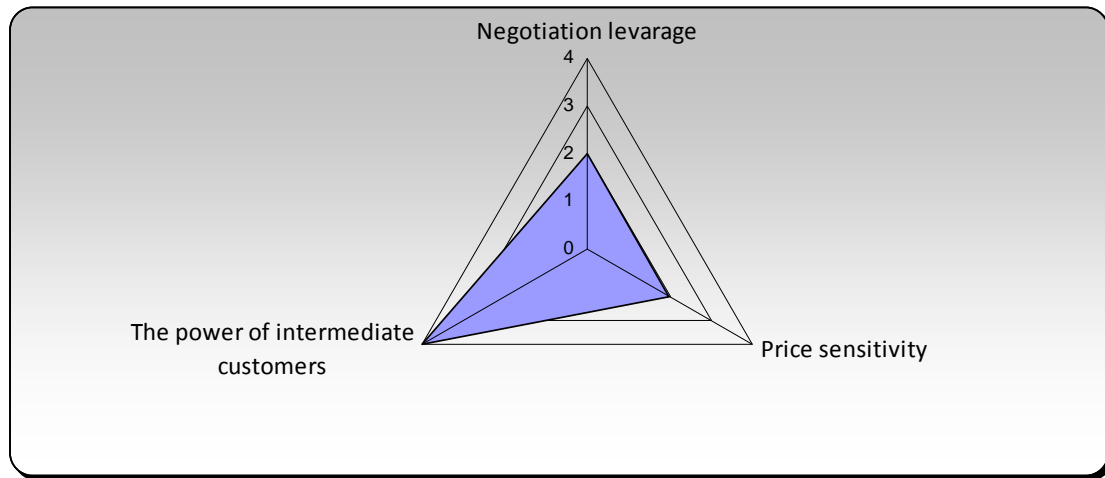
Intermediate customers are assumed to have strong power. The buyers of botulinum toxin are hospitals and medical practices as well as beauty clinics. These tend to have strong brand loyalty which enables them to withhold known practices, quality and service. Strong loyalty also results from influential branding campaigns targeting end users and customers demands. This can also partially explain why Allergan holds more than 85% of the market share. Strong loyalty towards a particular producer will increase a buyer's negotiation leverage when considering switching. Additionally, buyers must comply with high levels of internal regulatory requirements, norms and certification imposed by central authorities when dealing with the medicines. This makes switching more difficult and hence more expensive. However, in some cases the government sponsors some drugs which makes it a powerful negotiator towards the botulinum toxin manufacturers.

To conclude, the power of buyers in BTX market has been driven by several factors. These are negotiation leverage, price sensitivity and the power of buyers/ intermediate customers. It has been presented above that negotiation leverage and price insensitivity act in direction of decreasing the power of buyers and customers while the intermediate customers influence the power in opposite direction. (Figure 7)

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<sup>84</sup> Medical News Today's web site, <http://www.medicalnewstoday.com/articles/148704.php>, 18.10.2009.

**Figure 7. The power of buyers**



### The power of suppliers

In the pharmaceutical industry usually the power of suppliers is usually high and one of the reasons for this is that subcontractors in USA are required by the FDA also to fulfill a variety of legislation.<sup>85</sup> Fulfilling regulative framework is both time consuming and expensive and therefore a source of bargaining power of a supplier. Another problem in the pharmaceutical industry is that the (sudden) loss of (an established) material supplier will cause an interruption in the manufacturing process which will then influence production and selling activities in a negative direction.

However, the production of botulinum toxin differs from the above mentioned characteristics. In order to produce BTX, a company has to cultivate the *Clostridium botulinum* bacteria. It is the cultivation and the maintenance of *C. botulinum* that determines the quality of the toxin produced. In addition, the toxin production is highly sensitive to the laboratory conditions.<sup>86</sup> Therefore, it is not surprising that the manufacturers choose to produce it themselves rather than subcontracting it: “We ferment, purify and characterize the botulinum toxin used in our product Botox®”<sup>87</sup>. “The Ipsen group currently manufactures the toxin itself”<sup>88</sup>

<sup>85</sup> Allergan Inc., (2008) Form 10-K for 2007.

