



The Feasibility Study of Sativex in China

(Thesis for Master of Science in Business Administration)



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August 2007

Colophon

Title:

The Feasibility Study of Sativex in China

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Executive Summary

Cannabis, with another name as marihuana, is popular with drug addicts. But with the same function it has, cannabis can also work as a good pain reliever when other pain killers do not work effectively. Sativex is one of those cannabis-based medicines with the main function of pain relief. It first appeared in Canada in 2005 and brought good news to MS patients. This is the object for this paper, and it will take place in China where cannabis has not been used for medical purpose.

The objective of my principals is to ‘grow cannabis, manufacture Sativex and sell it within China’. So in this thesis, an elaborate plan for Sativex to enter into China will be developed. This objective brings us to the problem formulation of this thesis:

What strategic entry strategy should be applied for Sativex to enter into Chinese market and how to implement the strategy into practical operations?

In order to answer this problem, I developed several sub-questions and answered them step-by-step. Information gathering is the first step I went into. The information collection for the context of Sativex and its characteristics, marketing situation and the like was done in the Netherlands through visiting my principals and their company, and also Internet searching. Basic information of Sativex was indicated in chapter 3 and other information gathered in this phase was kept in mind as background knowledge throughout the whole research.

When everything was done in the Netherlands, I flew to China for the next steps because this research could be conducted more practically and information is more available in the target country.

After a complete analysis of the principals’ objective, I looked into the current situation in China for the possibility of realizing their objective. In this step, I concluded that ‘sell Sativex’ is the precondition for ‘grow cannabis’ and ‘manufacture Sativex’, so I investigated the narcotic drug market in China first to see if there is sales potential for Sativex in this market. Conclusions were made as Sativex has sales potential in China, so the next is to think about what strategy should be applied to realize the objective.

Some theories from Root were applied in the phase of choosing entry strategy. Various entry modes were explained with their advantages and disadvantages. Then based on the conditions of Sativex, I made trade-offs among those entry modes and finally chose the proper mode for Sativex, that is, *licensing*. This refers to the problem of selecting a good local licensee.

So later on, more practical plans for the entry activities were made in chapter 6, mainly concerning ‘selecting local licensee’ and ‘applying for the approval of Sativex’.

After all the plans were finished, a feasibility study considering financial aspects and political aspects was done in order to see the possibility of achieving the objective through the strategy chosen and plans made, also to test if the strategy chosen in the beginning was appropriate.

As a result, the strategy was proved to be proper. But it does not mean that the principals' objective can also be achieved. Due to the immaturity of Sativex in the international market and strict policies in China for narcotic drugs, it is very hard to predict the success of entry. Still, there is a chance for 'Sell Sativex' to be realized now though it is not easy to foresee the result.

So in the end, I gave some recommendations to my principals if they would like to have a try now. First of all, look for a 'good' local partner who can help them with the local activities, for example, dealing with government for the clinical trials approval. Secondly, doing more investigations when taking actions in China is necessary, because there are some shortcomings in this thesis that might give biased information. At last, paying attentions to special cultural features in China is also recommended, such as 'guanxi' and bribery.

If the principals do not want to enter into China now but later, based on the results given in this thesis, I would like to suggest them keep an eye on the policy changes in China and international market developments for Sativex, in order to make sure that they will not miss the right time.

Abbreviation List

ADS	Advanced Dispensing System; the system to assist and monitor patients with taking Sativex daily
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
GSP	Good Sales Practice
MHRA	The Medicines Healthcare Products Regulatory Agency
MS	Multiple Sclerosis
THC	Tetrahydrocannabinol; the active ingredient in cannabis plants

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Chapter 1 Introduction

1.1 Background and Objective

Sativex (the object of this research) is a cannabis-based medicine in the form of oromucosal spray, containing a defined quantity of specific cannabinoids. Clinical trials and researches are still ongoing in order to put Sativex into more areas of curing chronic pains. Till now, the main functions of Sativex, which have already been proved, are to cure the pains caused by MS and cancers. The scientists who discovered it and now continue research in this medicine, function as the principals of this graduation assignment.

GW Pharmaceuticals Company in the UK acts as the investor to conduct further developments of Sativex, including clinical trials, marketing and other related activities based on the 'know how' of the principals. And the Bayer Company takes the responsibility to penetrate the markets (now mainly in Canada). In April 2005, Sativex entered into its first market in Canada and brought a new treatment of relieving pains of MS to the patients. It used oromucosal spray instead of pills which makes the speed of relieving pains faster and leads to less side effects because it is a botanical product.

However, though already sold in Canada, Sativex still triggered the debates of medical marihuana widely. Many countries still take cautions in medical use of marihuana. GW Pharmaceuticals Company is now making efforts to enter into American market but it is foreseen to take a very long time to get an approval. Regulatory submission in four European countries (the UK, Spain, Denmark and the Netherlands) for the use of Sativex in the symptomatic relief of spasticity in patients with MS began in September of 2006, but until the 20th of July 2007, GW announced that it had chosen to withdraw its current regulatory application for Sativex in Europe and that it expected to resubmit an application for approval in 2008.¹

Though facing a lot of difficulties, progresses are being made. In Canada, efforts were made to extend the approval to the treatment of cancer pains, and on the 19th of June 2007, the approval was given by Health Canada. In the US, FDA permitted Sativex to enter directly into Phase III trials in cancer pains, allowing later stage of development to commence during 2007. Later on in June of 2007 Sativex license agreement was signed with Otsuka in the US.² In the lab, further encouraging data from Phase III trials in MS Spasticity and Neuropathic Pain has been obtained.

¹ GW EU Regulatory Withdrawal; Jul 20th 2007; from GW Pharmaceuticals website; <http://www.gwpharm.com/index.asp>

² Health Canada Approves Sativex® For Cancer Pain; Aug 7th 2007; from GW Pharmaceuticals website; <http://www.gwpharm.com/index.asp>

As a conclusion of Sativex international, the success from North America has been seen while the temporary failure in the EU countries happened not long ago. GW Company is making efforts to resubmit in EU countries and extend Sativex worldwide.

In China, however, narcotic drugs are restricted in the area of medical use by government, from the supply of raw material, production to distribution. But with the growing number of patients in cancer and the lack of effective treatment of relieving pains, some new narcotic drugs have been imported from abroad recently. Sativex could introduce more chances to patients in China for relieving pains as well. So Sativex may have the possibility of being developed in China.

GW Pharmaceutical Company in the UK bought the patent of these cannabis-based medicines from my principals. And it takes charge of granting the sales right to other companies in different countries; conducting further developments of Sativex and kinds of clinical trials; dealing with local government for the approvals; and the like. According to the negotiation between GW and my principals, my principals keep the right of using the patent in China, so they want to investigate the Chinese market now and see if it is feasible to grow cannabis, manufacture and sell cannabis-based medicines in China.

This brings me to the following objective for my research:

The objective of this research is to develop a plan for the entrance of Sativex in Chinese market.

1.2 Problem Formulation

Based upon the background of the research and the formulated objective, the problem formulation is defined. The following aspects are considered in order to come to a well-defined problem formulation.

- The objective of the study indeed involves a development of international market entry strategy, which involves four elements (choosing the target product→setting objectives and goals→choosing the entry mode→designing the marketing plan). The principals aimed to investigate all the cannabis-based products in all area, but due to the limit of time and resources, I did some pre-market research and chose cancer as the area to be studied so that Sativex (the only product functioning on relieving cancer pains) is the target product in this research. Principals' objective is to grow cannabis, manufacture and sell Sativex within China. So what I have to do is to assess the environment in China in order to see what entry mode is suitable and if it is possible for them to conduct this entry mode and how to do it.
- Because of the specialty of Sativex, legal consideration is vital to the feasibility study. In China, government operations are not transparent and the problem of corruption exists, so looking for a good local partner can be very helpful for

practical operations. Therefore, this study will emphasize the selection of a local partner and the legal approval of Sativex.

Based on the above statements, the problem formulation is defined as follows:

What strategic entry strategy should be applied for Sativex to enter into Chinese market and how to implement the strategy into practical operations?

A proper strategy will lead us to a more thorough analysis of the environment in China, thus we can know if Sativex will be legally accepted and also economically feasible in the potential market.

1.3 Research Questions

Problem formulation has provided a strategic view and an overall goal for the study, and it will be broken down into some research questions as the answers to construct the whole thesis. The logic of constructing this thesis basically follows ‘The Elements of an International Market Entry Strategy’ [Root 1998], which will be presented in chapter 2.1 in details. Some modifications were made mainly based on principals’ objectives, which we will see in the modified figure of ‘The Elements of an International Market Entry Strategy’ in chapter 2.1.

My research questions are:

- 1 What is the related information of Sativex, since it is a special product and most of people are not familiar with it?
- 2 What are the key issues considering principals’ objectives, and the possible obstacles?
 - 2.1 Grow cannabis in China: What is the situation for growing cannabis in China now and, what may be the main obstacle?
 - 2.2 Manufacture Sativex in China: What is the situation for manufacturing narcotic drugs in China and, what may be the main obstacle for Sativex?
 - 2.3 Sell Sativex in China: Is there sales potential for Sativex in China? If yes, then what may be the main obstacle?
- 3 How to choose the right entry strategy for Sativex?
 - 3.1 What are the strategic options?
 - 3.2 What are the advantages and disadvantages for each option?
 - 3.3 Which option will be the final choice for Sativex?

- 4 What are the practical project plans according to the entry strategy chosen?
 - 4.1 How to select a proper local partner?
 - 4.2 How to apply for the licensing of Sativex from SFDA?
- 5 Looking back, is the entry strategy feasible in practice in China?
 - 5.1 Is it feasible for Sativex to enter into China with this strategy politically?
 - 5.2 Is it feasible for Sativex to enter into China with this strategy financially?

1.4 Research Methods

This part indicates which research methods are needed; and what kind of data will be acquired in order to answer the research questions.

The research here involves exploitive and explorative methods, which means a lot of information related to the objective-analysis would be exploited and alternative choices will be made on the basis of the analysis as explorative work.

The method of data collection involves the choice between primary data and secondary data, and the techniques designed to use the data collected.

Primary data tends to be costly but very important for some research items. On the purpose of getting first-hand and accurate information, primary data shows the importance. In this research, some primary data will be collected from the principals concerning the characteristics of Sativex and the current situation concerning safety, efficiency and effectiveness of this medicine because Sativex is still new and information about it in public is not sufficient. Also, primary data is needed from the hospitals that will be the customers of Sativex to better fulfill the market assessment and feasibility study.

Secondary data is as important as primary data in this research. It is hard to get first-hand data for estimating the gross market for pain cure medicines, so secondary data available in the Internet, magazines or books is necessary to complete this research. Though secondary data can be low cost and easier to get access to, the problems of outdated and bias do exist, so further certification and study is needed based on the indicators from secondary data.

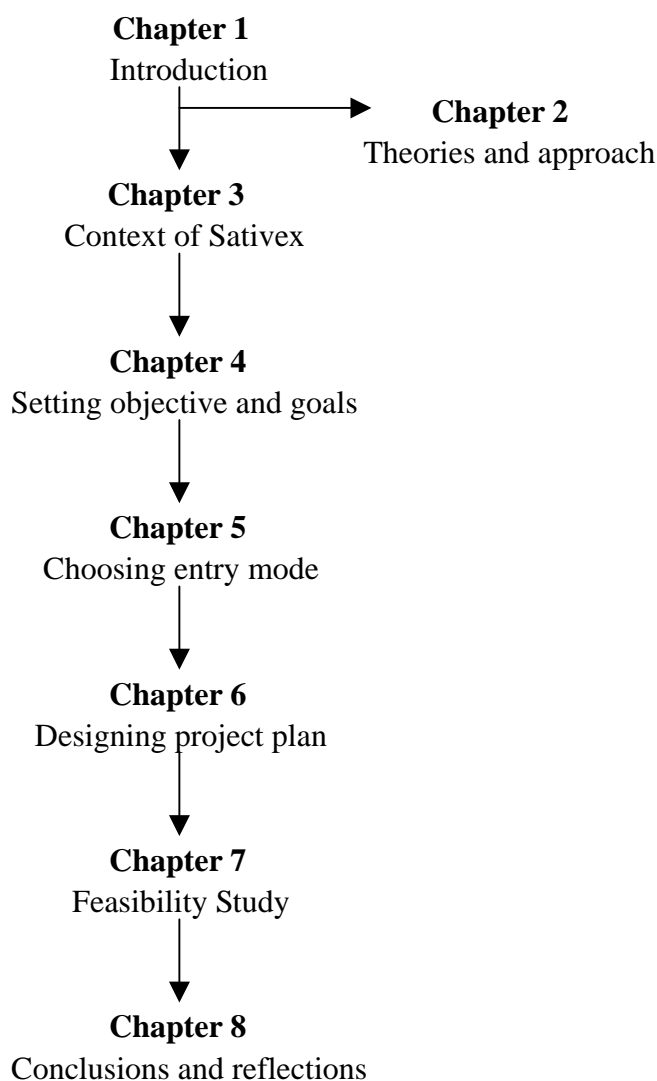
For this research, first of all, qualitative primary data will be collected from the principals about Sativex in order to get to know the characteristics of the product and therefore be prepared to investigate competitive advantages. Then secondary data of the current development of Sativex collected from the company website and other sources from the Internet will be used to get a more thorough understanding of the legal, market, and other issues of Sativex international.

After an overview of Sativex, an elaborate description of principals' objectives will be conducted with some qualitative and quantitative data to study the current situation in China related to the objectives. Then for designing the project plan, qualitative second-hand data will be collected from the websites and some other sources for selecting local partner and for licensing.

Finally, quantitative and qualitative second-hand data is collected together with primary data to study the feasibility.

The research will be conducted first in the Netherlands in order to get better contact with the principals for primary data and clear communication of the research purpose. Then activities will mainly happen in China so that direct contact with staff in the hospital, government departments and the like will offer more reliable data for the research.

1.5 Structure of the Thesis



Chapter 2 Theories and Approach

2.1 Introduction

After writing the research plan it is necessary to determine which approach and theories of international entry mode strategy will be used as a framework to find a solution for the problem formulation in a scientific way.

This chapter is the result of the literature research done in the Netherlands. The purpose of this chapter is twofold. On one hand, I want to conduct the research under the theoretical logic from the literature in order to make the study more scientific and the analysis more thorough. On the other hand, the theories from the literature will also be tested by the practices of research to see the application value.

First of all, I would like to introduce the theoretical framework that will be used as a guide to conduct this research, which was mentioned in the previous chapter. ‘The Elements of an International Market Entry Strategy’ model [Root 1998] will be applied here as the main structure of this thesis, but some changes have to be made in practice. We will see the changed model below:

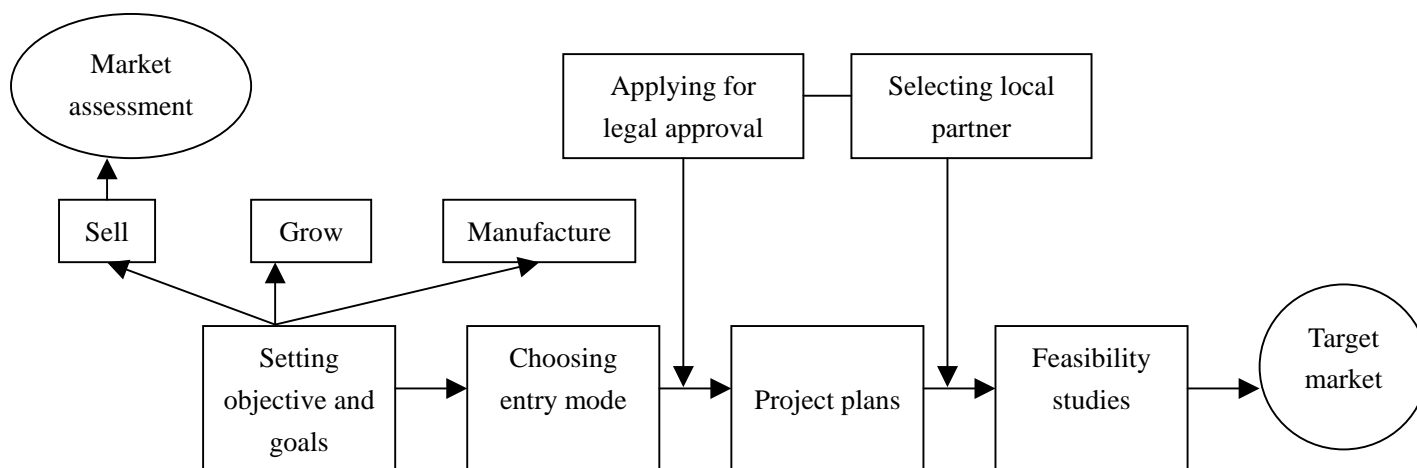


Figure 2.1: The Elements of an International Market Entry Strategy [Root 1998]

2.2 Setting Objective and Goals

The choice of target product and market is the first step of entry strategy. But in case that China has been chosen as the target market by the principals, there is no need to conduct ‘choosing the target market’ in this research. And according to my principals, all the cannabis-based products from GW Pharmaceuticals could be target products in

China. But because of limited time and resources, I will choose Sativex from all the products to be the target product in my research and I will give explanations for my choice in section 4.3.

Therefore here comes ‘setting objectives and goals’ the first step of my research. The objectives set in this research are based on the principals’ demands. So first of all, a detailed description of principals’ three objectives will be given and the reasons of each objective.

Grow cannabis & Manufacture Sativex

In the section of ‘grow cannabis’ and ‘manufacture Sativex’, mostly the qualitative data will be collected to describe the current situation in China and then I will analyze the main obstacles.

Sell Sativex

In this section, a description of the target product will be conducted through data collection and market assessment is undergoing in order to see if ‘sell Sativex’ could be possible in China.

In the introduction part of ‘sell Sativex’, data from GW website indicating the characteristics and functions of Sativex and other cannabis-based products is gathered. Also, those information will be completed by some primary data from my principals so that our understanding of Sativex could be clearer. This part is the preparation for the following ‘market assessment’.

In the ‘market assessment’ part, the two-step analysis method will be applied. This method consists of two levels of market screening: industry market potential analysis and company sales potential analysis.

Estimating industry market potentials:

Two fundamental approaches may be used to estimate industry market potential: top-down and bottom-up. In the case that the number of final users of this kind of medicines is hard to calculate from the bottom, I choose ‘top-down’ approach to estimate the market size and growth. Secondary quantitative data about the amount of narcotic drugs consumed in China in recent years is used to assess the market size and market growth, so a conclusion of the industry sales potential can be made, which is called the first step analysis.

