MANUFACTURING DIVERSIFICATION THROUGH SELECTIVE DRUG TRANSFER: A RISK MITIGATION CONSULTING CASE OF A PHARMACEUTICAL COMPANY OPERATING UNDER WARTIME CONDITIONS

by

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LIST OF ABBREVIATIONS

CMO - Contract Manufacturing Organization

CDMO - Contract Developing and Manufacturing Organization

ISO - International Organization for Standardization

GMP - Good Manufacturing Practice

GxP - Good Practice

CNS - Central Nervous System

COGS - Cost Of Goods Sold

GM - Gross Margin

CIS - Commonwealth of Independent States

CTD - Common Technical Document (format of a registration dossier)

MA - Marketing Authorization

API - Active Pharmaceutical Ingredient

MCDA - Multi-Criteria Decision Analysis

CDA - Confidential Disclosure Agreement

RA - Regulatory Authority / Affairs

BC - Business Case

DD - Due Diligence

NPV - Net Present Value

INTRODUCTION

Pharmaceutical business is one of the leading and most profitable industries worldwide. Besides the commercial aspect, the field entails a social responsibility towards patients, involving uninterruptedly supplying them with required medicines at any time and any place. Operating in the Ukrainian market today means being an unstoppable and resilient unit, serving in highly volatile circumstances, which are not predictable even within a week. For Acino Ukraine, a member of international group Arcera, the year 2025 has become a period of vulnerability exposure - the full-cycle manufacturing division - Pharma Start plant, also serving as a prominent R&D center, proved to be a single point of failure. Acino Ukraine medicines targets to sustain patients' treatment across 20+ therapeutic areas, mainly: cardiology, neurology, psychiatry, gastroenterology, endocrinology and others. In July 2025 the stability of operations were interrupted when a missile attack in Kyiv resulted in a total halt of production of the site. The incident highlighted over-reliance on a single manufacturing division during the wartime, leading to both business instability and lack of commitment to secure access to life-saving medications. The purpose of this thesis is to develop a manufacturing diversification and risk mitigation strategy for Acino Ukraine by identifying priority drugs for transfer, selecting suitable outsourcing sites, and validating the financial viability of the project. Beyond revenues, manufacturing diversification is no longer a choice but a demand to ensure therapeutic continuity. Disruptions in supplying critical medicines jeopardize public health safety levels. By cooperating with contract manufacturing organizations, Acino can guarantee a mitigation strategy of production disruption, hedging both financial and social responsibility risks.

CHAPTER 1. ANALYTICAL SECTION

1.1 DESCRIPTION OF THE COMPANY AND ITS RESULTS IN RECENT YEARS

Pharma Start is a full-cycle pharmaceutical company, acquired by the international pharmaceutical group of Acino companies headquartered in Zurich, which now has become a part of Arcera - global life science company headquartered in Abu Dhabi. Since then, it has been serving as a production site for the manufacturing of solid dosage forms for Acino Ukraine.

Nowadays Acino Ukraine is divided into two units: Pharma Start, which is a production plant combined with external distribution process and Acino Ukraine group office, which is engaged in operational activities of the business on the territory of Ukraine.

The company is focused on emerging markets, delivering medicines via development, manufacturing, licensing out/in and contract manufacturing across 20+ therapeutic areas, such as: cardiology, neurology, pediatrics, psychiatry, gastroenterology, endocrinology and others. In 2025 the number of plant employees reached more than 330 people. The total number of employees on the manufacturing site and within the office department reaches 873 people in Ukraine. The consolidation with Pharma Start enabled Acino, part of Arcera, to acquire a pharmaceutical plant capable of producing 2 billion tablets and capsules annually and its own R&D center, which consistently releases 2-3 new products each year. The manufacturing facilities perform the full cycle of development, production, and packaging of solid dosage forms alongside dietary supplements. The plant has expertise in the production of complex generics in the form of modified-release, film-coated and uncoated tablets, and covers the capabilities of dry and wet granulation, compression, and drying of drugs as well. The company performs primary packaging of PVC//Alu, PVC/PVDC//Alu, Alu/Alu,

etc., as well as secondary packaging in the form of blisters, cardboard boxes, plastic jars, and insertion of booklets and instructions. The plant operates in accordance with ISO and GxP standards, which are confirmed by international ISO certificates and comply with UA GMP, EU GMP. Pharma Start's production facilities, which are in accordance with international standards and practices, allow the company to expand its product portfolio, which as of January 1, 2024, included more than 300 assortment items alongside 38 proprietary pharmaceutical brands. During the period 2015-2024 investments in production modernisation reached over $40 million.

As of June 2025, Acino Ukraine ranks third in the Ukrainian pharmaceutical market and first as the international company in terms of pharmacy sales of medicines, accounting for 3.73% of the market share in monetary terms *(see Appendix A)*. By the end of 2025 Acino Ukraine holds third position in the Ukrainian retail market growth rates and second as an international firm *(see Table 1.1)*.