<sup>86</sup> Schantz E.J., Johnson E.A., (1992). Properties and use of botulinum toxin and other microbial neurotoxins in medicine, Microbiological review, American society for Microbiology, March issue

<sup>87</sup> Allergan Inc., (2008) Form 10-K for 2007, pg. 14

<sup>88</sup> Ipsen (2008) Registration document for 2007, pg. 39



However, there is only one company found that manufactures and sells all seven serotypes of botulinum toxin: Metabiologics Inc. However, Metabiologics produces botulinum toxin only and exclusively for research use. This gives Metabiologics high power on supplying botulinum toxin for R&D activities. On the other hand, Allergan secures its independence in that aspect too by fully integrated research and development organization with in-house discovery programs.<sup>89</sup>

Since there are no real suppliers in the production of the toxin and since the companies conduct the (most of the) production process by themselves it can be concluded that the bargaining power of suppliers is low or it does not exist at all.

### Threats of new entrants

The entry barriers for the botulinum toxin industry are similar to those of pharmaceuticals. They include high R&D costs, patent costs, long periods of clinical testing and regulatory approvals of the drug use, access to distributional channels and huge marketing and sales costs.

The main characteristics of the industry are high R&D costs, patent costs, regulatory approvals of the botulinum toxin products as a drug and clinical testing costs. A new entrant will have to face these costs that are immense and long lasting. Strong established producers such as Allergan or Ipsen, are well aware of their position in the botulinum toxin pharmaceutical market. Therefore, they maintain their heavy investment into further BTX R&D<sup>90</sup> in order to preserve their key positions and also to make a new entrance less desirable. For example, Allergan invested as much as \$797,9 million in its R&D activities in 2008, of which a great share was spent on activities related to Botox® and it aims to maintain this trend in the future.<sup>91</sup> In addition to high R&D related entry barriers, the BTX manufacturing process is also technically expensive, complex and requires

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<sup>89</sup> Allergan Inc., (2008) Form 10-K for 2007.

<sup>90</sup> Mentor Corporation, (2007) Annual report for 2006

<sup>91</sup> Allergan Inc., (2009) Form 10-K for 2008.

significant lead time.<sup>92</sup> For example, in 2007 Ipsen invested €17,7 million for the facilities to produce a new packaging unit for Dysport®.<sup>93</sup> Not only that heavy investment in R&D, and patenting the use of BTX are means of incumbents to impede discourage new entrant these factors also present high capital requirements a new entrant has to consume.

Another great barrier lies in the fact that BTX products and (production) procedures are subject to the regulatory review and assent. BTX used in therapeutic treatments requires approval of medial regulatory bodies such as FDA in the USA or EMEA in the European Union. Cosmetic use of BTX is a subject to regulative assessment as well, but having a FDA approval is not a necessity. Furthermore, the manufacturing facilities are also controlled and evaluated. For example, a facility of Mentor Corporation is subject to regulation by the US Department of Health and Human Services, Centers for Disease Control due to the nature of the biological agent used to manufacture BTX product.<sup>94</sup> Failure to comply with the regulations affects the manufacturing process, delivery time, as well as the sales and income results of a producer and therefore increasing the power of this barrier. In addition, constituted access to regulative and legislative bodies makes it easier (due to the experience) for a producer to challenge a new entrant's patent applications on the botulinum toxin issues. For example, there has been a patent and competition law dispute with Merz Pharmaceuticals in 2006 concerning the Xeomin® and Botox®. Although a mutual agreement was reached in August 2006, disputes like that pose additional costs on new entrants.

Current industry players have established access to and relationships with different sorts of distribution channels. In order to strengthen distributional channel and/or intermediate customers, producers have also developed training modules and seminars to update physicians regarding the BTX products.<sup>95</sup> Furthermore, they sign license agreements with other big pharmaceutical companies through which they gain access to new markets. For example, through the license to GlaxoSmithKline, Allergan entered the Japanese and

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<sup>92</sup> Allergan Inc., (2008) Form 10-K for 2007.

<sup>93</sup> Ipsen (2008) Registration document for 2007

<sup>94</sup> Mentor Corporation, (2007) Annual report for 2006

<sup>95</sup> Allergan Inc., (2008) Form 10-K for 2007.