Estimating company sales potentials:

Based on the industry-level analysis, I continue with this level of analysis in order to get a more accurate estimate of market potentials for Sativex.

In this phase, information of competitive products in this narcotic drug market will be collected as well as the characteristics of the target product from the introduction part,

so some comparisons (referred to price, functions, marketing factors and so on) could be made and thus a conclusion of company sales potential can be made.

2.3 Choosing Entry Mode

2.3.1 Introduction of Various Entry Modes

Based on the knowledge from chapter one of 'Entry Strategies for International Markets' [Root 1998], there are three main categories of entry mode. In this part, I will give the definition of each entry mode and also some related information such as advantages and disadvantages.

2.3.2 The Table of Analysis for Sativex Entry Mode

After the introduction of kinds of entry modes, factor analysis of Sativex will be conducted in this part. Table 2 'External and Internal Factors Influencing the Entry Mode Decision' in chapter 2 of 'Entry Strategies for International Markets' [Root 1998] is modified and then applied in this section. All the possible entry modes are offered in the table with their advantages and disadvantages under certain conditions. Then I fit the conditions of Sativex into this table and analyze. The second step of this study is the selection of the proper entry mode. This choice is made based on the conditions we have and also the restrictions. Some factors must be considered when making decision and trade-off is necessary. I can just say I have chosen the most proper entry mode but not the perfect one. I used the calculation of scores for each entry mode, the one with the highest score is chosen.

2.3.3 Final Choice of Entry Mode

A more detailed explanation of having the final choice will be presented in this part. What is more, the following model (figure 2.2) and theories from chapter 6 of 'Managing in Developing Countries: Strategic Analysis and Operating Techniques' [Austin 1990] will be explained here too. We will analyze the reasons of making this final decision through another aspect.

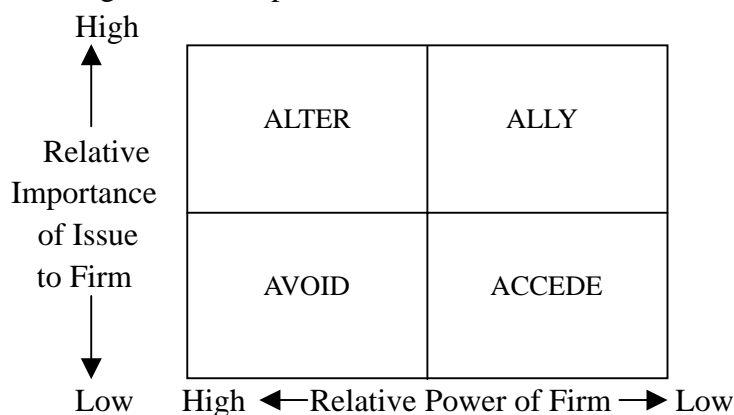


Figure 2.2 Strategic Approaches to Government Relations [Austin 1990]

2.4 Designing Project Plans

In this sector, plans are mainly about selecting local licensee and getting the approval for Sativex.

2.4.1 Selecting Local Licensee

The knowledge of ‘picking the right partner’ from chapter 5 of ‘Entry Strategies for International Markets’ [Root 1998] will be helpful for selecting the local partner. But in practice, I am not going to select a local licensee strictly according to theories since the situation is different. My task is offering some useful information of local related companies to my principals and searching for a possibility of realizing Sativex in China but not as formal as establishing a local partner. So I will have a profile according to the principals’ objectives – ‘grow cannabis, manufacture Sativex and sell Sativex’ in mind, and then gather information of all the possible partners in China. Later on, some selections will be made and also suggestions for the principals.

2.4.2 Applying for the Approval of Sativex

This phase of the paper will answer the question ‘How to get the licensing from the Chinese government?’. Information from the website of the State Food and Drug Association will be collected on the purpose of understanding the basic knowledge of how to apply for kinds of certification such as GCP, GMP and GSP. Also, some information about SFDA and the functions of each department will be presented to make things clear.

2.5 Feasibility Study

This part could be said as a small review of all the above sections because a systematic analysis of feasibility will be made, including financial feasibility study and political feasibility study. In this part, mostly practical work will be conducted. Some useful primary data from related organizations could be very helpful. Explorative work accounts for the major of this section.

Chapter 3 Context of Sativex

3.1 Company Context

The company context of Sativex is valuable for knowing more about the current situation and the developments of Sativex, and who can make contributions and how. It is a bit complicated, so I am going to draw a map in order to elaborate the relationships among related companies clearly.

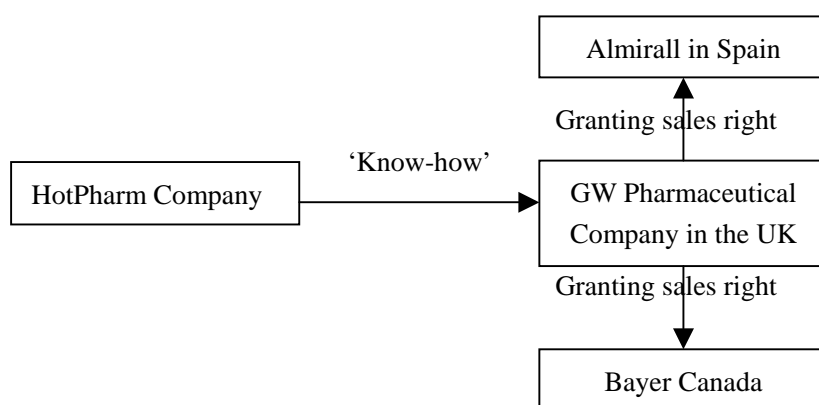


Figure 3.1 The Relationships Among Related Companies for Sativex

1. **HotPharm Company:** This is a small-size company located in the Netherlands, with my principals David Watson and Michael Rich as joint owners. This company keeps the ‘know-how’ of producing cannabis-based medicines with high THC ingredients. The functions of this company contain looking for new investors for the new products; keeping updating the technology, that is, the ‘know-how’; cultivating cannabis in the Netherlands; exploring new markets; offering technology support to GW Pharmaceutical Company and acting as a shareholder.
2. **GW Pharmaceutical Company:** It is licensed by the UK Home Office to work with a range of controlled drugs for medical research purposes. Sativex is the lead product from GW. GW got the ‘know-how’ from HotPharm and owned its own research team to develop the registered product Sativex. GW was originated from 1998 for cannabis products research and till now, it has already formed a systematic organization with 120 employees. The functions of GW include botanical research, breeding and cultivation; pharmaceutical production; pharmaceutical development (analytical, formulation, drug delivery); regulatory; medical/clinical; pharmacology; software/electronics; intellectual property; quality assurance; and supply chain/logistics.³ Everything GW has done contributes to the developments of Sativex and other cannabis-based medicines,

³Corporate Information; 2007; from the homepage of GW;
http://www.gwpharm.com/corporate_management_team.asp

for example, expanding international markets to Canada, the US, four European countries; conducting clinical trials to get approvals and so on. All of these will do good for the entrance of Sativex in China, because the more developed Sativex is, the bigger the possibility to enter into China. I have kept an eye on the website of GW during the whole research.

3. **Bayer Canada:** Bayer is an international pharmaceutical sales company originated from Germany. Bayer Canada got the licensing from GW to explore the market in Canada and succeeded. This success means a huge step for Sativex's international expansion. As referred in chapter 1, progresses are being made in Canadian market.
4. **Almirall in Spain:** This is a middle size company which also got licensing from GW to explore the markets in Spain but the approval has not been gained yet.

3.2 History Context

After describing all the related companies for Sativex and their relationships, I would like to introduce more about the cannabis products (I will use THC instead of cannabis later because it is the active ingredient of Sativex) in the world. Since this kind of products always trigger a lot of debates about medically used marijuana worldwide, so here we have to see how the international environment goes till now for THC medicines.

The earliest THC product is MARINOL from Unimed Pharmaceuticals approved since 1985 by the US FDA, which was regulated under Schedule II of the Controlled Substances Act at the beginning. MARINOL has two uses: first, it treats nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional treatments; second, it also treats appetite loss associated with weight loss in people who have acquired immunodeficiency syndrome (AIDS).⁴ With many years' clinical results and company's efforts, MARINOL has already been listed under Schedule III of the Controlled Substances Act, which indicates a lower abuse potential for the product. It is the only approved THC product in the US.

The second one is Nabilone (Cesamet®) produced by Cambridge Laboratories. Cesamet® (Nabilone) is a new therapeutic option for treating patients with chemotherapy-induced nausea and vomiting (CINV) who have failed to respond adequately to conventional antiemetic treatments.⁵ Eli Lilly Pharmaceutical marketed it since 1985 and then withdrew it from the market in 1989 for commercial reasons. In 2000, Valeant Pharmaceutical bought it from Lilly and currently sells it both in Canada and the UK. On 15th of Feb 2007, Valeant acquired the commercial rights to Nabilone in the United Kingdom and other European markets from Cambridge

⁴ About Marinol; 2006; from Solvay Pharmaceuticals, Inc.; <http://www.marinol.com/aboutmarinol/index.html>

⁵ About Cesamet; 2007; from Valeant Pharmaceuticals International; <http://www.cesamet.net/index.htm>

Laboratories for \$14 million.⁶ Valeant owns the UK as the sole marketer.

Then in 2005, Sativex was approved in Canada after the appearance of Nabilone for MS pains as a more advanced product, which has better effects in the form of oral-spray instead of capsule or tablet. And it has extended the approval to the treatment of cancer pain on the 19th of Jun 2007. The applications in the four EU countries were already withdrawn but a reapplication will be submitted. Progresses are being made in the US since 2006.

In China, THC products have not appeared before and cannabis is listed in the schedule of controlled narcotic drugs and, it has not been applied for medical use till now. China is a 'zero' market for THC products, so is for Sativex.

3.3 Conclusions

This chapter introduced the company context and the history context of Sativex. Company context explained the relationships among the related companies to Sativex and their contributions to the developments of Sativex worldwide. History context elaborated the developments of all the cannabis-based medicines in the world and the current situation of Sativex international.

There are four companies involved for Sativex: HotPharm is a small company owned by my principals in the Netherlands and its main contribution to Sativex is the 'know-how', based on which Sativex was developed. GW contributes to the further developments, regulatory approvals, marketing and other related activities for Sativex. Sativex is the lead product owned by GW Pharmaceuticals and only GW has the right of licensing sales right to other companies in the world. My principals act as the shareholder of GW and give technical support. Granted by GW, Bayer and Almirall take charge of exploring the markets in Canada and Spain separately.

Compared with MARINOL and Nabilone, Sativex is relatively new to the world as the third cannabis-based medicine since the year 1985. Progresses are being made in Canadian and American markets while a temporary failure happened recently in the EU markets. And in China, the market for medical cannabis is still 'zero'.

Till now, the related information of Sativex has been presented and it is not a 'stranger' any more. All the information mentioned above will work as the background knowledge for the following chapters. Following the research questions, I would like to start with the principals' objectives, that is, the objectives of this paper for the next step. More information concerning Chinese market will be given during the explanations of objectives in order to gain an overview of Sativex in China.

⁶ News releases; Feb. 15th 2007; from Valeant Pharmaceuticals International;
.http://www.valeant.com/mediaCenter/newsArticle/newsArticle.jspf?objectId=4188

Chapter 4 Setting Objective and Goals

In 1990s, the principals visited China for investigating the feasibility of Sativex once. After doing some researches and also visiting the SFDA in China, they knew that was not the right time to enter into China because the narcotic drug market was still very strictly controlled by the government. Now, because of the more mature international environment for cannabis-based medicines, the principals want to enter into this market again in China. Is China ready for Sativex now or just like in 1990s? This is the problem that should be answered throughout this research step by step.

In this step, I will begin with the objective the principals want to achieve this time. During the analysis of each goal, some answers will be given out, which will offer the basis for strategy designing. As the principals proposed, the final objective is to **grow cannabis**, **manufacture** and **sell** Sativex in China. I will discuss those three goals separately in the following content.

4.1 Grow Cannabis

The core technology of my principals is the transformed cannabis seed with high THC. In order to grow standard cannabis plants for producing Sativex, the initial plant is grown from seed but all subsequent plants are grown from cuttings or 'clones' so that they are genetically identical. What is more, the cannabis plants are grown in highly secure computer-controlled glasshouses. All aspects of the growing climate, including temperature, humidity, air change and photoperiod, are computer-controlled so that the plants are grown to very strict pharmaceutical standards to ensure continuity of supply.

So in order to manufacture Sativex in China, a place with all the devices and technology for growing high THC cannabis plant is necessary. Let us see the environment for growing cannabis in China.

In China, only industrial cannabis is allowed to be grown. Industrial cannabis means the cannabis with very low THC (<0.3%) that will not be abused as drug; and medical cannabis means the cannabis with normal level of THC (>0.5%) that can also cause addiction problems. The Holly Group is the only organization that is allowed to grow industrial cannabis, which is located in Yunnan. Under Holly's permission, industrial cannabis is grown in some places in Yunnan, Gansu and some other provinces. Growing industrial cannabis should be inspected by related local government departments and controlled by very strict regulations; medical cannabis is not allowed to be grown in China now.

Therefore our task in this research is to investigate the possibility of growing the high THC cannabis plants in China under the environment described above and, if yes what strategy we can use to realize this possibility. The main obstacle in this part is that medical cannabis is not allowed to be grown in China; because the market for medical cannabis does not exist in China, so there is no need to grow this ‘dangerous’ plant in case addiction problems may happen. So we have to go to the ‘sell’ part to learn that if there will be a market for Sativex in China first and then comes the ‘grow’ research.

4.2 Manufacture Sativex

Manufacturing Sativex involves two patents (also technologies); one is the ‘spray technology’ which means an approved spray pump by MHRA in the UK; the other is the extraction technology for extracting needed ingredients from the cannabis plants. So this means that certain devices are needed to manufacture Sativex.

Based on the researches the principals did 20 years ago and the knowledge they have now, they think investing technology and devices in China to produce Sativex is technically possible. So they decided to look into the possibility of manufacturing and then selling Sativex within China.

As said before, there is no presence of medical cannabis in the market yet, so it is the same that no manufacture of cannabis-based medicines is available in China now. But I will describe the narcotic drug production, since cannabis is on the list of narcotic drug in China. A specific GMP should be obtained for manufacturing narcotic drugs from the SFDA; there is a control on the number of enterprise which can produce narcotic drugs, if the supply can still meet the need then hardly could a new enterprise get the approval for producing narcotic drugs; for these enterprises, a day-to-day online inspection is needed to ensure all the activities done by the enterprises are legal. So we can see strict policies are executed to the manufacture of narcotic drugs in China.

On the bright side, fortunately, there do exist some companies in China which produce narcotic drugs. So looking for a local partner could be a choice to fulfill this objective. Thus, our task for this objective is to develop a strategy to make manufacturing Sativex possible in China.

However, there are still preconditions for manufacturing Sativex----growing medical cannabis and selling Sativex should be allowed in China, and selling Sativex is the initial condition for all. Therefore, I am going to look into ‘selling Sativex’ in the next section and then make a conclusion for those three objectives.

4.3 Sell Sativex

As mentioned in ‘grow cannabis’ and ‘manufacture Sativex’, there is still no market for cannabis-based medicines in China, so it is hard to tell the possibility of ‘grow cannabis’ or ‘manufacture Sativex’. ‘Sell Sativex’ is the precondition for growing cannabis and manufacturing Sativex because only when there is a market for cannabis-based medicines, then grow and manufacture can be discussed. Therefore in this part I will look into the Chinese market to learn if it is possible to sell Sativex in China through ‘market assessment’. Furthermore, information of distributing Sativex will also be mentioned in this section.

4.3.1 Introduction

The principals asked me to look into every area where cannabis-based medicines can be applied. But it is not realistic to do research about all the diseases since time and resources are limited. Cannabis is on the list of controlled narcotic drugs in China, considering about its specialty, I will choose the most emphasized disease by Chinese government as the area of research, that is, cancer. The reason of choosing most emphasized disease is that the government is more likely to allow the development of controlled narcotic drugs only when it is to some extent necessary.

Before the market assessment of Sativex, I would like to introduce all the cannabis-based medicines from GW briefly so we can know why Sativex was chosen as the target product but not other cannabis-based products from GW.

Product portfolio

The graph below presents all the pains that could be relieved by all the products and the clinical processes they are in till now. Researches and clinical trials are being conducted in order to take each function to the ‘approval’ step, and progresses are realized gradually.

The function of relieving MS pains was approved by Canadian FDA in 2005, and the function of relieving cancer pains was just approved in 2007. The product with those functions is named Sativex. As said before, I choose cancer as the area for research though MS is the first one to be approved. Here is my reason: MS is more popular in the Western countries than Asian countries; the rate of MS occurrence keeps climbing up in Western countries but is much lower in the Asian countries like China; the higher the latitude, the higher occurrence rate for MS; Canada is one of the high MS occurrence countries⁷, so the cannabis-based medicines got approval on relieving MS pains in Canada. When the product comes to China, some changes have to be made to fit Chinese market. In China, cancer is the up-to-date issue. The rate of occurrence has not been controlled yet while the rate has already gone down in developed countries.

⁷ The Developments of MS Research; from China MS website; <http://www.chinams.org/Web/research.asp>

The government is making efforts to promote activities concerning preventing, curing cancers, as well as relieving pains from cancers. So cancer is chosen to be the target area for research and therefore Sativex becomes the target product.

