# Joint Venture Agreements in the Pharmaceutical Industry

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Joint venture companies are frequently used in the pharmaceutical industry for various commercial purposes, including joint market development for certain products, conducting joint research efforts and/or clinical trials or simply to create synergies for the joint venture partners. The present article intends to provide a bird's eye view of various important aspects when contemplating to enter into a joint venture relationship and to provide practically relevant tips and help with regard to the crucial success factors when drafting and negotiating a joint venture contract.

#### 1. Definition

"Joint ventures" are commonly defined as a business arrangement in which two or more parties agree to pool their resources (characterized by shared ownership, shared return and risks) for the purpose of accomplishing a specific task.

The ways in which a joint venture agreement can be structured in the pharmaceutical industry are manifold and depend on the specific business purposes the parties wish to achieve, i.e. whether the parties want to pool their resources for joint research efforts, joint marketing efforts or simply for certain specified pre-determined commercial or scientific tasks.

The following article will highlight some important features of joint venture agreements and how they are applied in the pharmaceutical industry.

#### 2. Joint Ventures as One of Several Possible Cooperation Vehicles

Every company that intends to start business cooperation with another

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company has a broad range of possibilities to start and structure the cooperation. These investment alternatives should be carefully analyzed before a joint venture contract is agreed upon, in order to find the optimal form for the intended cooperation between the parties. According to the experience of the authors, sometimes premature decisions are made in favor of a certain form of a coop-

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eration, without having considered in-depth the pros and cons of the various cooperation alternatives available.

To begin with, parties could start to cooperate without tying up in a separate legal entity and could simply start on the basis of a mere contractual cooperation arrangement. An example for such a contractual cooperation arrangement is a distribution agreement, where one firm offers their products to the other firm (often in another country) for marketing purposes and physical distribution. In such scenario both companies stay completely independent and a cancellation of the contract is possible at all times (depending on the details of the respective distribution agreement). However, in some countries and jurisdictions such contracts can only be terminated if a payment of a compensation fee is made to the distributor.

Another form of cooperation between pharmaceutical parties consists in entering into a license agreement. Under a licensing arrangement, one party offers to the other party a certain right (Latin: "licet") to use patents, trademarks and in some cases know-how compensated via license fees for a fixed time frame. Since the licensor gives the licensee the right to use patents and other intellectual property rights (e.g. trademarks etc.), the cooperation reaches a higher degree of interaction between the parties than a mere distribution agreement. In comparison to a mere distribution agreement, the risk for the licensor is significantly higher, as the licensor has to make sure that the licensee works according to his quality and other technical standards and that the licensee does not transfer the licensed technology to a non-authorized third party.

A special kind of license agreement is the "Know-How Licensing Agreement", which is often used when a product is already off patent, e.g. Aspirin, and the life cycle of such products still continues. The commercial rationale for such Know-How Licensing Agreements for off patent products is that the licensee wants to avoid costs and time that would otherwise have to be spent for product registration.

An even more intense form of cooperation is the joint venture that is discussed in detail in this article. The intensity of this form of cooperation is significantly higher in comparison to other forms of cooperation, as there is not only a contractual engagement between the parties but also a joint investment and usually also a jointly established legal entity.

#### 3. Reasons for Starting a Joint Venture

The reasons for entering into joint venture contracts are manifold. The most obvious one is in countries where mandatory local laws exist, where foreign investment participation is only possible via a joint venture (e.g. Thailand). This used to be the case in China up to the end of the 90 s. Joint venture companies have been the classical form of the market entry into China.

Regardless of legal restrictions that exist for foreign investment in various countries, there are a number of compelling commercial reasons that are in favor of setting up a joint venture company. First and foremost, a joint venture provides immediate access to local know-how and local resources and speeds up the time to market a product.

By engaging a local partner, the immediate access to local knowhow – e.g., developing a biological product and the country specific circumstances – will be adequately taken into account in a specific market. Another reason for the engagement in joint venture companies often lies in the immediate access to local distribution channels. The establishment of these channels often takes several years and sometimes seems to work according to the principles of trial and error. Last but not least, investors also cite a diminished entrepreneurial risk for setting up a joint venture company, because in view of the participation of another partner a smaller capital involvement is required. Furthermore, there is a second legal entity with legal responsibility involved.