Chinese markets. Medy-Tox has signed a technology transfer and commercialization agreement with Q-Med AB and openly seeking global marketing partners in worldwide commercialization and development of their BTX products.<sup>96</sup> Ipsen has license agreements with Aestetica and Galderma that are valid until 2039 and enabled Ipsen to access the USA, Canada, Japan, the European continent, Latin America and the rest of the world.<sup>97</sup>

Sales and marketing cost are also ample. Not only do the current players have well established relationship with distributional channels, but they also have established strong brands. The “leading” product on the market is Allergan’s Botox®. This product has been present on the market for the last 20 years and has a market share of more than 85%. This product has achieved such a strong image that the whole BTX industry is often named after it. This has enabled it to gain customers’ affection, acceptance and finally satisfaction over the past two decades. Although the market has been dominated by Allergan, each new entrant (Ipsen, Merz, Mentor Corporation) offered a BTX product (Dysport, Purtox, Xeomin) that was more pure than Botox®. Their main argument to acquire new or takeover customers is higher BTX purity and therefore, less side-and adverse-effects to the BTX treatments. More on product differentiation and competition on other factors than price, as well as on customers switching costs, has been mentioned in the rivalry among existing competitors part.

Finally, economies of scale apply to BTX production especially regarding the R&D and marketing costs.

It can be concluded that there are several factors determining the threat of new entrant. These include economies of scale, product differentiation, capital requirements, switching costs, access to distributional channels, market growth, regulations, incumbent’s reaction to the new entry and a number of companies that hold the great stake of the market. The factors act in different direction. While centralization of market share around Allergan, moderate switching costs and market growth encourage the entrance of new players, the

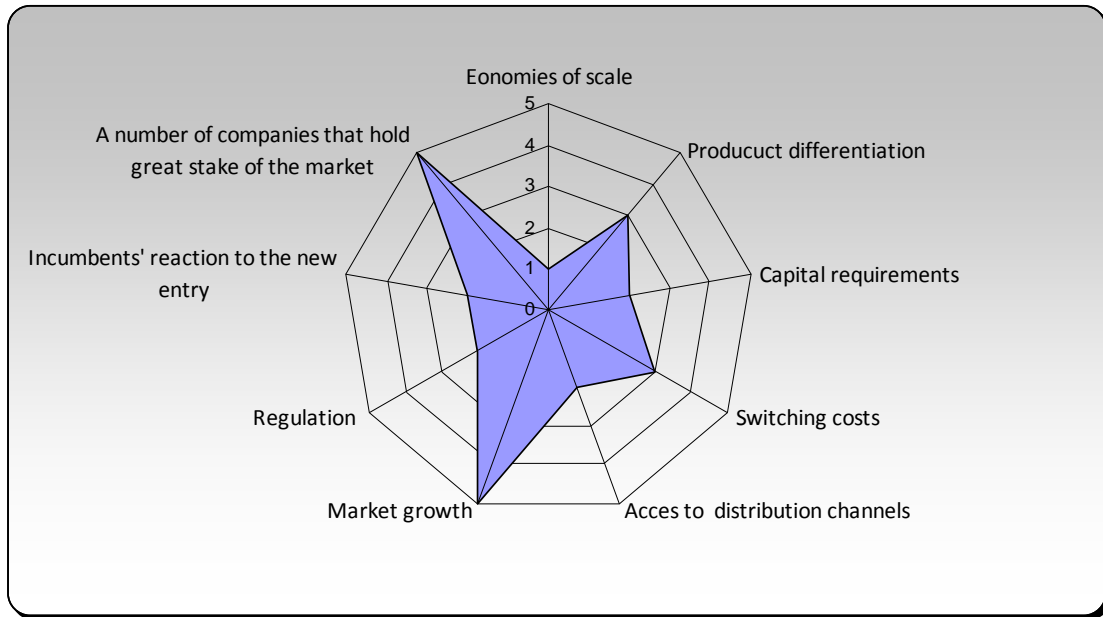
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<sup>96</sup> Medy-Tox Inc Technology, [http://www.medy-tox.co.kr/2008\\_eng/](http://www.medy-tox.co.kr/2008_eng/); last visited 02.08.2008.