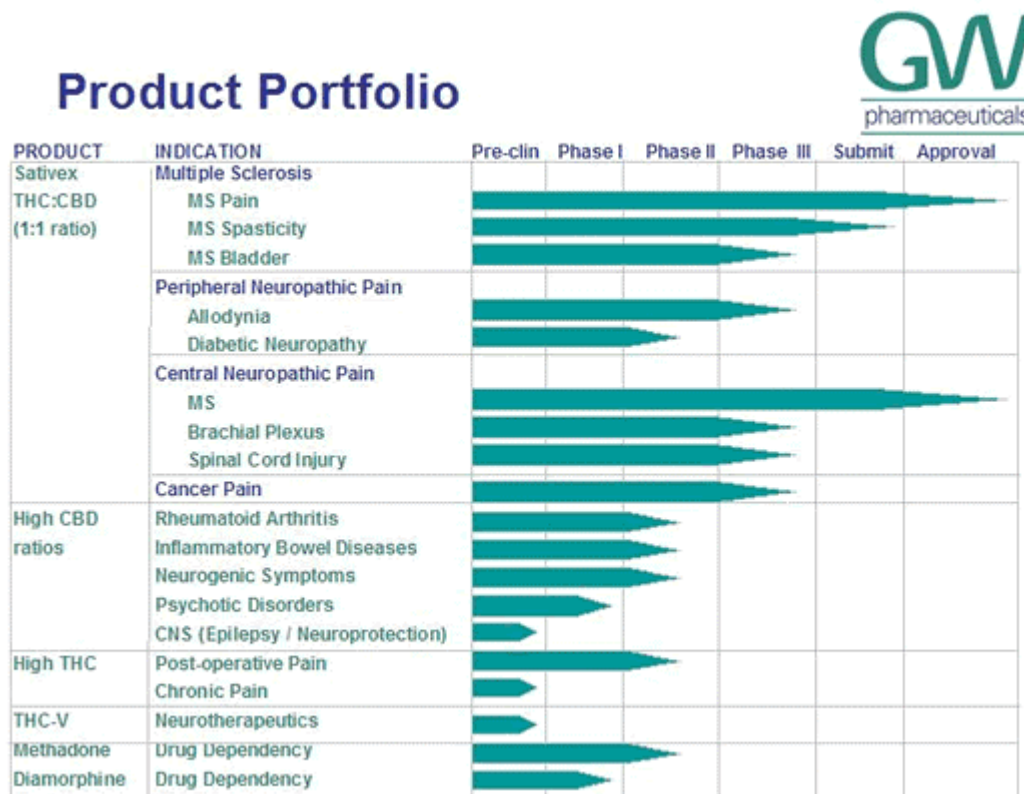


Figure 4.1 Product Portfolio of Cannabis-based Medicines [GW Pharmaceuticals 2007]

4.3.2 Market Assessment

After deciding the target product and area, an analysis of current market is necessary to decide whether the target country is suitable for the target product. In this case, the ‘two-step analysis’ [Root 1998] will act as the guide to conduct market assessment. This method consists of two levels of market screening: industry market potential analysis and company sales potential analysis (see section 2.2).

1. Estimating industry market potentials:

Two fundamental approaches may be used to estimate industry market potential: top-down and bottom-up. In this research, I choose ‘top-down’ approach to estimate the market size and growth.

In China, the statistics of cancer patients is not complete, so it is hard to use the data of consumers to estimate the market size and growth. Instead, I use the consumption data of narcotic drugs in China to do this estimate. Before analyzing the data, I would

like to introduce the ‘3-ladder pain cure method’ which influences the narcotic drug market indirectly and is important. ‘3-ladder pain cure method’ is the principal way of treating cancer pains, and ‘pain killers’ in China are applied to cancer pains according to this method. Chinese government agreed to introduce new narcotic drugs because they can perfect this method.

3-ladder pains cure method:

Pains can be divided into 3 levels:⁸

- 1) 1st level: 1~4 the lightest level of pains. Patients have the feelings of pains but they can endure them and live as normal. In this level, medicines like aspirin but not narcotic drugs are used.
- 2) 2nd level: 5~6 the middle level of pains. Patients have strong feelings of pains so that they cannot sleep. In this level, some weak narcotic drugs are applied such as Codeine.
- 3) 3rd level: 7~10 the highest level of pains. Patients have very strong feelings of pains and they cannot sleep, while sometimes they also have neurotic disturbance. In this level, strong narcotic drugs are applied like Morphine and Pethidine.

In China, treatments for the 1st level pains are already sufficient and the government need not take many efforts to improve pain control level for 1st level pains now, but the situation is different for 2nd and 3rd levels of pains. Narcotic drugs are the main treatments for those two levels of pains, and the treatments for 2nd and 3rd levels of pains are not sufficient due to the strict policies on the use of narcotic drugs. Before the 21st century, cancer patients had to suffer a lot from strong pains just because there was a quota for each patient on the narcotic drugs. The level of pain control in China was much lower than the international level. We can see the proof from the following tables.

Years	A	B	C	A:B	A:C	B:C
1997	15.80	0.77	0.081	20.5	195.1	9.5
1998	17.83	0.93	0.087	19.2	204.9	10.7
1999	17.79	0.38	0.110	46.8	161.7	3.5
2000	22.28	0.38	0.130	58.6	171.4	2.9
2001	24.00	0.47	0.163	51.1	147.2	2.9

A: Developed countries; B: Developing countries; C: China

Table 4.1 The Comparison of Morphine Consumption in China with other Developing Countries and Developed Countries (mg/per person) [Kong 2005]

Seen from the data in table 4.1, the gap is huge between China and developed countries. Even among developing countries, the pain control level in China is much lower than the average level. So in order to raise the pain control level, the new policy was pushed out--‘prevent cancer patients from pains’-- by the Chinese government.

⁸ 3-Ladder Pain Cure Method; Feb. 3rd 2005;
<http://www.fx120.net/JBZT/ZHONGL-/atzxl/ATCS/200502030852513533.htm>

The reason that the Chinese government pushed out this policy is that Chinese government was forced to catch the international pain control level. We can see what the situation was before this new policy and what happened after the new policy from table 4.2.

Years	Morphine	Codeine	Pethidine
1984	4	328	1097
1989	10	403	2135
1991	28	441	2596
1996	144	2528	2622
2000	162	3870	2361
2001	213	5127	2447

Table 4.2 The Consumption of Three Main Narcotic Drugs in China (kg) [Kong 2005]

From table 4.2, we can see a sudden increase of the use of Morphine and Codeine, and a gradual increase of traditional narcotic drug Pethidine in the end of 20th century. The Chinese government not only tried to improve the treatments for 2nd and 3rd levels of pains by increasing the amount of narcotic drugs, but also adopted new types of narcotic drugs to perfect the 3-ladder pain cure method. For example, Pethidine was the mainly narcotic drug in China with instant pain relief function, but because of its strong side effects, Chinese government has cut down its amount in the market gradually and finally stopped it. Instead, Morphine took place of Pethidine in this area. What is more, other narcotic drugs are now available in the market for these two levels of pain, for example, Oxycontin and Durogesic.

So in the narcotic drug market, not only the amount was increased, but also was the sort of narcotic drugs. More kinds of narcotic drugs were introduced for 2nd and 3rd levels of pains on the purpose of perfecting the 3-ladder pain cure method. Thus we can conclude that there could be a market for more new narcotic drugs to enter into this growing market, such as Sativex.

However, the market size for narcotic drugs is relatively small compared to international level. But the market has kept growing from the end of 20th century and the growth rate also climbed because the government keeps improving the 3-ladder pain cure method. So in this step of analysis, we consider the Chinese market is attractive for Sativex to enter into.

2. Estimating company sales potential:

Based on the industrial level of analysis, I continue with this level of analysis in order to get a more accurate estimate of market potentials for Sativex. In this phase, information about competitive products was gathered and comparisons will be made to see if Sativex has the competitive advantages to be accepted in the new market. The information of competitive products to Sativex was listed in the following table and some explanations were made below the table.

Category	Fentanyl Transdermal System	Morphine Sulfate Controlled-release Tablets	Oxycodone Hydrochloride Controlled-release Tablets	Cannabis Oromucosal Spray****
Produced by**	Janssen Pharmaceutica In Belgium ALZA Ireland Ltd. In Ireland	Beijing Mundipharma Ltd. In China	Bard Pharmaceutical Ltd. In the UK	GW Pharmaceutical Company In the UK
Imported by**	Xian-Janssen Pharmaceutical Ltd. In China	None. Local product	NAPP Pharmaceutical Ltd. In the UK	None
Distributed by**	China National Pharmaceutical Group Corporation	China National Pharmaceutical Group Corporation	China National Pharmaceutical Group Corporation	None
Price in China***	84.4yuan/2.5mg sticker	4.39yuan/10mg tablet	9.4yuan/10mg tablet	Unknown
Duration of permission**	2004-01-21~ 2009-01-20 2006-09-12~ 2011-09-11	2002-07-10~ no limit date	2004-01-21~ 2009-01-20	Not yet
Function*	Relieving middle to high levels of cancer pains; The effect can last for 72 hours; 150mg Morphine = 1mg Durogesic	Relieving middle to high levels of cancer pains; The effect can last for 12 hours; mg Morphine = mg Mei Shi Kang Ding	Relieving middle to high levels of cancer pains; The effect lasts for 12 hours; mg Morphine = mg Oxycotin	Relieving middle to high levels of cancer pains; more instant effect; 2mg Morphine = 1mg Sativex; No increase of the dosing level in the long-term
Product name**	Durogesic; Durogesic D-TRANS	Mei Shi Kang Ding	Oxycotin	Sativex
Market	17,128,499 Yuan in 2004*****	No data	No data	No data

*see the appendix 1 for the amount comparison with the same pain relief function between morphine and the drugs above

**all the information with this ** mark is from www.sda.gov.cn

***the information of price is from www.xjdrj.gov.cn/articleimages/2006-5-24/mzbtb.xls

****all the information concerning Sativex is from GW website and my principals

*****the data is from www.xinyoo.com/news_show.asp?type=3&Id=325

Table 4.3 New Narcotic Medicines in the 21st Century

There are kinds of narcotic drugs in China, for example, cocaine, concentrate of poppy straw, Dihydroetorphine, Diphenoxylate, Fentanyl, Methadone, Morphine, Opium, Oxycodone, Pethidine, Poppy Shell, Codeine and so on.⁹ For cancer pains, Pethidine was used most often before and morphine is the one now. Some new drugs have been introduced into this market to perfect the '3 ladder pain cure method'. Some of them were developed locally and some were imported from abroad. In this table, I chose some new narcotic drugs, which were introduced into Chinese market after the stop of Pethidine, because they construct the new narcotic drug market and they can present the competitive product market for Sativex.

Comparisons and Conclusions:

1. Advantages of above three products compared with traditional narcotic drugs in China:

- 1) Less amount with same pain relief effect
- 2) Instant pain relief function as traditional morphine with another function constant effect (Durogesic 72 hours and the other two 12 hours)
- 3) Less side effects than Pethidine

2. Comparisons among three new narcotic drugs:

- 1) Same pain relief function with longer effect: Oxycontin and Mei Shi Kang Ding have the same pain relief effect with traditional morphine. The most obvious advantage is that both products are in the form of controlled-release tablets, which means these products can last for longer effect besides instant pain relief function.
- 2) Better pain relief function with longer effect: Durogesic has much better pain relief function than morphine with the same amount. Another advantage is the same as Oxycontin and Mei Shi Kang Ding, which is longer effect.
- 3) Price difference: Oxycontin and Mei Shi Kang Ding are sold in a relatively low price, while Durogesic is sold at a much higher price. Oxycontin is imported from the UK, so with similar functions, it is a bit more expensive than Mei Shi Kang Ding, which is produced locally. Durogesic is imported from Belgium, and with stronger pain relief function, so it is sold at a much higher price.
- 4) Form difference: Oxycontin and Mei Shi Kang Ding are in the form of tablet, which means their usage is limited, for example, patients with stomach cancer who can hardly swallow anything cannot use tablets. But Durogesic is in the form of sticker, patients just need to stick it on the skin where they feel pains, so patients with stomach cancer can use it.
- 5) Sativex: Concluded from GW website and descriptions from my principals, Sativex has the same advantages as Durogesic: one is that it has better pain relief function than morphine; the other is that it is in the form of oral spray not tablet so it is more widely applied than tablets. Meanwhile, Sativex has more advantages: One is that it is botanical product so that it will not bring serious side effect as

⁹ The list of controlled narcotic drugs in China; Sep 27th 2005; from SFDA homepage; http://www.sda.gov.cn/cmsweb/webportal/W945325/A64004861_1.html

compounded products, such as Pethidine which has been stopped in China; the other is that there is no increase in the dosing level of Sativex in the long-term from the results of the lab in GW, which is very emphasized by SFDA.

3. Comparisons between Durogesic and Sativex:

Fentanyl within Durogesic and cannabis in Sativex can be used as drugs illegally, so the WHO put them in the list of controlled narcotic drugs. Fentanyl and cannabis were both listed as controlled narcotic drug by Chinese SFDA.

In 1986, cannabis appeared in the market for medical use for the first time, and the product is Marinol (it is used to treat nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional treatments¹⁰). In 2005, Sativex was approved by Canadian FDA for relieving MS pains and in 2007 for cancer pain relief. GW has licensed Sativex to Bayer Healthcare for the UK market and to Almirall Prodesfarma for the remainder of Europe though they have not got approval.¹¹

In 1990, Durogesic was originally approved by the FDA in the US and Fentanyl started as medical drug. Then Durogesic was continually approved by many other countries: Belgium, Australia, Brazil, Egypt, Malaysia, South Africa, South Korea, U.K., and so on.¹² In 1999 it entered into the Chinese market as controlled narcotic drug.

Seen from the market situation, Durogesic was approved in the US in 1990 and entered into China in 1999. Sativex was approved in Canada in 2005; now the approval in the US is undergoing and getting developments. Durogesic could be a good example for us to learn from when studying the feasibility of Sativex.

Conclusions of company sales potential:

From the comparisons above, we can see Durogesic is the more direct competitive product to Sativex compared with Oxycontin and Mei Shi Kang Ding because they have more similar advantages. Durogesic has proved a success of imported narcotic drugs in China with its sales of 17,128,499 Yuan in 2004 (the total sales of narcotic drugs in China is about 600,000,000 Yuan in 2004) and a continuous growth of consumption till now¹³. This does not mean that Sativex has no more space in the narcotic drug market. One narcotic drug cannot work on all kinds of patients, that is why the Chinese government is trying to perfect the '3 ladder pain cure method' and introduce more new medicines. Cannabis has a long history of relieving pains and has

¹⁰ Product Information—Marinol; 2007; from Solvay Pharmaceuticals Inc.; <http://www.solvaypharmaceuticals-us.com>

¹¹ Corporate Information/History; 2007; from GW pharmaceuticals; http://www.gwpharm.com/corporate_history.asp

¹² Product Names Abroad; from Jassen-Cilag; http://www.janssen-cilag.com/medication_abroad/?_requestid=178073

¹³ Opium Medicines Account for the Main Market for Cancer Pains; Aug 24 2005; from XINYOO website; http://www.xinyoo.com/news_show.asp?type=3&Id=325

not appeared in Chinese narcotic drug market yet. So if the government wants to introduce more new narcotic drugs than Sativex with so many advantages could be a good choice. So the conclusion is that Sativex has sales potential in China.

4.3.3 Conclusions of ‘Sell Sativex’

From the market assessment above, we conclude that Sativex has potential to enter into the Chinese market. First, the market size is growing for narcotic drugs and SFDA allowed new medicines imported from abroad like Durogesic. Second, the comparison of competitive products like Durogesic gives a successful example already for Sativex. Just like the industrial sales potential, Sativex also has the company sales potential in the Chinese market.

However, there are still some obstacles for realizing ‘sell Sativex’. The application of GCP and GSP is the main obstacle which comes from SFDA, and I consider them as political factor. What we have to do is to think a way to solve these problems.

4.3.4 Distributing Sativex

Since the distribution system for narcotic drugs is relatively simple in China, so there is no need to give many attentions to it. I would like to contain it in the section of ‘sell Sativex’ in order to make the following sections clearer.

There is a sole distributor for all the narcotic drugs in China, which is a nation-owned enterprise named as China National Group. The departments that belong to China National Group especially for narcotic drugs in Beijing and Shanghai take charge of distributing all the narcotic drugs from all the producers to the first-line suppliers permitted by SFDA. Then the first-line suppliers will distribute the products to the final consumers, that is, certain hospitals. All the organizations in this cycle have already got permission from SFDA and are responsible for illegal distributions.

So when Sativex goes to the phase of distribution, then China National Group is the only one should be involved.

4.4 Conclusions

As a conclusion, the principals have three goals, that is, ‘grow cannabis’, ‘manufacture Sativex’ and ‘sell Sativex’. Since there is no market for cannabis-based medicines in China, cannabis is not allowed to be grown in China, neither the production of Sativex. So ‘sell Sativex’ is the precondition for the other two goals.

From the market analysis, I concluded that Sativex has sales potential in China now, so ‘sell Sativex’ has the potential to be realized. The main obstacle could come from SFDA and other related government departments, for example, the application of GCP.

However, the principals' objective is not just limited to 'sell Sativex'. The current situation in China is hard for 'grow cannabis' and 'manufacture Sativex', because if 'sell Sativex' will be achieved or not is still unknown. And the obstacles for those two goals mainly come from the absence of 'sell Sativex'.

So what we have to do next is to develop a proper strategy in order to make 'sell Sativex' realized in China. The strategy of in which way Sativex enters into Chinese market and how to solve the upcoming obstacles during the project plans is already demanded now. Thus it is time to discuss about the 'strategy'.

Chapter 5 Choosing Entry Mode

Based on the objective and goals set above, and the might-be obstacles, we said that a thoughtful strategy need be developed in order to reach our final objective. In the previous chapter, it concluded that ‘sell Sativex’ has the potential to be realized in China now, and ‘grow cannabis’ and ‘manufacture Sativex’ should depend on the outcomes of ‘sell Sativex’. However, to what extent will Sativex go should be discussed later, because in which way Sativex can enter into Chinese market has to be considered first. Only when Sativex has entered into China, just selling or manufacturing and then selling it could be possible to think about. Therefore, in this chapter I am going to choose a proper entry mode for Sativex, which consists of the first part of the whole entry strategy.

5.1 Introduction of Various Entry Modes

Before choosing the proper entry mode, I would like to explain all the possible entry modes first based on the knowledge from ‘Entry Strategies for International Markets’ [Root 1998].

Indirect and agent/distributor exporting

Export entry mode means that a company’s final or intermediate product is manufactured outside the target country and subsequently transferred to it.¹⁴ This mode is confined to physical product but not service or technology. The difference between direct export (including agent/distributor export and branch/subsidiary export) and indirect export is without or with middlemen in the home country. Agent/distributor exporting is transferring physical products through middlemen in the target country.

Branch/subsidiary exporting

Branch/subsidiary exporting is one of the direct exports, which means a company relies on its own branch or subsidiary in the target country to sell the physical products in this country.