According to the experience of the authors, joint ventures are also used when an investor plans to acquire a company: Firstly a certain equity percentage of the target company is acquired, combined with the option for the acquiring company to purchase the majority of the shares of the local target company after a certain time period or after fulfillment of certain commercial milestones. The advantage for the acquiring company is not only a guaranteed continuity of the company's management but also the opportunity to familiarize itself in-depth with all business details of the target company. The authors discovered (more than once) that during the course of the joint venture cooperation between the parties various deal breakers were discovered (e.g., "creative" accounting practices, etc.) of the company to be acquired leading to a complete new evaluation of the target company.

Whether and to what extent the above-mentioned reasons are ultimately convincing really is a matter of personal experience and belief. It could be argued for instance that nowadays local know-how could be purchased in most markets via hiring experienced local staff, without the need of establishing a joint venture company. Moreover, the argument of "shared risks" is usually becoming less convincing once one of the partners runs into financial difficulties, so that the remaining partner has to absorb all entrepreneurial risks alone. However, it is not the main purpose of this article to evaluate and finally judge the pros and cons of joint venture companies. The focus of this summary rather lies in the important aspects and legal considerations of setting up joint venture companies.

#### 4. Important Topics Which Should be Clarified Before Closing a Joint Venture Agreement

It may sound trivial but the importance of screening the future joint venture partner cannot be emphasized enough. More often than not, the screening of the target company is not carried out in sufficient detail or sufficient depth. In performing a due diligence not only for objectivity reasons, one should not merely rely on in-house specialists but also engage the assistance of independent experts. The partner "in spe" should be especially scrutinized regarding the real ability to provide the local know-how and enhance the joint venture's mid-term and long-term goals. To merely have an inactive local partner as joint venture Partner would not justify the negotiation and administration work involved in this process.

Before starting the negotiations with the potential partner, the commercial milestones which should be reached, should be fixed in the draft agreement and quantitative as well as, qualitative key performance indicators should be agreed in every detail. Before signing the contract it should be stated very clearly, at what time which goals have to be reached by the joint venture company in order to provide a rational basis for the parties to measure and verify the success of the joint venture company.

After agreeing on the milestones in very concrete terms – i.e., "what" the joint venture has to achieve exactly –, the second most important issue is to discuss and agree on "how" and in which manner these commercial goals should be achieved in detail by the joint venture company. This means how and by which means the business and commercial goals of the company can be reached in detail? Ultimately, this comes down to outlining the business strategy of the joint venture company. Sometimes strategy and goals are not clearly separated but are intertwined, having the effect that the strategy is considered the goal. Such conceptual mistakes may inevitably lead to wrong entrepreneurial decisions on the level of the joint venture company.

In addition, an initial discussion topic between the parties should focus on the correct legal vehicle the parties wish to use for their joint venture. Which legal entity would be the most suitable for the parties' commercial purposes? Usually this will be a limited liability company under the respective jurisdiction to be chosen. Concerning this important item, a consensus with the partner should be reached early on during the negotiations.

Another crucial topic where a consensus should be reached prior to signing the joint venture agreement is the determination of the profit and loss sharing between the parties. In case no common understanding is reached before a joint venture contract is signed, a possibility of a conflict between the parties is already preprogrammed.

The initial discussions of the joint venture are usually considered as the "honey moon period" of the joint venture and for understandable reasons the parties are not inclined or neglect to discuss the outlining of an exit strategy for the joint venture. However, parties should take a realistic view of their intended commercial set-up up-front. According to the experience of the authors not all joint companies have a long period of existence and in some cases the joint venture's duration lasted only a relatively short period of between 5 to 10 years. Therefore, in order to avoid protracted discussions in case the 'going should get tough", it is advisable to consider all eventualities from the outset.