Table 1.1. Ukrainian pharmaceutical retail market and growth, 2025

Company	**Growth rate (market) % 16,18**
Teva (Israel)	21,31
Kiev vitamin factory	17,91
Acino (Switzerland)	17,25
Farmak (Ukraine)	11,52
Darnytsia (Ukraine)	-23,82

Source: Proxima research, retail market (Drugs), retail prices 2025
https://proximaresearch.com/news/the-ukrainian-pharmaceutical-market

Besides that in 2025 Acino Ukraine ranked first among pharmaceutical companies in terms of sales in the nervous system treatment segment, exceeding the market growth rate by 1.34 times, holding the third position *(see Table 1.2)*.

Table 1.2. Acino Ukraine – ATC N class Ukrainian retail market growth, 2025

Company	**Growth rate (market) % 9,33**
Farmak (Ukraine)	20,37
Reckitt Benckiser (Great Britain)	16,80
Acino (Switzerland)	16,80
InterChem (Ukraine)	-4,63
Darnytsia (Ukraine)	-31,43

Source: Proxima research, retail market (Drugs), retail prices 2025
https://proximaresearch.com/news/the-ukrainian-pharmaceutical-market

In the cardiology segment, the company ranks fifth in the Ukrainian market and first as the international company, with a growth rate 2 times higher, overperforming the market growth, being on the top of the rank table *(see Table 1.3)*.

Table 1.3. Acino Ukraine – ATC C class Ukrainian retail market growth, 2025

Company	**Growth rate (market) % 15,77**
Acino (Switzerland)	30,75
Servier (France)	22,93
KRKA (Slovenia)	20,22
Kiev vitamin factory	16,23
Darnytsia (Ukraine)	-2,74

Source: Proxima research, retail market (Drugs), retail prices 2025
https://proximaresearch.com/news/the-ukrainian-pharmaceutical-market

The company is a multiple winner of the Panacea competition, the largest and most prestigious pharmaceutical competition in Ukraine. In 2023 the company won awards in the categories “Company of the Year. Foreign Manufacturer”, “Pharmfront,” and “Drug of the Year.” The prescription product Difors, which belongs to the group of drugs for the treatment of hypertension, became the drug that won the “Drug of the Year” award for the third time. The company is famous for its significant

contribution to the field of central nervous system. One of the leaders on the Ukrainian market is the drug Quetiron, which belongs to the group of antipsychotic drugs. In addition to its presence in the neurological and cardiological fields, Acino is famous for its product Bifren, which belongs to psychotropic drugs, i.e., the treatment of anxiety disorders, receiving an award in the “Drug of the Year” category. Acino’s recognition by business communities is confirmed by its inclusion to the top 50 best employers of 2024 according to Forbes.

In 2024, Acino Ukraine LLC, together with Pharma Start LLC, generated ~7.3 billion UAH of revenue, of which net profit amounted to ~951 million UAH. The main structure of Acino Ukraine revenue consists of wholesale of pharmaceutical goods, retail sale of pharmaceutical goods in specialized stores, wholesale of other household goods, and agents involved in the sale of a variety of goods. At the same time, the income structure of Pharma Start LLC is formed by manufacture of pharmaceutical preparation, wholesale of pharmaceutical goods, technical testing and analysis, research and experimental development in biotechnology.

Summarizing the company's achievements and its position in the pharmaceutical market, it is clear that despite operating under martial law and constant operational challenges, Acino Ukraine manages to maintain high ratings for key performance indicators in targeted therapeutic areas.

1.2 PROBLEM STATEMENT

After the attack in July 2025, the company sold the warehouse stocks, which were in the other place. The incident highlighted Acino’s over-reliance on a single site and vulnerability to external shocks, reaching total losses amounted to ~ €10,000,000, reflecting the value of destroyed

pharmaceutical equipment and damaged infrastructure. This issue creates the following threats: significant financial losses associated with infrastructure damage and revenue drop down; medicine shortages; reputational risks and decline in the ranking of leading pharmaceutical companies in Ukraine. The situation has a strategic nature, since even after the full restoration of the plant, a threat of repeated attacks still remains. The main audience concerned with the development of a strategic risk diversification model is Acino's top management in Ukraine and at its headquarters in Abu Dhabi, as well as the production, finance, and business development departments, and external partners such as distributors, who are also primarily interested in uninterrupted supplies.

The most appropriate way to undergo the emerging challenge is to diversify production capacities through partnerships with CMOs and to develop a resilient supply chain strategy with multi-sourcing model, risk mitigation, and a tech-transfer roadmap. Such a solution is aimed to ensure at least partial continuity of the production secured with the assistance of contract manufacturing organisations, keeping revenue flows, collaboration with distributors and maintaining market position on the pharmaceutical market of Ukraine.