Licensing

Licensing is one of the contractual entry modes (long-term nonequity associations between an international company and an equity in a foreign target country that involve the transfer of technology or human skills from the former to the latter), which means a company transfers to a foreign equity for a defined period of time the right to use its industrial property (patents, know-hows, or trademarks) in return for a

¹⁴Franklin R. Root (1998). “Designing Entry Strategies for International Markets”. In: Franklin R. Root (1998). *Entry Strategies for International Markets*. Jossey-Bass, San Francisco, p. 6-7

royalty or other compensation.¹⁵

Equity investment/production

Investment involves ownership by an international company of manufacturing plants or other production units in the target country. It can have two modes: sole venture (new establishment or acquisition), and joint venture (new establishment/acquisition; other).

Conclusions

A company's final choice of an entry mode is always the result of several forces and, often those forces are conflicting. So the process of making decision is very complicated and many trade-offs have to be made, for example, the more the company involves, the more risks it will take with increasing control, and the company must choose between control and risk. But sometimes, a combination of several modes will be a choice for a company.

In the following section, I will list the conditions Sativex has, the advantages and limitations of each entry mode, and then trade-offs will be made and a final decision must come out.

5.2 Analysis of Sativex Entry Mode

It is clearer to compare all the entry modes with factors set in one table. Table 2 of 'External and Internal Factors Influencing the Entry Mode Decision' [Root 1998] will be applied here as the model, and some changes have been made according to the real situation. I put the factors which apply to Sativex in the column of table 5.1, and I also gave weight to each factor from 1 to 5 (1 means the least important and 5 means the most important). Then I put the possible entry modes in the line of table 5.1, and I gave one point to the entry mode that fits to the factors of Sativex. Later on, I multiplied the weight and the point for each factor, and calculated the scores for each entry mode. The entry mode which gets the highest score will be the proper one.

¹⁵ Franklin R. Root (1998). "Designing Entry Strategies for International Markets". In: Franklin R. Root (1998). *Entry Strategies for International Markets*. Jossey-Bass, San Francisco, p. 7

Factors *	Indirect and Agent/Distributor Exporting	Licensing	Branch/ Subsidiary Exporting	Equity Investment/ Production
External Factors Foreign Country				
Low sales potential (3)	1 (3)	1 (3)	0 (0)	0 (0)
Poor marketing infrastructure (3)	0 (0)	0 (0)	1 (3)	1 (3)
Restrictive import policies (5)	0 (0)	1 (5)	0 (0)	1 (5)
Restrictive investment policies (5)	1 (5)	1 (5)	1 (5)	0 (0)
Great geographical distance (1)	0 (0)	1 (1)	0 (0)	1 (1)
Great cultural distance (1)	1 (1)	1 (1)	0 (0)	0 (0)
High political risk (3)	1 (3)	1 (3)	0 (0)	0 (0)
Internal Factors				
Differentiated products (2)	1 (2)	0 (0)	1 (2)	0 (0)
Service-intensive products (4)	0 (0)	0 (0)	1 (4)	1 (4)
Technology-intensive products (2)	0 (0)	1 (2)	0 (0)	0 (0)
Limited resources (5)	1 (5)	1 (5)	0 (0)	0 (0)
Total	19	25	14	13

*The factors listed in the category of 'Factors' are the conditions applying to Sativex
 Numbers: 1 indicates the entry mode that fits to the condition of Sativex; 0 indicates the entry mode does not fit to the condition of Sativex
 (Numbers): The number means the weight given to each factor

Table 5.1 External and Internal Factors Influencing the Entry Mode Decision [Root 1998]

There is no standard for giving weights to the factors, and weights can be adjusted according to different products, for example, for political sensitive products like medicines then political factors will be given high weights; for cultural sensitive

products like food then cultural factors will weigh higher; and so on.

Chinese government keeps pharmaceutical products highly localized and very strict policies are carried out to foreign investors into pharmaceutical industry, also the imported pharmaceutical products. For narcotic drugs, the attitudes of government are much more sensitive, so I gave highest weight 5 to the factors 'restrictive investment policies' and 'restrictive import policies'. In case that government policies and regulations change for narcotic drugs, for example, liberal import policies are pushed out (other factors unchanged) then we can see the total scores will change: indirect and agent/distributor exporting (24); licensing (20); branch/subsidiary exporting (19) equity investment/production (8), so the final choice could be indirect and agent/distributor exporting.

The principals may change the entry mode if more resources can be committed to this project, so I weighted 'limited resources' 5 because the commitment of resource is the principal force changing the principals' decision of an entry mode. Suppose conditions are 'liberal investment policies' and 'substantial resources' (other factors unchanged) then the total score will be: indirect and agent/distributor exporting (9); licensing (15); branch/subsidiary exporting (14); equity investment/production (23), and we can see equity investment/production is the final choice.

Weights were given to each factor for reasons especially for Sativex, and I will explain the reasons one by one in the next section 5.3. If conditions in China change for Sativex in the future, this model can still be used and different results will be obtained.

5.3 Final Choice of Entry Mode

The entry mode which gets the highest score is the final one chosen for Sativex in the table. The table above is clear but not analyzed in details about the conditions of Sativex and the reasons of choosing the final entry mode. So in this section I will go into the details of every condition of Sativex.

1. ***Low sales potential:*** Though in China, the amount of narcotic drugs has been climbing gradually since the beginning of 21st century; when compared with developed countries and some other developing countries, the sales amount of narcotic drugs is still small in China. Sativex has sales potential in China because of its attractive advantages, but the Chinese government could be very strict to the entry of new narcotic drugs when they are not accepted very commonly, so that the amount will be limited in the beginning. For these reasons, export and licensing are more suitable as entry modes.
2. ***Poor marketing infrastructure:*** China National Pharmaceutical Group

Corporation is the sole distributor of narcotic drugs in China. There is no other choice in this marketing infrastructure; all the companies have to rely on this sole distributor. So a local company who has good relationship with the distributor should work as an assistant to conduct the marketing activities. Market factors are important to the decision of an entry mode but not decisive (for example, restrictive import policies can exclude export entry mode which may be favored by market factors) so that I gave the first and second factors 3 for weight.

3. **Restrictive import policies:** Every country has restrictive import policies to narcotic drugs, so has China. Not like other common products, Sativex which contains cannabis will face extremely restrictive import policies. It is hard for a foreign company to convince the Chinese government that this sensitive medicine will be safe under a foreigner’s control and transportation. The local government is inclined to believe in local companies, so export could be hardly successful. Relying on local partners, like licensing or equity investment can be easier for Sativex in China. Political factors are more important than other factors when deciding the entry mode for Sativex because if the government does not give permission then nothing can be continued. We can also use the following model to help explain the strategy chosen for political reasons.

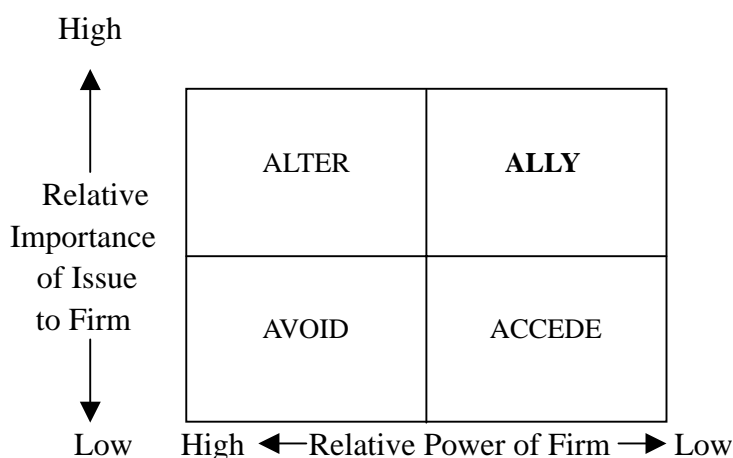


Figure 5.1 Strategic Approaches to Government Relations [Austin 1990]

Compared to the Chinese government, the principals’ power is very limited, so we have to choose ‘ally’ or ‘accede’ if Sativex wants to enter into China. But political issue is also very important to this project, so the only way to deal with the powerful government is looking for a strategic alliance in China to bargain with the local government. But if we ‘accede’ with the local government then most probably that Sativex will return home soon after an application by my principals alone. So licensing to a local company or setting up a new company locally through investment would be the choice.

4. ***Restrictive investment policies***: I gave ‘restrictive import policies’ the highest weight because the political factor is the decisive one when deciding if Sativex can be accepted in China. And in the analysis of this factor, investment and licensing were preferred, but which will be more proper? In China, enterprises that can produce narcotic drugs were strictly limited and controlled by Chinese government. Foreign investors are not allowed to set up pharmaceutical companies in China except as a joint venture with local companies. Cannabis is even not for medical use now in China, so investing a company to grow cannabis and produce Sativex is far from reality currently. So sole venture cannot be the right entry mode for Sativex. This important factor has excluded the investment entry mode because it is not permitted in China now. Then licensing to a local company is the choice left.
5. ***Great geographical distance***: This factor suggests a high transportation fee could be a problem for exporting entry mode, which also support the licensing but not very important, so I gave 1 for weight.
6. ***Great cultural distance***: Cultural distance can be an obstacle for my principals to set up subsidiary or investing equity alone. This also suggest them look for a local partner or a middleman to deliver their products. Also, this is less important than market or political factors, so I gave 1 for weight.
7. ***High political risk***: It is not for sure that the policy from SFDA and other related government departments will be stable in the period of executing this project. For example, recently in June of 2007, the former head of SFDA was executed because of bribery and a new head is in charge now; the new head pushed out some policies to inspect the application procedures of new medicines more strictly. So if some accidents happen during the application of Sativex, I do not think my principals can go through them by themselves better than local people because they do not know China well enough. This may lead to a failure of this project. So for this reason, a local partner is required. Risk factor can be important once it happens, so I weighted it as 3.
8. ***Differentiated product***: Sativex has distinct advantages over its competitive products so it does not need to compete on a price basis, which means high costs generated from export can be absorbed. This factor also explains why I gave ‘great geographical distance’ 1 for weight. However, this factor just indicates that export can be favored but it is not a decisive factor, so I weighted it 2.
9. ***Service- intensive product***: Sativex is service-intensive because in the process of licensing, clinical trials are necessary so that experts of this product should offer assistant in the whole process. Also when it is put into market, patients need special assistance called ADS in the process of using Sativex. Experts on

Sativex will give suggestions on the feedbacks from ADS to the patients after use, in order to find a stable dosage for a certain patient. Also if any problems rise during the process, experts should take charge of them. So many services before, in and after use will be needed; branch or equity investment should be good choices. This factor is very important not only for the choice of an entry mode, even when other entry mode is chosen this factor should still be taken into consideration, because service must be with Sativex during all the activities, so I weighted it as 4.

10. ***Technology-intensive product***: Sativex is the new narcotic drug in the world with leading technology, so the principals have an option to license technology in China. This factor indicates that there is a privilege for licensing but not decisive so I gave 2 for weight.
11. ***Limited resources***: All the possibilities finally come to this factor, the principals' limited resources. The principals are not able to put large investment in China because they do not have money, neither can they penetrate this large market with their current resources. What they can offer is just the 'know-how' but not any investment. This reason can explain why our final choice is licensing but not equity investment. This factor is decisive to the final choice between licensing and investment, so I weighted it 5.

Based on the explanations above, we can see that because of restrictive government policies on import and investment, the export and investment entry modes are excluded even when some important factors favor them, so licensing is the final choice.

However, licensing is the choice for the current situation in China, the entry mode for Sativex can be changed if the situation changes. I already gave some examples in section 5.2 in case that some factors change.

Anyway, a single entry mode may not meet the needs of the principals and the local partner. My principals may want more control but licensing will only bring them cash payment. Also, the local partner may face a lot of difficulties in the clinical trials because they do not know so well about the technology and the knowledge of Sativex. So I suggest a combination of entry modes could solve some problems that might happen.

The licensing entry mode can be modified a bit. The 'know-how' can work as the technology equity then a joint venture is born. The connection between both parts will be tighter and the problems above can be solved too. One issue must be reminded here that the final decision of how to work out the 'know-how' has to depend on the negotiation between them. Here, I can just suggest 'licensing as a joint venture' could be the entry strategy.

If licensing for cash payment is the final result, I will suggest my principals to do the profitability analysis carefully.

$$\textit{Profit contribution of the licensing venture} = \textit{Incremental revenues} - \textit{Incremental costs (during the life of the licensing venture)}$$

A detailed prescription of the profitability analysis will be presented in the appendix 2 of ‘Profitability of a Proposed Licensing Venture’.

But if licensing as a joint venture is the final agreement then looking for a good local licensee or partner is very important, which will be discussed later in the project plan.

5.4 Conclusions

In this chapter, I made a final decision for the first part of the whole entry strategy, that is, an entry mode for Sativex to enter into China. First of all, I introduced various entry modes, including export, licensing, investment, and branches/ subsidiaries. Then I used a table to get the highest ranked entry mode—licensing as the final decision. In this table, political factor and the resources of my principals were most emphasized because they are decisive factors. Market factors are also important but not as decisive as above two, thus I weighted them as middle. While cultural and geographical factors could influence the final decision but not to a great extent, so I weighted them the least important.

I gave explanations to each factor in section 5.3 and the reason of reaching the final decision. In the end, I suggested that licensing as a joint venture could be considered as ‘know-how’ works as a part of the equity of a joint venture, because in practice a combination of entry modes may work better.

Till now, the first part of entry strategy has been fulfilled and it is time to complete this strategy. What is the next is to design the project plan, which will give details on how to do ‘licensing’ in China, for example, how to select local licensee; and how to get the approval from SFDA, etc.

Chapter 6 Designing Project Plan

Since the first part of the whole strategy has been complete in the last chapter, now it is time to design some details for practice, that is, what needs to be done according to the entry mode we have chosen. I will call the details ‘project plan’, which includes selecting local licensee and applying for the approval of Sativex.

Selecting a good local licensee (partner) is the first step of realizing licensing or a joint venture, and it is also my responsibility during this project for my principals. The following activities such as invitations and negotiations are not within my task scope, so I will not discuss them here. Then, the most concerned aspect—the approval of Sativex—by my principals will also be discussed in this plan, because this is the most important and decisive link in this project. Only when there is a chance for the approval then my principals will consider what to do next. So I am also asked to look into this issue carefully. First of all, I will introduce how to select a prospective local licensee.

6.1 Selecting Local Licensee

According to the principals and the objective of the project, there could be several kinds of local licensee, considering the function of growing, manufacturing and selling. I will select local licensee according to those three functions.

The whole process of producing Sativex has already been explained in chapter 3, so I will not mention it again here.

From the process described in chapter 3, we can see the principals have three ‘know-how’s: 1) they offer the special cannabis seeds 2) they offer knowledge of the computer-controlled environment for growing cannabis plants 3) they offer extract technology and the patent of spray device.

So in order to grow, manufacture, and sell Sativex in China, we have to look for a partner who can offer the place for growing cannabis plants; a partner who can have the equipments and produce Sativex; a partner who can do the marketing for Sativex. Actually, it is better to tie the growing and manufacturing functions together because it makes the whole production process easier. But in fact, it could be hard for one company to combine those two functions due to the constraints from the government, growing environment and the like. So I will make local partner with growing function an independent one.

The selling function could be separated from growing and manufacturing. But in fact,

all the manufacturing companies in China also have the selling function. So I will make local partners with sole selling function as one section because they are experts on selling; and I will make the manufacturing companies with selling function as one section because they emphasize more on production but not on selling. As a conclusion, I will focus on three kinds of local licensee: 1) partner with growing function 2) partner with selling function 3) partner with manufacturing and selling function.

All the enterprises I will give in the following sections are from the list of narcotic drug production enterprises by SFDA.¹⁶

6.1.1 Local Licensee with Growing Cannabis Function

Supply of raw material is the precondition of production, so on the first consideration, I look for a company which has business related to cannabis growing. As said before, the Holly Group is the only organization that can grow industrial cannabis, so I choose the Holly Group as the first candidate to be analyzed.

Holly Group is a privately owned incorporation with Holley Holding, Ltd. as the parent company. It has more than 30 years' history with total assets of RMB 4.3 billion and a staff of around 8,000. Holley is a trans-regional, multi-industry and export-oriented enterprise, holding 4 publicly listed companies (3 domestic ones and 1 NASDAQ). The company's businesses cover metrological instruments, power equipments, information technology, biopharmaceuticals and real estate. Holly has bases in Kunming, Guangzhou, Beijing, and in some other cities; its manufacturing plants and research institutions have spread to Thailand, U.S.A. and Canada.

What is related to our research is the HollyPharm Group, which consists of Chongqing Holly Share Holding, Kunming Pharmaceutical Corp., Wuhan Jianmin Pharmaceutical Groups Corp. Ltd., Holly Life Technology in Hangzhou, and Beijing Holly Jiuzhou Pharmaceutical Commercial Ltd.. And to the subject of cannabis, only two of them are involved, Chongqing Holly Share Holding and Kunming Pharmaceutical Corp..

1. Chongqing Holly Share Holding

Chongqing Holly Share Holding is the first one who made Chinese medicine international and it takes charge of growing industrial cannabis.

Chongqing Holly has experience and technology available for growing cannabis, which could provide a more convenient environment for cooperation and reduce initial investment. Secondly, the good aspects are not limited to growing cannabis, this company did research on medical cannabis and reduced its THC level so that

¹⁶ The inspection announcement to special medicines production enterprises and blood products manufacture enterprises; Nov 20 2006; from Huayuan Medical website; <http://www.hyey.com/Article/Data/teshuyaopin/200611/81549.html>

industrial cannabis could be developed and grown. Reducing THC may have some similarity with the principals' core technology—increasing THC, so to the point of technology support, Chongqing Holly has a group of experts help with the research of cannabis-based products. Thirdly, this company has much experience with international business in pharmaceutical area, which means the knowledge of international cooperation will help the 'local licensee' cooperation easier. Finally, Chongqing Holly won many prizes for its contributions to Chinese medicine, so the relationship with government should be good because the Chinese government is promoting the development of Chinese medicine. And the new high-tech from Sativex may also be encouraged for the sake of supporting Chinese medicine. Also, its parent company is a big organization which can be tough when negotiating with the government.

Points: good relationship with local government; experience with growing cannabis and research; international oriented; new high-tech introduced for the development of Chinese medicine is supported by local government; *no experience with narcotic drugs.*

2. Kunming Pharmaceutical Corp.

Kunming Pharmaceutical Corp. is a company whose main area locates in botanical medicines. It has R& D, production lines, national and international marketing network for its botanical medicines.