In the framework of an exit strategy, it should be clearly laid down, what has to be done in case of a termination/liquidation of the joint venture in all details. That means in case of winding down the company, what will be the fate of the intellectual property, what happens with the assets of the company, what shall happen to the employees, how about any non-compete undertakings, etc. Instead of liquidation should each partner have a right to acquire the shares of the other company?

Another practically very important point is the valuation of the joint venture's shares. Of course, during the winding up of a joint venture, a professional accounting firm can always be hired to assess the value of the joint venture company's shares. But to avoid time and cost for such valuation exercise, it seems preferable that the parties already agree in their joint venture agreement upfront what type of evaluation formula for the share price they will follow in case of a dissolution of the joint venture.

#### 5. The Importance of the Human Resource Factor

A frequent reason why some joint ventures fail is a lack of proper attention to the human resources factors. When working out the future company's business strategy, the strategy for key employees should also be established between the parties.

First a competence profile for future key employees in the joint venture should be set up and the main components of this strategy should be attached in an appendix to the joint venture contract. In this respect it is most important to lay down all skill sets that the joint venture key employees should possess, in order to enable the company to achieve its milestones and business goals. In case the joint venture is established in a foreign country, intercultural competences and sensitivity to the corresponding business environment are also key aspects and very important. In this context it is good that increasing value is put on the knowledge of the respective language spoken in the country. Of course, almost everybody will speak/understand

English, but English on its own often keeps business contacts on a surface level or even an artificial level. Obviously not every CEO will have the ability to talk fluently in the language of the host country. However, the knowledge of some foundations will facilitate the entrance to the host country's culture and business environment tremendously.

Looking at the joint venture staff's remuneration level, almost always different salary- and award systems are in place between two joint venture partners, which - if not properly addressed - can easily lead to dissatisfaction among the joint venture's employees. Therefore, the creation of a common salary and award system within the joint venture is essential. Hiding the existence of different salary and award systems might be possible for a certain (short) period of time. However, in all likelihood this is bound to surface sooner or later. This is not only true for the mere remuneration, but also for other perks and benefits. The overall working atmosphere can easily be poisoned once an employee discovers that the other joint venture partner's employees have for instance a more generous pension plan.

Sometimes it proves to be cumbersome to find competent key employees for a joint venture in a company, as employees might fear that secondment to the joint venture could lead to a break in the personnel career path or even a dead-end street. Such obstacles can easily be circumvented if a return to the mother company is already addressed in the respective employment contract.

An important success factor for all joint venture companies is the establishment of good institutionalized communication channels between the joint venture company and their respective shareholder companies. Laying down the structure of decision processes in writing is a first step but will only lead to success when procedures are not only written on a piece of paper, but will be realized in daily life. The best Employee Handbook will not replace verbal communication, which has the role of an early warning system recognizing potentially unwanted developments in the joint venture company.

#### 6. Details of Joint Venture Agreements

The first important aspect to be addressed is whether the joint venture contract will be drafted for a legal system that belongs to the so-called "civil law" jurisdiction or for a "common law" jurisdiction. This differentiation is of crucial importance for the way in which the joint venture agreement will be drafted. As a general rule, a joint venture contract for a common law jurisdiction will be drafted in a more detailed manner than a joint venture agreement that is drafted under a civil law system. The degree of detail (which translates directly into more or less pages for the joint venture draft) is due to the fact that the common law is in general less abstract than a civil law system, i.e., focusing more on cases ("precedents") than on statutory provisions. Therefore, more eventualities have to be addressed in a joint venture contract under a common law system than would be the case in a civil law system. This is also due to the fact that common law judges are more hesitant in filling contract gaps through interpretation than civil law judges, requiring a joint venture agreement in a common law jurisdiction to go into more detail. Civil law systems do not need that as they possess detailed codifications that can always be used as a fallback position.

One question, which always comes up before negotiations start, is whether it is recommendable to first start with a "Letter of Intent", which is sometimes also called a "Memorandum of Understanding". The typical answer of a seasoned lawyer will always be "It depends." Generally speaking, even a Letter of Intent requires quite some time to be discussed/drafted and even more time for the parties to agree on the content. Considering the time factor, whenever possible it seems preferable to start with a draft of a detailed joint venture agreement right away.