<sup>97</sup> Ipsen (2008) Registration document for 2007

other determinants impede new entrances. Graph below presents the named factors and how they leverage a potential of a new entrant. If a factor is influencing a new entrant positively it will be graded with higher grades. On the other hand, if a factor is discouraging new entrance it will be assigned lower grades.

**Figure 8. The threat of new entrants**



## 5. CONCLUSION AND RECOMMENDATIONS

The aim of this paper was to analyze whether the BTX industry is a profitable to enter. Since the Porter claims that the industry is profitable if the structure of the industry is attractive, the Porter's five forces model was used to determine the structure of BTX industry and its attractiveness. The model was used particularly because it helps to define different forces shaping the industry structure.

In order to define how the forces influence the industry, drivers defining a particular force were evaluated. The evaluation of these elements is summarized in the table below (Table 3.).

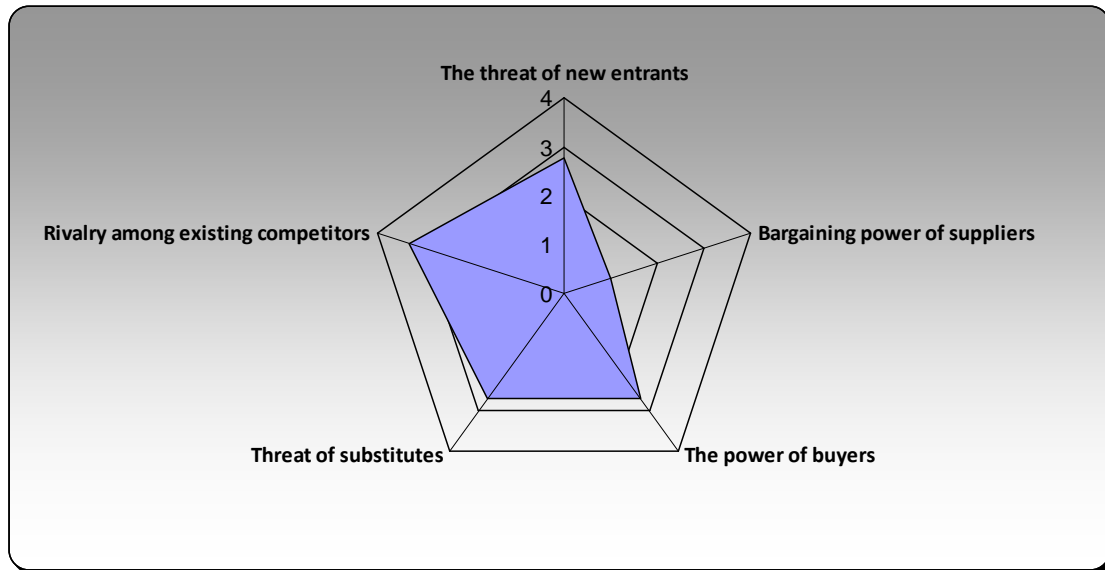
**Table 3. Evaluation of drivers shaping the Porter's five forces of BTX industry**

	The factor increases the force/threat/power if it is:	BTX industry case
<b>The threat of new entrants</b>		
Entry barriers	low	high
Economies of scale	high	high
Product differentiation	low	medium
Capital requirements	low	high
Switching costs	low	medium
Access to distribution channels	easy	difficult
Market growth	high	high
Government policy/Regulations	low	high
Incumbents' reaction to the new entry	high	medium
A number of companies that hold great stake of the market	low	low
<b>Bargaining power of suppliers</b>	high	low
<b>The power of buyers</b>		
Negotiation leverage:	high	low
Price sensitivity	high	low
The power of intermediate customers	high	high
<b>Threat of substitutes:</b>		
Quality and function of a substitute	high	medium
Switching costs	low	diverse

<b>Rivalry among existing competitors:</b>		
Numerousness of competitors	high	low
Industry growth	low	high
Exit barriers	high	high
Commitment to the industry business	high	high
Price competition:	high	medium
Competition on other dimensions	low	medium