Sativex is also botanical and Yunnan (the province Kunming locates in) is the place good for cannabis growing. This company can offer similar conditions to Sativex as Chongqing Holly does.

But, Chongqing Holly and Kunming Pharmaceutical have no experience with narcotic drugs, which means no experience on production, sales and distribution. Narcotic drug is unlike normal medicines, the government has strict policies on the supply, production and distribution. Quota is always there on each link from supply to distribution. So in fact, it is very hard to apply for a new narcotic drug production enterprise or a new raw material growing base. Thus I will look into the sole supplier of raw material for all the narcotic drugs in China.

Points: good relationship with local government; good location for growing cannabis; international oriented; major in botanical products the same as Sativex (also a botanical product); *no experience with narcotic drugs.*

3. Gansu Agricultural Medical Raw Material Station (Medical Opium Growing Base)

This is a nation-owned enterprise started from 1964 in Gansu province. It not only takes charge of the growing responsibility, but also arranges the distribution and quota

of opium.

This station is named by the government as the sole supplier of medical opium. It is very possible that when Sativex enters into the phase of growing cannabis after succeeds in clinical trials and sales, Chinese government will just allow this station to be the grower not any other organization. So I would like to introduce this station now, which may be useful in the future.

Points: the only legal organization to grow medical opium for all the narcotic drug production in China.

Conclusions:

From the information above, we can see that the companies with growing function do not have the permission to deal with narcotic drugs or medical cannabis. And what is already known to us, getting a permission is hardly possible because of the quotation from the government. So it is not easy to realize the growing function from the beginning.

Maybe it is time to look into the selling function first since selling is the precondition for the other two goals (as analyzed in the section ‘setting objectives and goals’). Furthermore, the quota of sales and distribution is easier to be increased, which has been approved by the market assessment above. From the market assessment, we can also see all the imported narcotic drugs are just limited to the area of sales but not production. So now I am going to investigate the possible local licensee with selling function.

6.1.2 Local Licensee with Selling Function

Considering selling function, the companies who have narcotic drug sales experience will be taken into consideration first. Obviously, there are two companies already in my mind based on the market assessment: Bayer Healthcare Co., Ltd. and Xian-Janssen Pharmaceutical Ltd.. I will analyze those two companies in the following context.

1. Bayer Healthcare Co., Ltd.

Bayer is an international, multi-industry organization originated from Germany, and Bayer Healthcare is the one who takes charge of pharmaceutical business. Bayer Healthcare Co., Ltd. in Beijing is a subgroup of Bayer Greater China Group, whose major function is selling pharmaceutical products.

Bayer Healthcare in China has no experience with narcotic drugs, so why I choose this company as a candidate? Because Bayer Canada takes charge of marketing Sativex in Canada and it got approval from Canadian FDA in 2005. This is the first

successful approval in the world for Sativex, so granting the marketing right to Bayer again in China might create another chance for Sativex.

First of all, Bayer has sales experience on Sativex more than any one else. It is possible for Bayer China to get some valuable support from Bayer Canada when applying for the approval and then marketing. Second, seen from the importation history of narcotic drugs in China, we can see all the successful importations were done by the subgroups of its parent company in China, for example, Durogesic and Oxycontin. So learning from other's successful sales strategy may lead us to a success. Moreover, Bayer China is a big group with good relationship with the government. We can see from the following event: Bayer's Integrated Polymers Site program was signed together by Chinese Premier Zhu Rongji, German Chancellor Gerhard Schroeder, and the Chairman of the Board of Bayer Dr. Manfred Schneider.

The disadvantage is that we have to look for another partner with production function if selling Sativex is fulfilled and there is a need to produce it, because Bayer's business is limited in sales but not production.

Points: experience of selling Sativex in Canada; good relationship with local government; an expert of pharmaceutical sales; *its business does not cover manufacturing pharmaceutical products.*

2. Xian-Janssen Pharmaceutical Ltd.

Janssen Pharmaceutica in Belgium is part of the world's largest healthcare company Johnson & Johnson in the USA. Janssen Pharmaceutica could be regarded as one of the creator of the parent company and it has strong research capability. Janssen has branches worldwide and Xian-Janssen Pharmaceutical Ltd. is one of them. Xian-Janssen is a joint venture of Janssen Pharmaceutica in Belgium, Shanxi Province Pharmaceutical Company, Shanxi Hanjiang Pharmaceutical Sharing Ltd., China Pharmaceutical Industrial Company, and China Pharmaceutical Foreign Trade Company. Durogesic is the product developed by Janssen in Belgium and imported by Xian-Janssen.

From the members of the joint venture, we can see Xian-Janssen has a high political position, at least in Shanxi province. What is more, it has good international business practices, which means the environment is more open for cooperators from abroad. The main reason I choose Xian-Janssen as one candidate is because of Durogesic. In the section 'company sales potential', I compared some competitive products of Sativex and Durogesic is the most direct one. But because each medicine cannot apply to all kinds of patients, so those two products differ in the functions. Xian-Janssen has made a big success on the sales of Durogesic, that is, creating 1/6 of the whole sales of narcotic drugs in China. And maybe it will be interested in Sativex on the purpose of enlarging its market of pain relief. So granting the sales right to Xian-Janssen may

also give Sativex a prospective result based on its successful sales experience with narcotic drugs.

The shortcoming is that Xian-Janssen does not have GMP for narcotic drug production, so in the long run, this licensee have high risk from the SFDA's refuse to produce Sativex.

Points: successful sales of Sativex's direct competitor—Durogesic; good relationship with local government; share sales experience of Durogesic when marketing Sativex; *no permits to produce narcotic drugs.*

Conclusion:

As a conclusion of local licensee with selling function, I think those two companies have their advantages and disadvantages separately. The biggest advantage is that they have separate successful sales experience of Sativex in Canada or the competitive product Durogesic in China, which makes them as an expert compared to other candidates on selling function. This is a good choice for the beginning of entering into China.

But the biggest disadvantage of them is the limitation of selling function, which means the cooperation with them may be temporary and the need to find another production partner is necessary in the future. So later on I will look for the local licensees with manufacturing function to see if a long-time cooperation could be realized through manufacturing function.

6.1.3 Local Licensee with Manufacturing and Selling Function

1. China National Pharmaceutical Group Corporation

As mentioned before, China National Group is the sole distributor of narcotic drugs in China. What I have not mentioned is that this group also produces narcotic drug, which is Codeine.

This group is the largest pharmaceutical organization in China, which is controlled by the central government since 1998. The special medicine department within this group takes charge of the production and distribution of narcotic drugs.

Its relationship with government is out of problem since it is controlled by the central government, and it has a very wide international business network. If this group can be the local licensee then we do not need to worry about the approval from the government, growing cannabis, distribution and production. The only problem is the cooperation with China National Group is not limited to business level, but the communication with the central government, which could be very hard for my principals and the chance is very small.

Points: the whole system of producing, distributing (no other companies have this function) and selling narcotic drugs; absolute advantage of relationship with local government over other candidates; prospective future after the cooperation; *too close connection with central government which makes the negotiation of cooperation extremely hard.*

2. Qinghai Pharmaceutical Factory Co. Ltd

Qinghai Pharmaceutical Factory Co. Ltd. is the national base of producing narcotic pharmaceutical raw material and preparations. The principal products contain Codeine Phosphate, Pethidine Hydrochloride and Morphine Sulfate, which are manufactured in compliance with international standards. It devotes to set up good reputation in both national and international market through high quality products and the effort of pursuing new products.

This company was developed from the nation-owned Qinghai Pharmaceutical Factory in 1958, which means its relationship with local government is good, but not as good as the China National Group. However, it is easier to get cooperation with a privately owned company than nation-owned company.

Points: GMP of producing various narcotic drugs; easier for negotiation of cooperation; good try of updating technology; international marketing experience; *not an expert on marketing narcotic drugs but more oriented on production.*

3. Beijing Mundipharma Ltd.

This is a Co. Ltd. company by Beijing Pharmaceutical Company in China and NAPP in the UK since 1993. It produces narcotic drugs with the GMP certification from SFDA in 2000.

Beijing Mundi has a lot of experience with narcotic drugs on production and sales:
2002-07-10: Morphine Sulfate Controlled-release Tablet with the name Mei Shi Kang Ding appeared in the market and then worked as the substitute product of Pethidine (names as Dulengding). It is the main product for relieving cancer pains now in China and Mundi Beijing is the only provider.

2003-03-25: Indometacin Controlled-release Tablet was produced and entered into the market.

2003-09-27: Tramadol Hydrochloride Sustained Release Tablet got the approval to be sold in Chinese market.

2004-01-21: Oxycodone Hydrochloride Controlled-release Tablet was imported from NAPP in the UK (Mundi's joint partner), appeared as a new pain relieving medicine for cancer patients.

Beijing Pharmaceutical Company was a nation-owned enterprise in the place where SFDA locates; because of the introduction of new high technology, it combined with

NAPP. Nation-owned enterprises could have more privileges than private or foreign enterprises on the consideration of political aspect. Since Beijing Pharmaceutical Company belonged to Beijing government and SFDA is also in Beijing, so the political relation can be better than privately owned companies in other provinces in China.

Another strength is that the partner of Beijing Mundi is from the UK, which means this company is more open than other local companies in international cooperation. And what is more, the products Mundi sells are the competitive products of Sativex so that it may be more familiar with this new narcotic drug market.

Points: GMP of producing various narcotic drugs; nonstop updated technology with the cooperation from the UK partner; sales experience of Sativex's competitive product Oxycontin; better relationship with central government than privately owned candidates in other provinces; international cooperation experience with NAAP; *potential conflicts from its partner NAAP in the UK and my principals' British partner GW.*

4. YiChang Humanwell Pharmaceutical Co., Ltd

YiChang Humanwell locates in Hubei Province with 6 years' history. It has strong research and developing ability on its own and this company has cooperation with the famous universities such as China pharmaceutical University, Peking University Health Science Center, Huaxi Medical University, Hua Zhong University of Science and Technology Tongji Medical College etc in order to strengthen its R&D capability.

YiChang Humanwell is one of the national designated anesthetics manufacturers of narcotic drugs. Because of its R&D ability, it keeps developing new narcotic drugs and new raw materials; for example, Fentanyl is only supplied by this company in China. This company was honored as the example of high-tech enterprises in the pharmaceutical field.

Humanwell is the supplier of medical raw material of many African and European countries for a long time, so it has experience of international business. It also has GMP for producing narcotic drugs. YiChang Human's conditions are most similar as Qinghai Pharmaceutical Factory Co. Ltd..

Points: GMP of producing various narcotic drugs; good relationship with universities for R&D strength, which is good for Sativex's technology support; good relationship with local government as a privately owned company; international sales experience; *not expert on marketing but on production.*

5. Shenyang No.1 Pharmaceutical Factory

It is one subgroup of Northeast Pharmaceutical Group in Liaoning province established since 1949, and one of designated enterprise of producing narcotic drugs. This is a company with really long history and also it devotes to developing new technologies and expanding its international business.

Its main products (narcotic drugs) are injected narcotic drugs such as injected codeine, injected Pethidine, and injected morphine. Though this factory is making efforts to expand its international business, South Korea is the only foreign market. Also, the development of high technology is not applied in narcotic drugs since no new narcotic drug was invented by this factory. And the relationship with the government is similar as Humanwell and Qinghai Pharm..

Points: GMP of producing injected narcotic drugs; good relationship with local government as other privately owned candidates; *no pursue of new technology on narcotic drugs; not much international experience so not open enough for international cooperation; not an expert on marketing neither production.*

Conclusions:

As a conclusion of local licensee with manufacturing function, in my opinion, this kind of local licensee is the most ideal for the long-term consideration. The reason is that the manufacturing companies also have the selling function. What is not as good as the companies I listed in the selling function is that, most of them do not work as an expert on marketing.

However, among all the manufacturing companies, there are some 'shining stars', for example, China National Group has absolute advantages over other candidates because it is a nation owned company with a special function of distributing solely and closer relationship with central government; Beijing Mundi is an expert on both marketing and manufacturing; Qinghai Pharmaceutical and YiChang Humanwell have their attractive characteristics though not as obvious as the above two; but Shenyang No1. is not a good choice.

Candidates with absolute advantages also have extreme obstacles for cooperation, for example, the negotiation with China National Group could be difficult because of the interfere from the nation while with privately owned candidate like YiChang Humanwell will be easier.

So although some of them have obvious advantages over others, it is better to keep more candidates in the list to achieve a successful cooperation as well as making the licensor more powerful.

6.1.4 Conclusions of Selecting Local Licensee

Before conclusions, I would like to make a conclusion of the points of all the candidates with two tables below.

Points \ Companies	The Holly Group	Bayer Healthcare Co., Ltd.	Xian-Janssen Pharmaceutical Ltd	Gansu Agricultural Medical Raw Material Station
Relationship with government	Good (central and local governments)	Good (local)	Good (central)	Very Good (nation owned)
Experience with growing cannabis	Yes	No	No	No (with opium)
Experience with selling narcotic drugs	No	Yes (expert on Sativex)	Yes (expert on Durogesic)	No
Experience with manufacturing narcotic drugs	No	No	No	No
Experience with international cooperation	Yes (having locations abroad & business with foreign countries)	Yes (an international company with a location in China)	Yes (a subsidiary to an international company Johnson & Johnson)	No
Technology	High (technology on growing cannabis)	No	No	No
Negotiation	Workable	Workable	Workable	Hard
Notes	The cannabis they grow is not for medical use	Bayer Canada is the expert on selling Sativex	There is a risk that they may not accept a competitive product	This is the only place where the material for all the narcotic drugs in China can be grown

Table 6.1 List A of Points for Local Candidates with Growing and Selling Functions

Companies Points	China National Pharmaceutical Group Corporation	Beijing Mundipharma Ltd.	Shenyang No.1 Pharmaceutical Factory	YiChang Humanwell Pharmaceutical Co., Ltd	Qinghai Pharmaceutical Factory Co. Ltd
Relationship with government	Very good (nation owned)	Good (central)	Good (local)	Good (local)	Good (local)
Experience with growing cannabis	No	No	No	No	No
Experience with selling narcotic drugs	Yes (sole distributor for all the narcotic drugs in China)	Yes (on related products, e.g. Oxycontin)	Yes (not expert on selling but more on production)	Yes (not expert on selling but more on production)	Yes (not expert on selling but more on production)
Experience with manufacturing narcotic drugs	Yes	Yes	Yes	Yes	Yes
Experience with international cooperation	Yes (not much, more local business)	Yes (with a partner from the UK as a joint venture)	No	Yes (international marketing experience)	Yes (international marketing experience)
Technology	Not high (no special technology on narcotic drugs)	High (technology from partner for inventing new narcotic drugs)	No (focus on traditional product, no R&D on new products)	Yes (good relationships with universities for R&D)	Yes (researches on inventing new narcotic drugs)
Negotiation	Hard	Workable	Hard	Workable	Workable
Notes	It can be the best choice if the cooperation can be made, but it is very hard to get it	Its partner in the UK could be a competitor to GW in the UK, so the cooperation may not be allowed by NAAP	It is really a conservative local company, little chance of cooperating with it	Privately owned company is easier to get cooperation with	Privately owned company is easier to get cooperation with

Table 6.2 List B of Points for Local Candidates with Manufacturing and Selling Functions

Concluded from three sections and two tables above, we can see looking for local licensees with growing function is the choice with smallest possibility, because medical cannabis is not allowed to be grown in China and if there is no market for medical cannabis then it is impossible for the Chinese government to give permit of growing it in China.

So I transferred to selling function. Two huge pharmaceutical companies Bayer Healthcare in China and Xian Janssen were chosen as the candidates. With their separate experience with selling related products, they may offer a good cooperation for selling Sativex in China. But the disadvantage is that both companies cannot produce narcotic drugs so the cooperation with them might be temporary, which is not compliant with my principals' final destination in the long run.

When it comes to local licensee with manufacturing and selling function, things are getting better. All the manufacturing companies can be long-term partners for Sativex and they have GMP and good relationship with either local (province level) or central government. Most of them keep devoting to developing new and high technology of making narcotic drugs and, good results were shown. The only disadvantage for most of them is a lack of experience with marketing narcotic drugs compared with those with selling function, because their task is more emphasized on production and no specific need of marketing is demanded. But some of them do not have this problem such as Mundi and China National Group though cooperation with them may be a new problem.

Trade-offs must be made when considering short-term or long-term oriented; more guarantee of success in the beginning or insurance of future development. So then the result of which kind of local licensee might be a better choice will come out. Local licensees with selling and manufacturing functions have their advantages and disadvantages, which seems hard to be substituted. So I suggest my principals grab the chance that the candidates may offer some good ideas and maybe some surprise. I advise my principals to write formal letters to each of them in order to know their interest on cooperation, and then more information about the companies can be got during the process of getting cooperation. And deeper investigation should be conducted during the second selection. I give the contact information of all the companies mentioned above in appendix 3.

6.2 Applying for the Approval of Sativex

This phase of the paper will answer the question 'How to get the licensing from the Chinese government'. Information from the website of SFDA will be collected on how to apply for clinical trials. Knowledge including how to get the approval will be presented to the principals, and some major obstacles that may cause failures will be discussed in the feasibility study.