In case there should be already a common understanding with regard to the economic projections and key indicators for the joint company upfront, the establishment of a short term sheet is justified. This sheet contains all economical key performance figures of the future joint venture company and may enhance the negotiation results.

Following international practice, each joint venture contract should start off with a "Preamble" (also called "Whereas Clauses"). For this part of the contract, it is recommended to clearly refer to and summarize all essential key presumptions and foundations for the joint venture - just in case the contract will ever become the object of a legal dispute. The underlying assumptions of the joint venture company are of essential importance in case a legal dispute should ever start. After reading the joint venture contract's preamble, it should be clear to an uninitiated reader, who is not really involved into this matter, why the parties wanted to engage in a joint company in the first place and which economical interest they had in mind for forming a joint venture company.

The next important item concerns the equity involvement of the parties: Which party owns how many percent of the joint venture company's capital? Unfortunately, a misconceived "equality thinking" is often found here, leading into a joint venture where each party owns a 50 % share portion. This might be attractive from an equality point of view. However, in view of practical experiences a 50/50 joint venture should generally be avoided if at all possible. In a 50/50 joint venture, both parties will have exactly the same voting rights. Once the first major difference between the parties occurs regarding the course of the joint venture's business, which cannot be settled amicably between the parties, the joint venture is immediately deadlocked and blocked, since no party has a chance to overrule the other party. Because of this reason, it is advisable that one party should always hold the majority of the joint venture company's shares, i.e., at least a minimum of 50,1 % of the company's shares, in order to avoid a deadlock of the joint company that under a worst case scenario might ultimately lead to the joint venture's dissolution.

Another point that is often hotly contested between the negotiating parties is the contribution in-kind to the joint venture, i.e., intellectual property rights, production facilities etc. Contribution "in-kind" into the joint venture is generally connected with special difficulties, as more often than not there are no generally recognized and generally accepted principles how such in-kind contributions are to be valued. In order to avoid endless back and forth discussions between the parties with different valuation ideas, it is recommended that an expert should undertake a binding determination of any contributions that are made in-kind. Once a value is established by this procedure, both parties should then accept such valuation as being binding for both parties.

In order to avoid that the joint venture company develops an uncontrolled existence of its own and undertakes business activities without coordinating such activities with the investors' shareholders, it is always recommendable to set-up a so-called "negative list" for the joint venture's management. This list enumerates the business events which always have to be approved by the joint venture company's shareholders at all times. In this respect it should also be recognized, that in some jurisdictions the role of a joint venture company's chairman is not just of a ceremonial nature, but that the chairman sometimes has a casting vote in case of a dead-lock in the company's board.

The nomination of the Board of Directors of the joint venture company is also of crucial importance. An attempt should always be made to place trusted and experienced employees of a shareholder's own company into key positions, e.g., Finance or HR. In addition, the joint venture contract should address, what kind of votes is required for what type of decisions, i.e., simple majority, qualified majority, or unanimous vote. In order to avoid that corporate meetings are called where just one party is present and to prevent the joint venture partner from carrying out any decisions on their own, the Articles of Incorporation/Constitution should always address the question, when a quorum is present and to make sure that a quorum is only present provided a minimum number of both parties is present at any meeting.

It should be regulated as well, what happens in case of disputes between the parties. It is strongly advised, that the contract contains a detailed mechanism on how to handle dispute resolution. In order to avoid that each dispute is put in front of a court or an arbitration tribunal, the introduction of a dispute resolution steering committee has proven to be very helpful. The steering committee is an institutionalized board, with delegates from both parties, not involved in the daily business of the joint ventures that always keeps some distance to the day-to-day business of the joint venture company. The steering committee should meet on a regular basis or at least whenever critical topics need to be discussed between the joint venture partners. Due to the fact that members of the steering committee are not involved in the company's dayto-day business, it is often easier for the members of the steering committee to find appropriate solutions and see a whole range of possible solutions, instead of viewing a single problem.