It can be concluded that among the five forces, the rivalry among existing competitors is the strongest force in BTX industry. This is mainly due to the high exit barriers and high commitment to the industry. Price competition and competition on other dimensions is moderate expressed. On the other hand, rivalry is weakening by small number of market players and promising industry growth that should continue the path in the future. The threat of new entrants, threat of substitutes and the power of buyers have moderate to high influence. In a case of the threat of new entry, this is mainly due to the high entry barriers that are shaped by high capital and regulative requirements and established relationship to the distribution channels. On the other hand, small number of manufacturers and promising market growth attract new entrants. Factors such as product differentiation, switching costs and incumbent's reaction to the new entry have moderate influence. Incumbent's reaction to the new entry is strongly expressed by manufacturers through maintenance of heavily investments in the BTX R&D. However, incumbents reaction to new entry is not characterized by price wars since producers are focusing more on penetrating the new markets. The tendency of strong influence of the power of buyers is due to the strong power of intermediate customers. The threat of substitutes is, on the other hand, mostly result of the emerging substitutes like REX that will gain power through increasing use and overcoming disadvantages of the current BTX products (side and adverse effects) in the future. Overall, the botulinum toxin industry is characterized by relatively strong rivalry, moderate threat of new entrants, moderate threat of substitutes, moderate power of buyers and low power of suppliers (Figure 9.). If this BTX industry structure is compared to the Porters structure of attractive industry which is characterized with few substitutes, modest bargaining power of suppliers and buyers, stable rivalry and high entry barriers it is evident that the BTX industry fulfills these criteria. Therefore, the BTX industry is assumed to be profitable to enter.

**Figure 9. Porter's five forces of botulinum toxin industry**



However, the main threats to a new entry lie in the high capital, R&D and patent costs. Also, threats are hidden in the high power of intermediate customers and increased usage of substitutes that overcome BTX disadvantages. Furthermore, although the suppliers have low bargaining power, a new entrant should be aware that this is due to the particularity of the BTX production process and hence the complex manufacturing plays a vital role for the industry profitability and hence should not be underestimated.

On the other hand, industry growth and few market players present opportunity for an entrant. A strength of the industry is that a high growth causes firms to concentrate more on penetrating new markets and customers instead of stealing customers from each other. Less price wars are assumed to take place as well. This is also supported by the fact that the industry is dominant by one producer which decreases the rivalry forces and also price competition. Furthermore, relative differentiation of the products and competition on the other dimension rather price can be source of positioning for a new entrant. The new entrant should seek to find the niche place among existing payers where it satisfies the needs that are not fully satisfied for example; to offer a product that has causes no immunologic reactions. Hence is could position itself as a producer offering a premium product that can be used over and over. Moreover, an entrant should take the advantage

of emerging markets. Existing players have been focusing their offers to the developing countries mostly since they have higher income and hence better purchasing power. However, the opportunity lies also in emerging markets like China or Brazil whose income is rising and hence will be more willing to purchase products that enhance quality of life like do BTX products. This is to be accompanied with the fact that the BTX cosmetic treatments are usually so demanded that customers do not wait for regulative approvals to be put into the power (which greatly decreases the entry costs).

To conclude, it has been shown that there are promising opportunities for a new entrant in the BTX market despite high entry barriers. In addition, future studies are encouraged to be done to analyze the appropriate market entry strategies particular to this industry.



## **Limitations**

There are some limitations of the case study research method used, as well as in the use of the document analysis data collection method. They include construct validity, personal integrity, prejudices and personal biases that may affect how the research has been conducted or which research methods were used. In addition, misinterpretation of written information may arise when conducting a document analysis. Desk research data collection includes limitations such as outdated or incorrect results and the amount of information available may be very limited. Subjective analysis used to illustrate the Porter's five forces elements is limited by author's personal and subjective interpretation.

Furthermore, companies are not eager to release their strategies. Thus analyzing them is difficult. Companies reveal only as much information as is required from them to publish or as much as they find it strategically beneficial. Hence, it has been difficult to obtain data that can potentially be of importance for the analysis. Therefore, the biggest limitation lies in the fact that the analysis has been performed only on the information publicly available and collected from secondary data.

Finally, limitations may result from the fact that the author of the topic had little prior-thesis knowledge of the botulinum toxin industry and therefore cannot guarantee that all of the analyses provided constitute a complete or correct picture of all forces shaping and influencing the industry.

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