First of all, I would like to introduce all the certification types of drugs from SFDA in China:

- GLP: quality inspection of medicine without clinical trials
- GCP: quality inspection of medicine with clinical trials
- GMP: good manufacture practices
- GAP: Chinese medicine manufacture practices
- GSP: good sales practices

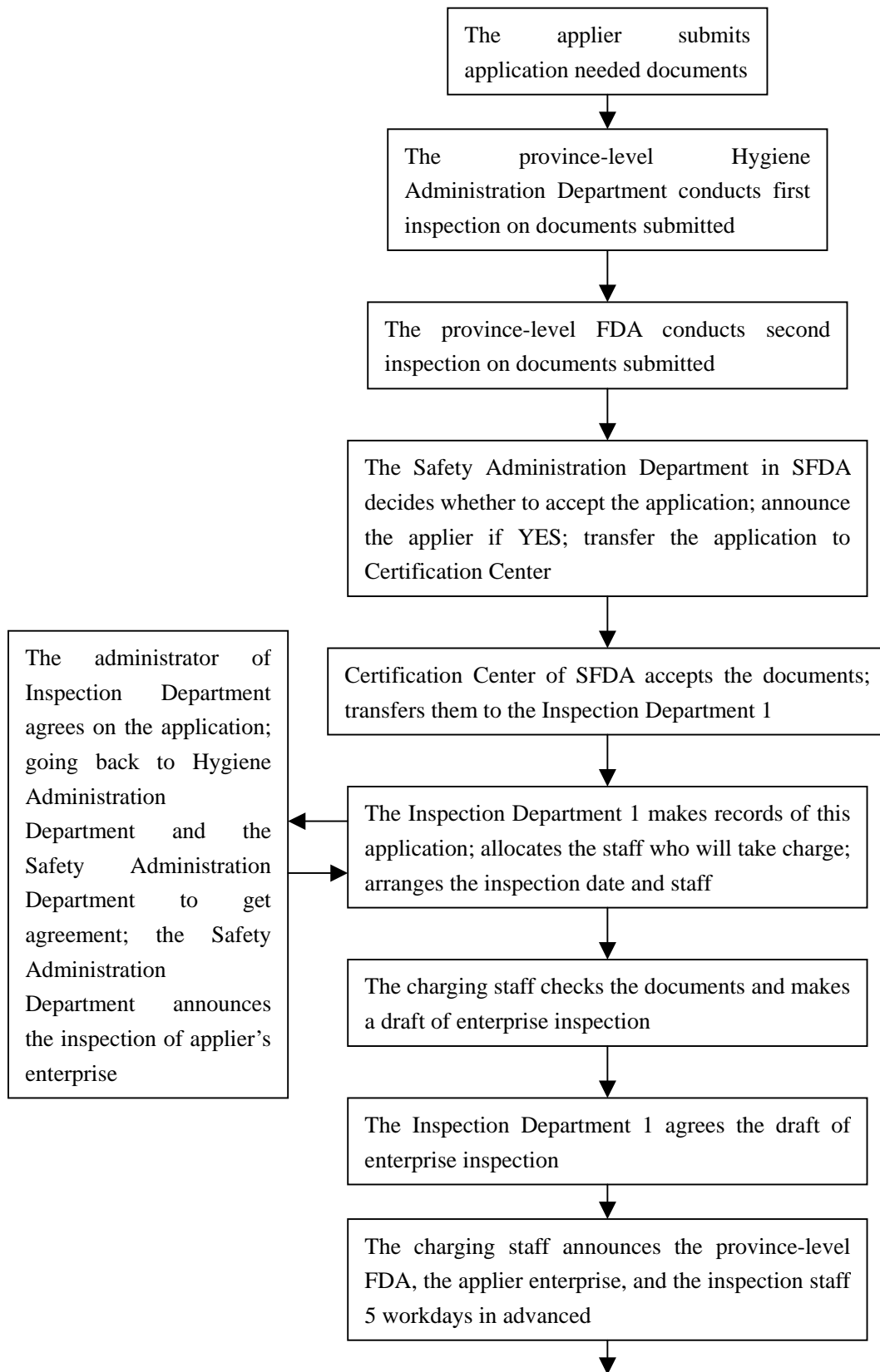
The Certification Administration Center, which is the subgroup of SFDA, takes charge of all the certification work for local medical products and the imported ones. It consists of Administrative Office, Inspection Department 1, Inspection Department 2, Inspection Department 3, Inspection Department 4, and Multifunctional Office. The two Offices are responsible for the organization's daily administrative, financial, political matters and ect. Inspection Department 1 takes over application of GCP and GLP; Inspection Department 2 deals with criteria, documents made for the application of GMP and GAP and related work in the process of application; Inspection Department 3 is responsible for all the jobs concerning GSP; and Inspection Department 4 is the service center for the GMP of medical equipments.

In the case of Sativex, I will describe the applying process according to different functions: growing, selling, and manufacturing. But first of all, an application of GCP is needed to get an approval for clinical trials before any other activities if Sativex wants to enter into Chinese market. I give the original document of applying for GCP from SFDA in Chinese (see appendix 4), and then I will translate it into English version.

6.2.1 GCP Procedures

Sativex is undergoing different steps of clinical trials in the EU countries, the USA and Canada, in order to get the approval of being sold in those countries. Each country has its own standard of clinical trials, so when Sativex comes to China, an application of conducting clinical trials is the first thing to do, that is, applying for GCP. Only when it is allowed to conduct clinical trials in China and then the clinical trials prove Sativex can be applied to Chinese patients, could Sativex have the permission to enter into the market.

111 workdays



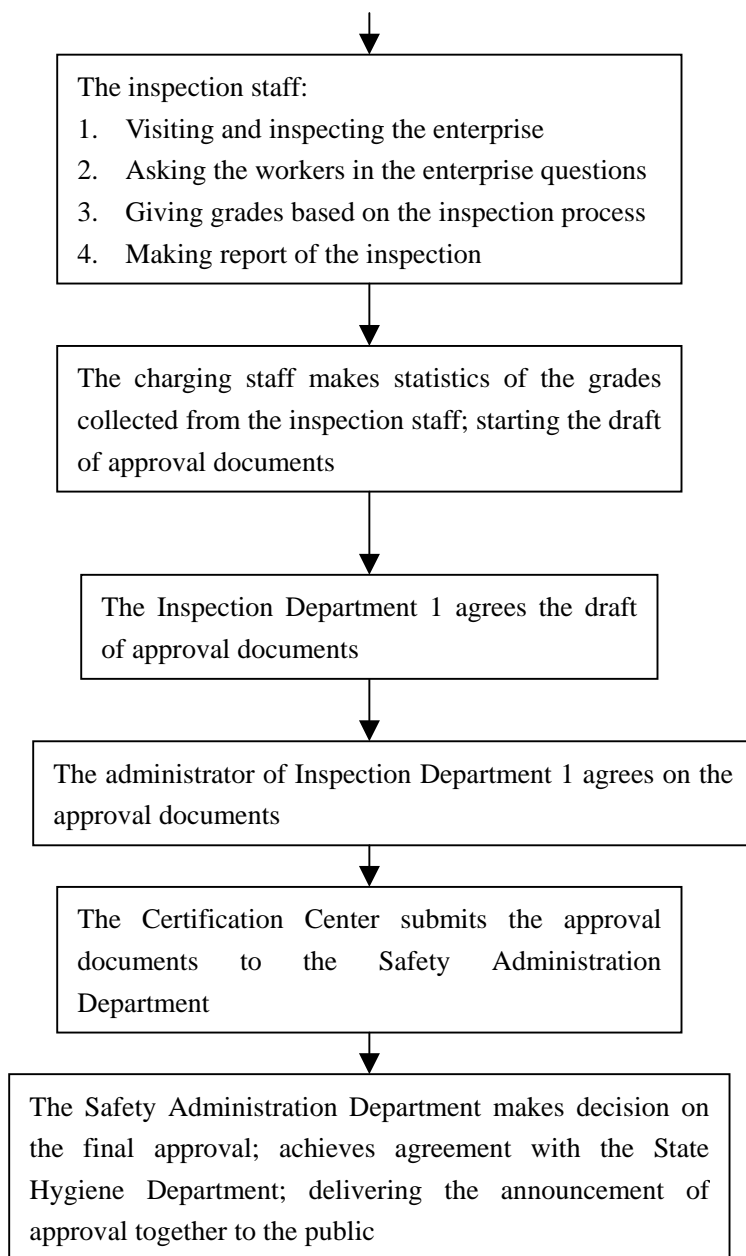


Figure 6.1 GCP Certification Procedures

Conclusions:

The government departments that are involved in GCP application include ‘province-level Hygiene Administration Department’, ‘province-level FDA’, ‘Safety Administration Department in SFDA’, ‘Certification Center of SFDA’, ‘Inspection Department of SFDA’, ‘Inspection Department 1’, ‘Safety Administration Department’ and ‘State Hygiene Department’.

The application should be submitted from the lowest level of departments ‘province-level Hygiene Administration Department’ and ‘province-level FDA’. After the agreements are made from both departments, then the higher level of departments in SFDA will accept this application.

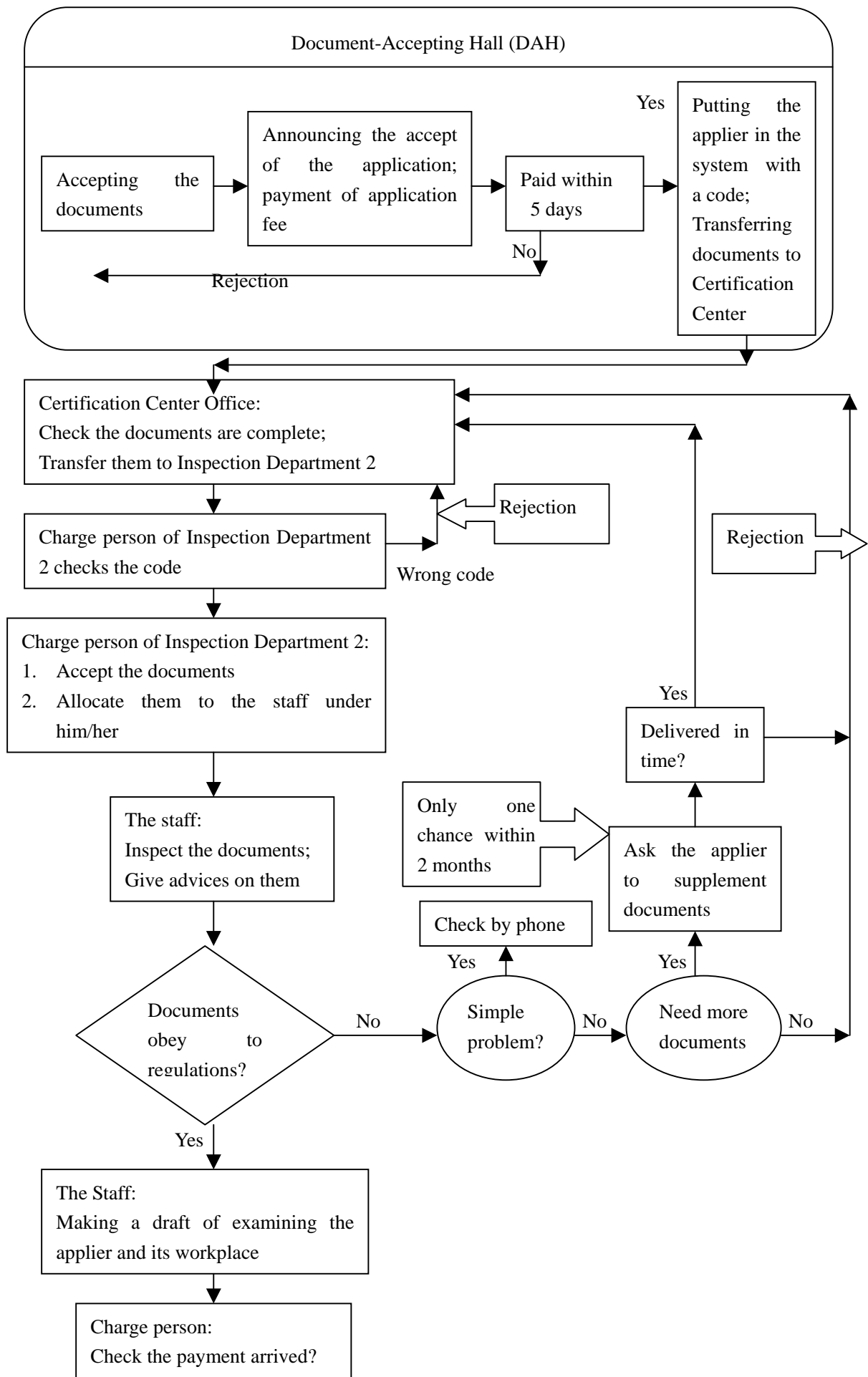
‘Certification Center of SFDA’ takes charge of the application documents; check if all the documents are theoretical accepted. ‘Inspection Department 1’ in ‘Inspection Department of SFDA’ is in charge of all the inspection activities including inspecting workplace of the enterprise. After a complete inspection by ‘Inspection Department 1’, ‘Inspection Department of SFDA’ receives the draft from ‘Inspection Department 1’ and agrees on it. Then ‘Safety Administration Department’ will give the final approval based on the draft, together with the agreement from ‘State Hygiene Department’.

The final decision is not made by SFDA itself, but together with the State Hygiene Department. The situation is the same at province level. Within SFDA, all the related departments have its own functions, and each one of them can influence the other ones. So the final approval is not decided by one department but the combination of all the involved departments. And the power is distributed among them so not specific one of them can have more power on the final decision.

6.2.2 GMP Procedures

Since the principals’ final objective is to manufacture Sativex in China, I have to consider about GMP, which is the certification of manufacturing certain medical products in China. In the section ‘selecting local licensee’, I have mentioned some narcotic drug manufacture companies. When evaluating those companies, the GMP they have should be examined very carefully. First of all, it is necessary to see which category (for example, tablet product or injected product) Sativex belongs to and, if the local partner’s GMP scope contains that category. If it contains, then there is no need to apply for a new GMP, which will cost much financial resource and time with great risk; if not, a new GMP have to be applied. So next I will give the procedures of applying for GMP to have an overview of how to apply for GMP in China.

The flow chart will be translated into English, the original version from the website of SFDA is presented (see appendix 5) too. The workdays needed can be seen in the original flow chart so I do not put it in the English version because of the size of the page limited.



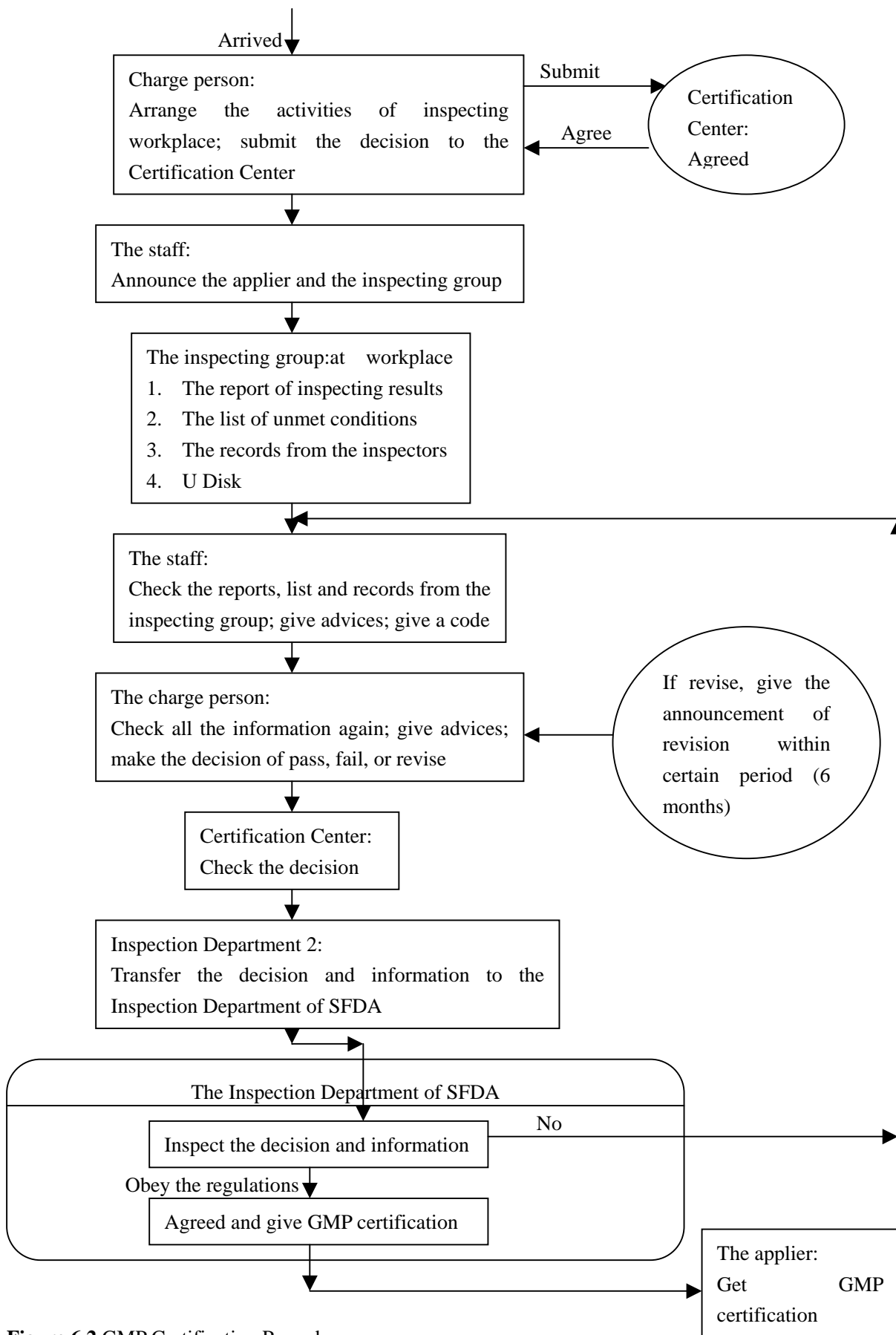


Figure 6.2 GMP Certification Procedure

Conclusions:

The departments in SFDA which are involved in GMP include 'Document-Accepting Hall (DAH)', 'Certification Center Office', 'Inspection Department', and 'Inspection Department 2'. All the involved departments are within SFDA, but not from other organizations like in GCP application.

'Document-Accepting Hall (DAH)' takes charge of application documents and checks if they are theoretically accepted, also charges fees. 'Inspection Department 2' in 'Inspection Department' is in charge of all the inspection activities, including inspecting workplace of the enterprise and making a final draft. After the final draft is made, 'Inspection Department' accepts it and decides if the final approval should be given. 'Inspection Department' is the final decider for GMP approval. Any problem happens in the process will be informed to the enterprise, and if the enterprise can solve it within the given time then the application will be processed again, vice versa.

GMP application is approved only by the 'Inspection Department' in SFDA, with 'Inspection Department 2' doing all the practical work. So the power is focused on one department 'Inspection Department', but not distributed as GCP.

6.2.3 GSP Procedures

The application of GSP is not accepted by SFDA from the year 2003. It is now done by provincial FDA where the enterprise belongs. Every enterprise needs a GSP certification to sell medical products, and the sorts of medical products it can sell are according to the scope given in the GSP certification.

When we choose local licensee for selling function, we have to see if that licensee has the GSP for Sativex (I mean this sort of medical products). The partners with GSP for Sativex have the privilege than those do not have it.