As last resort the dispute resolution clause may include one or several alternative dispute resolution mechanisms, including mediation. Especially if the parties wish to avoid that the details and contents of the dispute should be discussed in public in state court proceedings (which are always open to the general public), then arbitration should be seriously considered. With regard to arbitration, the parties should consider upfront whether they wish to have an institutional arbitration with one of the generally recognized arbitration institutions (e.g., ICC, LCIA, HKIA, etc.) or whether the arbitration should be conducted without institution on a so-called "ad hoc" basis.

As already mentioned above, the modalities of a dispute in case of liquidation should be clearly addressed in the joint venture contract. In case the joint ventures is liquidated, it should be laid down in the contract, which price is due for the shares of the joint ventures (in case one party wants to sell/acquire all shares), but it should be also laid down upfront, how the price-finding for the share is done. Such a valuation clause often helps to avoid a tough and costly dispute on how the value of the shares of the joint venture company should be determined and which procedure for the determination of the value should be chosen. The ways in which a valuation clause can be drafted are almost unlimited. The most important item for such valuation clauses is to make any chosen valuation procedure transparent and verifiable. In addition, the parameters used for the valuation should be acceptable for both parties and that these criteria - if required - could be verified by an external valuation body.

In case certain products are given to the joint venture company on a license basis, it is very important to define in the Joint Venture contract, which kind of license rights are given to the joint venture company, i.e., should these rights be exclusive, non-exclusive or just semi-exclusive. Should there be certain restrictions for such rights, either concerning the timing or certain geographical restriction?

Equally important in the joint venture agreement are clauses that address the question if and under which conditions the joint venture's shareholder are allowed to compete with the business of the joint venture company. Such non-compete clauses usually also address the question what rights the shareholders have to sell their products directly into the joint venture company's country of operation, what shall apply to product exports, etc.

Finally, the parties should agree which law applies to their joint venture contract. With respect to this question, the authors have experienced an "interesting" example of contract between a German and a Chinese company. Both companies could not agree on the application of either German or Chinese law. Ultimately and as a compromise, they agreed on the applicability of Swiss law, which none of the parties was familiar with and which in the end had very dramatic and unintended consequences for both parties.

In order to generate clear and quantifiable indicators for the performance of joint ventures (and if needed a right to cancel the contract), it is advisable, to agree on clear economic qualitative and quantitative milestones either directly in the joint venture agreement or in an amendment to the contract. This is the only way to have an objective yardstick for the joint venture's performance.

Last but not least, one should make sure that all important contracts for the joint venture are signed simultaneously in one batch (e.g., if there is also a license involved then the licensing agreement should be signed at the same time as the joint venture agreement) in order to avoid that the parties have reached a consensus regarding their joint venture contract but failed to reach a consensus towards other important ancillary contracts.

## 7. Reasons for the Failure of Joint Venture Companies

The most frequent reason for a failure of a joint venture company seems to be a lack of efficient communication between the involved parties. Furthermore, in case the goals of a joint venture company are not precisely addressed in writing and are based on a vague oral understanding. conflicts which could have been avoided are inevitable. The same is true, if the expectations of the involved parties are not aligned from the very beginning or divert during the course of the joint venture. This happens mostly if one of the involved partners asks himself the question, why he would (still) need a joint venture partner and which financial advantage "is in it" for him. Such a constellation often arises once the first hurdles are mastered, the business is running reasonably satisfying and the foreign partner has the feeling of already knowing all peculiarities of the country, where they invested.

Further reasons for a "casus belli" are diverting corporate cultures of the involved parties, which appear mostly in different remuneration and benefit programs. The business model of a joint venture might be as solid as possible, however, if the managers running this business are dissatisfied with their status due to diverting corporate cultures in their remuneration, this will prove as a deal-breaker at least in the long run.

Another cliff that is hard to circumvent could be the decision processes within the joint venture company. In case there is no real delegation of the decisions into the joint venture company and the responsible managers in the joint venture have no real responsibility and have to get back and obtain reassurance from their respective shareholders even for minimal investments, this will have a negative impact on the motivation of these managers and would be harming the positive development of the joint venture company in the long run.

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