The procedures of applying for GSP are not given by SFDA because each province has its own procedures that may have some differences. So if there is a need to apply for GSP, we need the local partner to go to the provincial FDA for the application information.

6.2.4 Conclusions

As described above, the application of each certification will take a long time and many financial and human resources. And in case something goes wrong in the process, there is a risk to fail. The success of application not only asks for the complete documents to be prepared and good conditions the applier has; but also the relationship with SFDA and provincial FDA.

We can see that not just one department takes charge of the whole application; two or more related but independent departments are responsible for the application at the same time. So in order to get the agreement from all the departments is not easy,

which may involve political issues. Also, it might need bribe during the application process that creates more risks.

Because the application is costly and risky, it is better to look for local licensee with the certification already so that there is no bother to apply again. And the risk will be limited to the GCP certification.

6.3 Conclusions

This chapter continues constructing the whole entry strategy after the entry mode has been decided in chapter 5, which includes ‘selecting local licensee’ and ‘applying for the approval of Sativex’.

As ‘licensing’ was chosen as the entry mode, it is asked to look for a good local licensee. ‘Local licensee with growing function’, ‘local licensee with selling function’ and ‘local licensee with manufacturing and selling function’ were introduced one by one in section 6.1. As a conclusion, ‘local licensee with growing function’ cannot be a proper choice from the beginning; ‘local licensee with selling function’ can be a good choice in the beginning, but in the long-term, ‘local licensee with manufacturing and selling function’ should be chosen. Two lists of points for the candidates were made to compare them on the advantages and disadvantages. The information in section 6.1 will work as the basic knowledge for my principals to choose local partner in the future.

In order to enter into China, the first decisive factor is that if we can get the approval from the Chinese government—SFDA. This approval should be done by the chosen local licensee. And in section 6.2, I gave elaborate information on how to apply for all kinds of certifications Sativex may need, including GCP, GMP, and GSP. Because too many resources and much time have to be spent on the applications, I suggest my principals to choose a local licensee that already has the needed certifications, such as GMP and GSP. But GCP has to be applied in the beginning especially for Sativex. What factors may affect the success of cooperating with a good local partner and applying for the approval for Sativex; if GCP will succeed so that there is a possibility for Sativex to enter into China; all these will be discussed in the next chapter ‘feasibility study’.

Chapter 7 Feasibility Study

After the entry mode has been chosen as the first part of the strategy and then the detailed project plans were designed for the last parts of the strategy, now it is time to test the feasibility of this strategy. Is the strategy I chose till now really suitable for the entry or it has some drawbacks we have not found? This chapter is going to answer this question.

Looking back to the chapter of ‘choosing entry mode’, there are some main criteria that influence the final decision of ‘licensing’, which will be discussed in this feasibility study to see if the option is the right one, or we need to make some changes to make the strategy feasible. Concluded from the criteria in ‘choosing entry mode’, financial and political are the main decisive factors, so I will discuss financial feasibility and political feasibility in the following section.

Before the feasibility analysis, I would like to give a flow chart for the entry activities, base on which I gave the items for feasibility study.

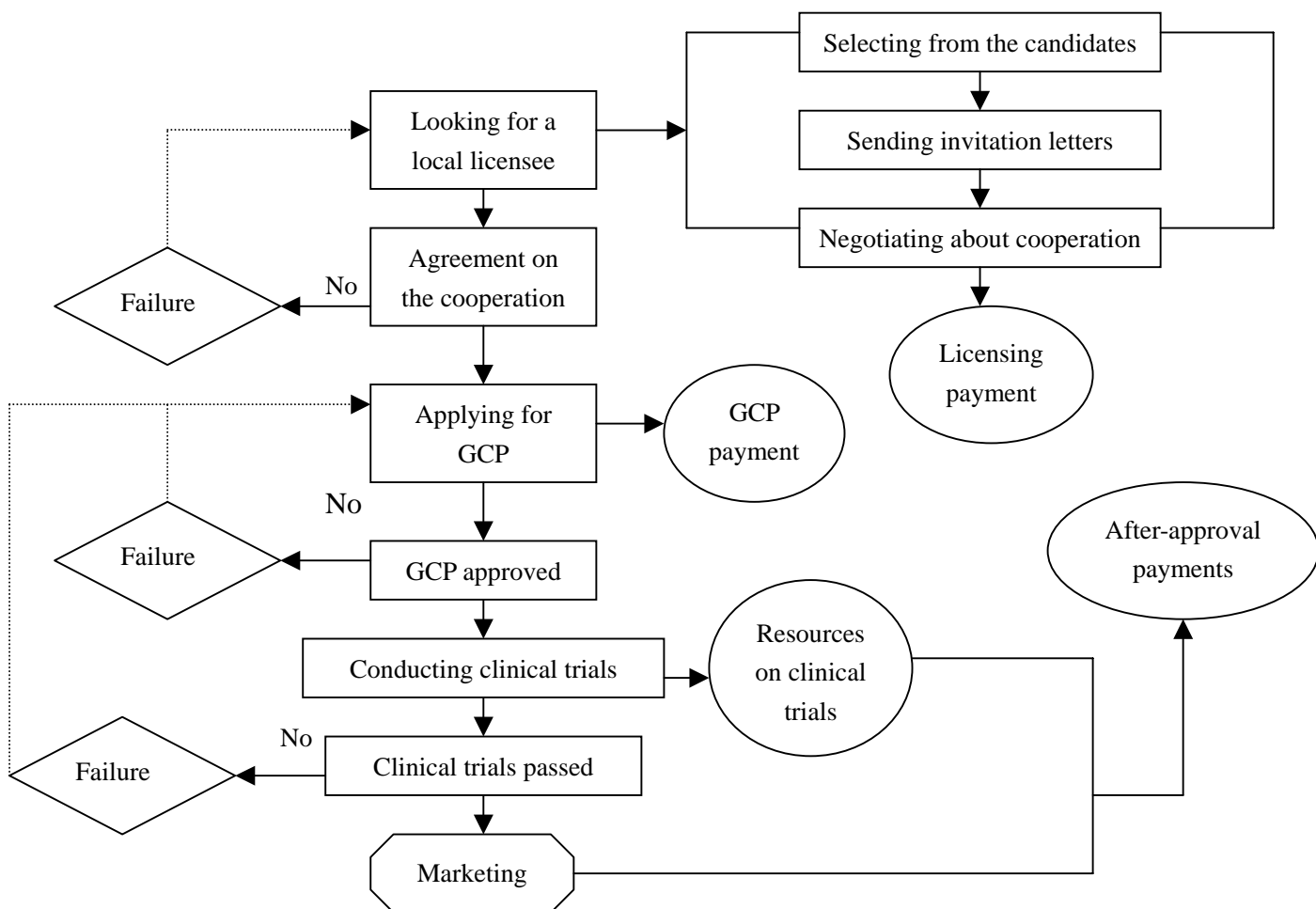


Figure 7.1 The Procedure of Entry Activities

7.1 Financial Feasibility

In this paper, financial feasibility is defined as if the project strategy and the project plan match the availability of the required resources.

I choose licensing for the project strategy due to the 'limited resources' my principals have. My principals have a small company for research and cultivating cannabis in the Netherlands. They have financial resources for their research and the overhead costs including travel fees for selling patent or other related business, but not enough resources for investing in exploring the Chinese market. So searching for the cooperation from a local partner is suggested to solve this problem. The candidates I gave in this paper all have strong financial force that will be affordable for the development of Sativex in China, but the problem is that whether they are ready to commit to invest the money for Sativex. So I will list some critical items that need to be invested in the project and, some alternative solutions will be figured out.

7.1.1 Licensing Payment of the Patent

German drugs group Bayer has taken on the marketing of Sativex in Canada, paying GW Pharmaceuticals £1m in cash for the license agreement since 31 March.¹⁷ In the way of licensing, the principals can choose to sell the patent to a local company in the return of immediate cash payment. This choice will take them no risk with fixed income, but there are some shortcomings we must pay attention to: 1) except the fixed income, the principals could lose the profit of selling Sativex in the future market; 2) principals will not have control on the business of Sativex in the new market through selling patent; 3) the local licensee may be reluctant to pay for the licensing fee at the beginning since it is hard to foresee the political feasibility (getting GCP approval from SFDA) of Sativex in China, so it will be difficult for principals to find a willing local licensee to take the high risk in the beginning.

Based on the analyst above, let alone the shortcomings for principals, the **main obstacle** for this critical item is that looking for a local licensee who is willing to pay for a huge payment for licensing can be difficult.

In order to solve this problem, the principals can change their way of selling patent. They can act as a **joint venture** with a local partner, making their patent as a share of the joint venture. This method can avoid the obstacle from the licensing payment. What is more, it can give the principals the chance of winning future profit from selling Sativex and the control of the future business of Sativex. The only problem of joint venture is that the risk my principals take will increase, that is, they lose the fixed income at the beginning and if the GCP approval is not successful, then they will just waste their time with no income. But in the case of selling patent in cash,

¹⁷ Latest News; Mar. 31st 2005; from GW Pharmaceuticals; <http://www.gwpharm.com/index.asp>

they will get cash whatever the GCP is successful or not.

Those two methods involve the choice between risk and control, so the final decision depends on the principals' and the local partner's balance between risk and control and also the negotiation between them to achieve an agreement.

7.1.2 GCP Payment

Applying for GCP involves several items of financial payment, including GCP procedure fees; work staff's salaries and compensations; guarantee payment of new medicine; the might-be bribery; and other payments.

The GCP procedure fees will be informed in every step of the GCP application process, which will not be a big amount so I will not discuss it much. The work staff's salaries and compensations should be paid steadily in the period of applying for GCP that will be decided by the HR manager. The guarantee payment and then especially the bribe payment could be unknown and the amount would be unsure, so I am going to discuss them in details later.

The guarantee payment of new medicine is asked by the SFDA on the purpose of insuring safety and unknown incidents in the process of all the activities related to the new medicine. The amount of guarantee payment is evaluated according to different medicines, based on the criterion from SFDA. The more risks the new medicine has, the bigger amount the payment should be. As known from a staff from a pharmaceutical company, the guarantee payment is around 10,000 yuan for regular new medicine. But for special medicine such as narcotic drug, this payment could be much higher. The information of the guarantee payment is not transparent in public by the SFDA, so I suggest my principals to take a deeper investigation on all the costs when applying for GCP.

The former Head of SFDA was executed because of bribery. It was said that some businessmen used bribery to get the approval for unqualified products through several important officers in the SFDA, especially including the Head. The process of application is not transparent and the applicants do not know what is going on in the process, and they do not know the real reasons of pass or fail either. The applicants have to wait for extra longer time and still do not know the result for years or they will fail to get the approval if they do not have 'guanxi' in the SFDA and proper bribery. Since the central government is taking actions on bribery all the time and the former Head of SFDA was already charged, it is in hope that the application of Sativex could be more fair, legal and transparent because of some new policies pushed by the new Head. But bribery is not an individual problem, it is the problem of the whole government system, executing one person or several persons will not root out this problem, maybe just relieve it. So we still have to consider about the 'guanxi' and bribery when applying for GCP from SFDA, because the time delay like three or five years might let us lose some important shares of the market and the waste of human

resource and money could also be a disaster. What is more, the longer time it takes, the more risks it will have. So in order to get a success in GCP or at least the avoidance of wasting money and time, bribery payment may be necessary and the amount is so hard to make sure, which is sure to be a big amount, much larger than legal payment.

As main items of the GCP have already been listed and explained, it is time to see the might-be obstacles for this link. Because the GCP of Sativex is the beginning of Sativex and also the decisive factor, so the success of GCP is very important which is also very uncertain and risky. GCP will take many financial resources and a long time, however the result cannot be told in advance. So looking for the investors in this stage can be hard because of the resources invested for a risky and uncertain result. After the GCP is successful, gathering investment can be easier.

When the financial feasibility comes to this stage, it seems the obstacle cannot be solved by both parts, neither the principals nor the local partner, because the risk of GCP is unknown to both of them. Anyway, looking for a strong and trustful local partner is better than struggling alone. Foreign enterprises cannot get the approval from SFDA on their own, joint venture or licensing is the regular and effective way for them. So for my principals, looking for a good and willing local partner is the way to make this link feasible. Offering an elaborate feasibility study and description of Sativex can be helpful when persuading the candidates to take the responsibility of applying for GCP.

7.1.3 After-approval Payments

If the GCP application can be successful and the clinical trials will go on to get a final permission to put Sativex into the market, and then the marketing of Sativex. The financial resources here would be a lot, but compared to the GCP application step, the risks are reduced. The clinical trials may take some years according to the former experience in Canada, and for sure it is different in China. An approval of GCP means SFDA has allowed a try for Sativex, and the clinical trials are the necessary procedure for healthy issues. Based on the successful clinical trials in Canada and the on-going clinical trials in some European countries, we have more confidence on it so that the risks will be less than GCP.

During the clinical trials, many financial resources must be invested to make sure the whole process go on well until the final permission is given. Investors will be willing to put their money here because there is less risk. A large amount of money is needed here to keep the daily clinical trials and other issues able to work. The might-be obstacle here is the insurance of a large amount of money, so a careful investigation of financial state of the local partner is important to prevent the in-process stop of financial resource.

In the case of a final permission from the clinical trials, later on marketing and other

management staff will continue. Financial feasibility related to this stage does not belong to the scope of this study, the marketing plan should be made and together with the financial experts going with the whole marketing process to make sure financial feasible.

7.1.4 Conclusions of Financial Feasibility

The study of financial feasibility is focused on the licensing, GCP application and clinical trials steps. Obstacles exist in each step, for licensing there are methods to solve the obstacle but it depends on the willingness of principals and local partners; for GCP application it is the most difficult to attract investors because great risk exists in this link, so persuading a competent local partner to take this project is the best way because of the principals' limited financial resources; as to clinical trials, a big amount of money is needed and an accurate investigation of financial state of local partner is demanded.

From this feasibility study, we can see the strategy I chose for entering into the Chinese market may need to be changed a bit. Looking for a local partner is supported from financial feasibility study, and what is more, a local partner with strong financial force is strongly recommended. Licensing for royalty payment may not work in the strategy of licensing based on the feasibility study, but in the form of a licensing as a joint venture. The 'know-how' is licensed as the technology share of the 'joint venture' and the principals offer the technical support during the whole process from GCP application to clinical trials. Furthermore, a detailed negotiation is needed between the principals and the local partner considering the financial issues to make sure the financial feasibility.

During the process of evaluating financial feasibility, the issue of political feasibility has already showed which was connected to the financial items closely. The political feasibility is very important to the financial feasibility and, to some extent decisive.

7.2 Political Feasibility

Sativex as one of narcotic drugs has triggered wide social discussions in Canada. The country that gives the permission to Sativex must consider this problem, which can be said political issues. The introduction of this special product may bring safety problems like drug abuse. Applying for the approval from SFDA is the first step for Sativex to enter into the Chinese market, so in this chapter I am going to talk about political feasibility.

Political feasibility will be discussed around the principals' objectives of growing, manufacturing and selling Sativex in China, and the strategies related to those objectives, for example, the application of all the certifications such as GCP, GMP and so on.

As discussed in the sections above, selling is the precondition of growing and manufacturing, so I will analyze selling first. Marketing assessment has already been done above and the conclusion is 'Yes', so there comes the political feasibility, that is, the GCP application.

7.2.1 GCP Application

GCP is the certification in order to allow the clinical trials of Sativex in China. Only when this certification is approved and the result of the clinical trials show Sativex is OK for the local patients can Sativex enter into Chinese market. There are already some examples of foreign narcotic drugs getting the permission to be sold in China, such as Durogesic and Oxycontin. And the Chinese government showed more open attitude to narcotic drugs, whatever the amount or the sort. The information and facts in the section of 'market assessment' has proved the open attitude. Till now, the macro political environment for Sativex is good, so the micro political environment has to be analyzed.

Micro political environment means SFDA, which decides whether to give permission to GCP application for Sativex. I have got some information from the new Head of SFDA through a friend, and it is said that if a foreign enterprise wants to apply for GCP of a new narcotic drug then the chance is nearly zero, but if it can cooperate with a local enterprise then the chance will be more than zero. From this information we can see that chance is there in the micro political environment, but it is hard to forecast the feasibility.

Learning from the success of Durogesic can help us to investigate the political feasibility. After nine years that Durogesic was sold in many countries including the USA, in 1999 it entered into the Chinese market. Since the safety and effectiveness were already proved in many other countries, Durogesic could have the permission to have the market in China. Sativex was just approved in Canada in 2005, but the approvals in the USA and some European countries have not been received yet, also the safety and effectiveness are still being tested in the Canadian market. From the comparison, it can be said that Sativex may not be mature enough worldwide in order to enter into the Chinese market. If it gets the approvals in the USA, and more European countries, then it could be easier for it to be allowed into the Chinese market.

The obstacles not only come from the immaturity, but also from the culture of 'guanxi' in China. Even when Sativex is mature enough internationally, the SFDA can also refuse to give the approval because of kinds of reasons. And now, 'guanxi' will play an important role in the process of applying for GCP. As referred in 'financial feasibility', bribery may also be needed here.

Hence, as a conclusion, it is better to say the macro political environment is good for Sativex and, the micro political environment offers chance for Sativex to have a try.

But because Sativex is not mature enough internationally, the situation is more difficult for it in China than that if the approvals in the USA and other European countries succeed. What is more, the culture of ‘guanxi’ and bribery in China should be taken into consideration in practice.

7.2.2 GMP Application

Suppose that Sativex is successful in the Chinese market for a while and there can be possibilities of manufacturing Sativex in China, then the application of GMP is necessary in the beginning.

Cooperating with a narcotic drug manufacture enterprise is the best choice to make manufacturing Sativex feasible in China. Because there is no need to apply for a new GMP and there is a quota in China on the number of enterprises which manufacture narcotic drugs. Here, the biggest problem is the political feasibility of growing cannabis. The manufacture of Sativex must be connected to growing cannabis with high THC.

As described before, there is no place to grow medically used cannabis in China and only one place for growing medically used opium, which is the raw material for all the narcotic drugs in China. If there is a market for Sativex in China, then growing cannabis might be allowed by SFDA. The possibility is even smaller than the GCP of Sativex in China when it is not mature enough. First of all, there is no experience that foreign narcotic drugs were produced in China. Then, opium is the only plant to be the raw material of all the narcotic drugs in China; no other ‘drug plant’ ever appeared in China till now. Seen from the strict control of the supply of raw material for narcotic drugs, it could be very hard to predict if the Chinese government will allow medically used cannabis to be grown in China.

The information gathered and the analysis we have for now, we can conclude that the political feasibility of manufacturing Sativex in China is nearly ‘No’ till now. We can hold the hope that because of the continuous developments of various cannabis-based medicines, the policies of narcotic drugs will be more open in the near future and, the international environment and debates of medically used cannabis would be nicer for Sativex, so that the manufacture and growth can be more feasible in China.

7.2.3 Conclusions of Political Feasibility

In the analysis of political feasibility, the objective of selling Sativex in China might be feasible now, but if this product is more mature internationally then the political feasibility in China can be larger.

On the contrary, the goals of growing cannabis and manufacturing Sativex in China are really difficult to be realized currently because it can hardly be political feasible concluded from the situation in China now. It is hopefully that policy changes which can be good for foreign narcotic drugs and Sativex could have better international and

national environments.

The strategy I chose for developing Sativex in China can help with the realization of selling function, but no better strategies could be found to realize the growing and manufacturing function now. Maybe it can be clearer after a success of selling Sativex in China. So in the political feasibility study, the strategy I chose before has been tested to be proper.

7.3 Conclusions

Feasibility study is finished till now and the strategy I chose for the project has been proved to be proper. In the financial feasibility study, a strong recommend of sufficient financial strength of the local partner was given. And ‘licensing as a joint venture’ was advised to share the financial risks in order to achieve financial feasibility. In the political feasibility study, the strategy of licensing or licensing as a joint venture are accepted both.

Obstacles exist in three financial aspects: licensing, GCP application and clinical trials. The one in licensing could be solved through efforts by both parties; but the one from GCP application is the most difficult, which is based on the investor’s willingness to undertake this investment and predict Sativex as a prospective product, also based on the principals’ ability of negotiation; for clinical trials the finance may be the largest but it is more acceptable by investors because the success is easier to be foreseen.

Political feasibility study indicates that the macro environment for selling Sativex is good while the micro environment (SFDA) is complicated, that is to say, there is a chance of selling Sativex in China, but whether we can get the approval from SFDA is not for sure. This obstacle in micro environment cannot be avoided in any other countries once the GCP application happens, so the political risk for this link should be taken as long as there is a sales potential for Sativex in China. I conclude it is politically feasible for selling Sativex in China.

However, for those two other goals—growing cannabis and manufacturing Sativex, it is very hard to predict, especially when the selling function has not been fulfilled. Let us say that in current situation in China, growing cannabis and manufacturing Sativex are not politically feasible since the strict policies on narcotic drugs’ production and the supply of raw material. But with the developments of medical cannabis internationally and the might-be success of selling Sativex in China, there could be a possibility, which will be studied in the future.

Chapter 8 Conclusions and Reflections

8.1 Conclusions

In this research, the objective is to study the feasibility of growing cannabis, manufacturing and selling Sativex in China. So I analyzed each goal then concluded selling is the precondition of two other goals. Through the industry market potential and company sales potential analysis, I made a conclusion that Sativex could have potential market in China since the size and growth of narcotic drug market are both increasing gradually.

In order to realize the 'selling' function, I chose a proper strategy to help Sativex penetrate Chinese market among some strategic options. The strategy I chose is 'licensing', which is not limited to sell the patent of Sativex to another company in return of fixed amount of cash. 'Licensing' means offering the 'know-how' to a local partner and cooperate with it in order to make the objective realized. In the feasibility study, the strategy has been tested to be the most appropriate.

Designing project plans elaborates some details of taking the entry strategy into practice. Selecting a good local licensee and applying for certifications are the two main activities that were discussed. I listed the possible local candidates for licensing and, according to each function, I categorized candidates and then analyzed them to see which ones could be proper to have a try and send invitations. In the section of 'applying for the approval of Sativex', I gave the flow charts of how to apply for GCP and GMP. Also, some information considering the Certification Center of SFDA and GSP was contained.

The feasibility study, which includes financial feasibility study and political feasibility study, is used to test the strategy chosen. Financial feasibility study aimed to look into if the investments would be gathered for Sativex successfully before the approval of Sativex and after that. And the conclusions are as follows: 1) Licensing payment which happens in the negotiation of cooperation, is a problem that can be solved by both parties. The feasibility depends more on the interests from principals and their partner, whether to pay for it or take it as a part of the equity of a joint venture can be negotiated 2) Financial feasibility concerning GCP application is the most difficult because it has the highest risk. The success of GCP application is very hard to be predicted so investors may not dare to invest money in this phase 3) Once the GCP is approved and it goes into the phase of clinical trials, investors will be more willing to invest money on the project because they have fewer risks and the success is easier to be foreseen.

The political feasibility study investigated whether each goal could be realized in

China based on the situation in China now. For ‘sell Sativex’, there is a chance because it has sales potential in China, but whether we can get the approval from SFDA is not for sure. However, the obstacle is unavoidable in any other countries when applying for the permission of conducting clinical trials, so I suggest this risk should be taken if Sativex still has sales potential in China. Thus I conclude it is politically feasible for selling Sativex in China. However, in current situation in China, growing cannabis and manufacturing Sativex are not politically feasible since the strict policies on narcotic drugs’ production and the supply of raw material. But with the development of medical cannabis internationally and the might-be success of selling Sativex in China, there could be a possibility.

8.2 Reflections

The objective of this research is to grow cannabis, manufacture and sell Sativex in China. After the whole study, we have to check out if the result of this research meets the objective set in the beginning.

From the whole analysis and especially the feasibility study, it can be seen that the objective could be partly realized by the strategy chosen currently in China. ‘Selling Sativex’ has been proved feasible based on the situation in China nowadays. Unfortunately, ‘growing cannabis’ and ‘manufacturing Sativex’ hardly can have the chance to be fulfilled, at least before the success of ‘selling Sativex’. In the hope of policy changes in China and more open international and national environments for medically used cannabis, the principals’ objective may be realized fully in the future.

It is also very necessary to look into the research itself to see if the result is worthy to be believed. So I would like to say something about the accuracy of this research and some shortcomings that could be compensated next time.

The source of data I used in this paper is not single, some is from research reports; some is from interviewees; some is from the homepages of companies and organizations under research; and the like. The second-hand data is to some extent artificial because of different purposes the offers have, but the first-hand data can compensate this weakness. However, the first-hand data from the interviewees may also have the risk of having subjective thinking but not scientific. So I analyzed second-hand data and first-hand data together to make sure the accuracy. For example, the ‘market assessment’ of narcotic drugs in China, I used the data from ‘Current Status and Prospect of Narcotic Drug Application in China’ [Kong 2005] for the proof of the increased market size and growth. In the same time, I had an interview [Xiaosong 2007] with a person in charge of medicines supply in one hospital in order to test the accuracy of Kong’s data. Though the accuracy has been ensured, the data from Kong is kind of old, which was only updated till 2001. The out-of-date data would influence the accuracy of this research’s result. I have tried to make up for it

through other methods because the data of narcotic drugs consumption is hard to obtain. More up-to-date data could be got if I can have good relationships with some narcotic drug manufacturing or sales company, or the SFDA. The principals should pay attention to this problem next time in order to get the inside information.

In the section of 'selecting entry mode', I chose some criteria for entry mode decision based on 'Entry Strategies for International Market' [Root 1998]. I have to admit the criteria I listed there are not good enough. Maybe some other criteria should be added or some of the existing criteria should be deleted or modified. More knowledge and experience I have to gain in order to make the choice of strategy more scientific, though in practice, this strategic choice can meet principals' demands and feasibility study.

In the end, the feasibility study may not be completed because I just chose two most important aspects for investigation. Some other aspects such as the choice of location, the acceptance of technology, and the protection of patent in China should also be considered in the entry strategy. But I do not know much about the technology and patent from my principals because they keep them secret, so I cannot do those feasibility studies. I suggest the principals take those aspects into consideration in the future.

After indicating the accuracy of this thesis, I think the construction or logic of thesis should also be discussed. The whole construction of this thesis has been shown in figure 2.1 in section 2.1, the model for that originates from 'Entry Strategies for International Market' [Root 1998]. I made some modifications according to the demands of this project (also demands from the principals), for example, designing project plan which should be done before designing marketing plan. When comparing my model with the model of 'The Elements of an International Market Entry Strategy' [Root. 1998], the first step 'choosing target product/market' was skipped because the market has already been chosen by the principals.

But for the next time when I do the same project, I will consider to take the first step into my model. The principals might choose China for the target market without sufficient analysis, just like many other people. They heard a lot about China and the huge potential market in China, so China becomes the first consideration to them because of the popularity in the world trade market. For this project, I think the first step is important. Looking for a country which is more open to the use of medical cannabis has to be done for the first step next time, and the result may be more pleasant to the principals than that in China.

I believe that there must be more worthy learning from this project and the way of applying theories into practice could be improved next time when doing it. So with time passing, I hope I can have a more complete, accurate, scientific and practical research for this project with more experience and knowledge I can gain. And in other

researches in the future, I will keep the shortcomings I had in this research in mind on the purpose of making those researches better.

8.3 Recommendations

As a result of this research, the principals' objective can just be realized partly, so I have some recommendations for my principals.

First of all, the objective of 'selling Sativex' is the precondition for the other two, so it is recommended to take this as the first step. There are some local candidates in the 'selecting local licensee' section, which can offer 'selling' function first and then if need 'manufacturing' function is also affordable. It might be a choice to send invitations to the local candidates and then decide more from the responses.

Secondly, I remind the principals of the shortcomings I referred in the previous section. More investigation are needed to have a more accurate result. My principals can get more inside and up-to-date information from their cooperation with local companies. A continuous research must be followed during the whole project.

Thirdly, I suggest my principals to pay attention to the special situation in China, for example, the problem of bribe and the culture of 'guanxi', and also a careful investigation of local candidates is necessary.

At last, since this project is politically sensitive, keeping an eye on the policy changes in China is also recommended.

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Appendices

Appendix 1 Effect Comparison of Morphine and Durogesic

Morphine by mouth for 24 hours (mg/day)	Durogesic (μ g/h)
<135	25*24=600ug=0.6mg
135-224	50=1.2mg
225-314	75=1.8mg
315-404	100=2.4mg
405-494	125=3.0mg
495-584	150=3.6mg
585-674	175=4.2mg
675-764	200=4.8mg
765-854	225=5.4mg
855-944	250=6.0mg
945-1034	275=6.6mg
1035-1124	300=7.2mg

Table 1: Effect Comparison of Morphine and Durogesic

Source: The instruction of Durogesic; Jul. 18th 2005; from Xian-Janssen Pharmaceutical Ltd.; <http://finance.sina.com.cn/xiaofei/consume/20050718/15031808649.shtml>

Name	The amount with same effect
Morphine	30
Codeine	200
Oxycondon	30
Pethidine	75

Table 2: The Amount Comparison Between Morphine and Other Narcotic Drugs

Source: Foley KM (1985). "The Treatment of Cancer Pains." In *NEJM*, Vol. 313, no. 2, p. 84-95

Appendix 2 Profitability of a Proposed Licensing Venture

Source: Franklin D. Root (1998). "Entering International Market through Licensing and Other Contractual Arrangements." In: Franklin R. Root (1998). *Entry Strategies For International Markets*. Jossey-Bass, San Francisco.

Profit contribution = Projecting incremental revenues – Projecting incremental costs

Projecting incremental revenues = Projecting running royalty revenues^① + other kinds of licensing revenues^②

① = a percentage of sales estimated in the target market

② = Lump-sum royalties (including disclosure fees) + Technical-assistance fees + Engineering or construction fees + Equity shares in licensee firm + Dividends on equity shares + Profits from sales to licensee (machinery, equipment, raw materials, components, or nonlicensed products) + Profits from purchase and resale of goods manufactured by licensee + Savings from use of licensed products in licensor's own operation + Commissions on purchases or sales made for licensee + Rental payments on licensor-owned machinery or equipment + Management fees + Patents, trademarks, and know-how received from licensee (grant-backs)

Projecting incremental costs = Opportunity costs^① + Startup costs^② + Ongoing costs^③

① = Loss of current export or other net revenues + Loss of prospective revenues

② = Investigation of target market + Selection of prospective licensee
Acquisition of local patent/trademark protection + Negotiation of licensing agreement + Preparation and transfer of blueprints, drawings, and other documents + Adaptation of technology for licensee + Training licensee's employees
Engineering, construction, and plant installation services + Contribution of machinery, equipment, and inventory to licensee

③ = Periodic training and updating of licensee + Maintaining local patent/trademark protection (including policing and litigation costs) + Quality supervision and tests + Auditing and inspection + Marketing, purchasing, and other nontechnical services + Management assistance + Correspondence with licensee + Resolution of disputes + Maintenance of licensor staff

Appendix 3 The Contact Information of All Licensee Candidates

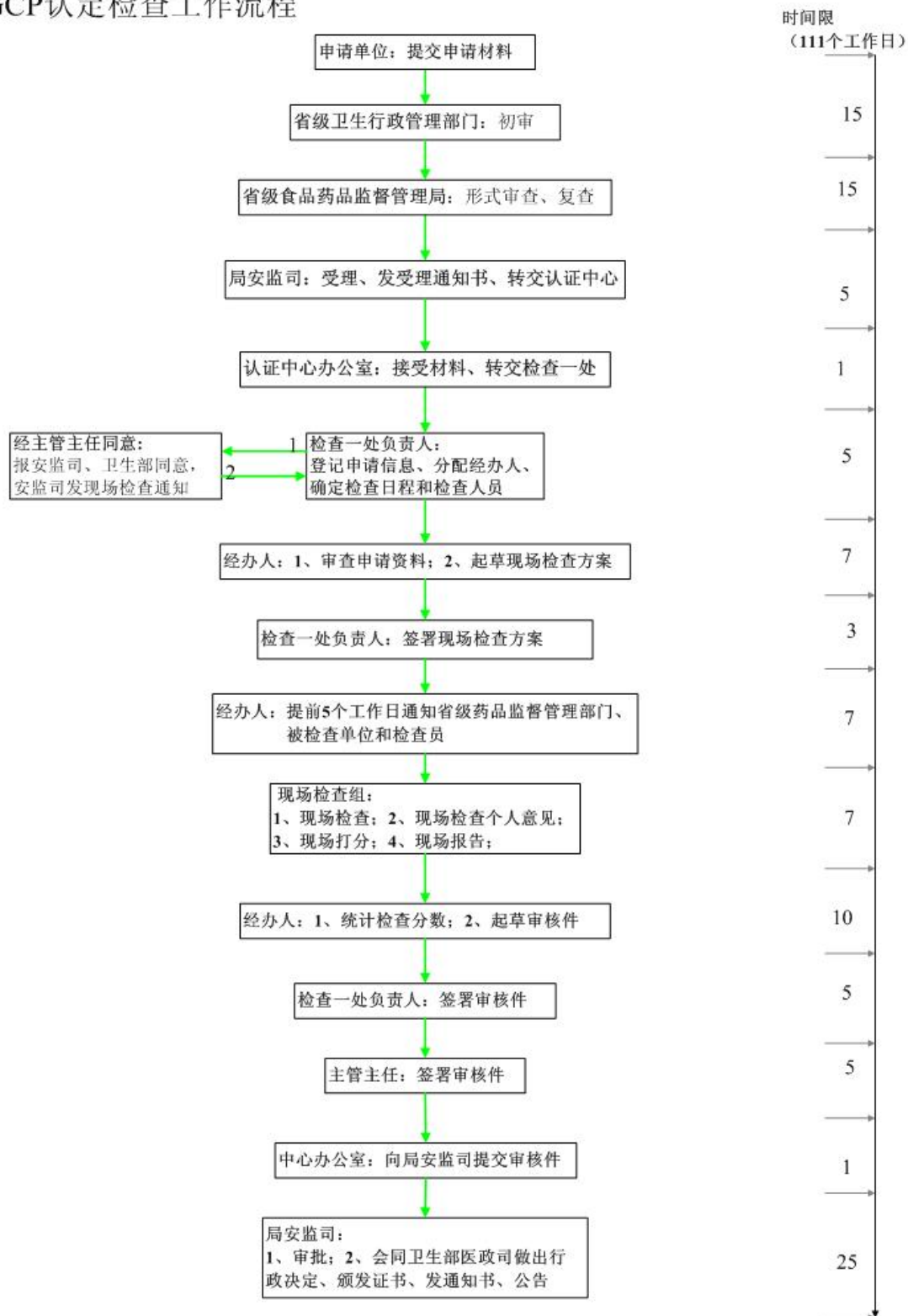
The Holly Group	Bayer Healthcare Co., Ltd.	Beijing Mundipharma Ltd.	Xian-Janssen Pharmaceutical Ltd.
4300#, Jiangnan Avenue, Binjiang District, Hangzhou, Zhejiang TEL:0086-571-81993212	7# Rongjing Dong Street, Economy and Technology Development District, Beijing TEL:0086-10-67882150	9#, Guanghua Road, Jianguomen, Chaoyang District, Beijing TEL:0086-10-65886668	18 th floor, A building, Yingke Center, 2#, Gongti Bei Road, Chaoyang District, Beijing TEL:0086-10-58218888
Gansu Agricultural Medical Raw Material Station	China National Pharmaceutical Group Corporation	Qinghai Pharmaceutical Factory Co. Ltd	YiChang Humanwell Pharmaceutical Co., Ltd
Changyuan Building, 19# Tianshui Nan Road, Lanzhou, Gansu TEL:0086-931-8829732	20# Zhicun Rd., Haidian District, Beijing TEL:0086-01-62019988	108# Qilian Road, Xining, Qinghai TEL:0086-971-5507206	18# Dalian Road, Yichang Economic & Technology Developing Zone, Hubei TEL:0086-717-6345005
Shenyang No.1 Pharmaceutical Factory			
54# Xinhua Nan Street, Tiexi District, Shenyang, Liaoning TEL:0086-24-25875291			

Table 3 The Contact Information of All Licensee Candidates

Appendix 4 GCP Certification Procedures

Source: GCP Certification; from the website of certification administration center of SFDA;
<http://www.ccd.org.cn/ccd/view?id=34>

GCP认定检查工作流程



Appendix 5 GMP Certification Procedures

Source: GCP Certification; from the website of certification administration center of SFDA;
<http://www.ccd.org.cn/ccd/view?id=31>

药品GMP认证流程