1.3 ANALYSIS OF DRUG PORTFOLIO SELECTION CRITERIA FOR MANUFACTURING TRANSFER

The analytical part of the consulting thesis focuses on the analysis of drugs manufactured at the Pharma Start plant, belonging to Acino Ukraine. The goal is to identify drugs that are the most suitable for transferring to external production sites. Products are evaluated using Multi-criteria decision analysis (MCDA) - a tool that allows to compare alternatives, in the current case, drugs that are

subjected to relocation. An in-depth assessment is carried out on the basis of specific economic, regulatory, strategic, and technological criteria, assigning them points on a constructed scale and multiplying them by the weight of each parameter. The list of criteria and their corresponding weights were defined after interviewing employees from project management/business development and marketing departments. In addition, the analytical part includes an analysis of the risks arising from the single-plant manufacturing process, as well as a market study of target contract manufacturers beyond Ukraine. For a complete understanding of the context of the company's activities, a description of its organizational structure, key achievements in the pharmaceutical industry, and main production characteristics are provided. Additionally, to strengthen the fulfillment of the analytical part, internal company data in the form of presentations, tables, and infographics, as well as data from open sources regarding the pharmaceutical retail market and key players in Ukraine were used.

The World Health Organization provides the following definition of technology transfer: Transfer of technology is defined as “a logical procedure that controls the transfer of any process together with its documentation and professional expertise between development and manufacture or between manufacturing sites”. It is a systematic procedure that is followed in order to pass the documented knowledge and experience gained during development and or commercialization to an appropriate, responsible and authorized party. Technology transfer embodies both the transfer of documentation and the demonstrated ability of the receiving unit (RU) to effectively perform the critical elements of the transferred technology, to the satisfaction of all parties and any applicable regulatory bodies (World Health Organization 286).

Hence, the transfer of technological and manufacturing processes to contract manufacturers secures a strategic instrument for diversifying the company's production capacity, ensuring the accurate reproduction and packaging of medicinal products in accordance with parental company’s standards. The approach helps to continue outsourcing manufacturing of drugs, thereby strengthening the operational resilience, significantly affected by the full-scale invasion.

One of the important stages of the transfer process is determining the list of criteria used to select drugs for transfer to contract manufacturing units. After surveying experts from the company, four priority criteria were identified: gross marginality, social responsibility, CTD / dossier readiness and manufacturing complexity.

Marginality determines the financial feasibility of the transfer. Product-level gross margin reflects the product's profitability prior to other related operational expenses that may vary depending on manufacturing model, thus being one of the most stable and comparing indicators for assessing transfer feasibility. By transferring drugs to external production sites, the company inevitably faces expenses rather than profits in the initial stages. In particular, because of CMO incorporating its own markup into manufacturing price, leading to slight decrease of drug's gross margin. Additionally, contract manufacturing units will cooperate for purchasing raw materials directly with suppliers, not Acino being an intermediary. Since the raw materials volumes are expected to be much lower than Acino purchases, the transferring companies may face less favorable price conditions, influencing the decrease of products gross margins as well. For illustrative purposes, assuming that gross margin compression of up to 8-10% for a product. The drug with a gross margin of 50% will result in 40-42% of post transfer gross margin. Taking the drug below the minimum acceptable gross margin level will result in declining further, turning the transfer to be financially unjustified. Following such logic, the sufficient percentage of gross marginality is accepted as at least 50%. This is a minimum threshold to ensure the financial viability of the transfer process and avoid the extension of the payback period, serving as a buffer to compensate for the margin compression associated with CMO-based production. A gross margin of the drugs less than 50% leads to longer payback periods, which is associated with higher investments in technological and manufacturing transfer.

The next parameter considered in this section is social responsibility. In this context, the social responsibility is determined by the company's purpose to ensure uninterrupted access to medicines for prolonged or lifelong therapy. A significant share of Pharma Start's own drug portfolio consists of

medicines prescribed for patients with chronic diseases who require continuous medication control, such as Parkinson's disease, epilepsy, and schizophrenia. Furthermore, medications like Levocom - targeting Parkinson disease, and Ariprazol - treating schizophrenia and bipolar disorder, are included in the National Reimbursement Program (Міністерство охорони здоров'я України). This state-led program defines these drugs as essential for public health, meaning that disruptions in supply will undermine the government's ability to ensure access to medication to all population groups. Treatment stability and continuity is a successful key for such therapies. According to medical protocols, the prescription of drugs within the same brand is essential to guarantee patient's safety and positive dynamic. At least, the disruption in supply of a specific medication may lead to deterioration of health, including frequent seizures of epilepsy, and in the worst case, hospitalization and jeopardization of a patient's life. Therefore, this indicator measures to which degree the product shortages would affect vulnerable patient populations, thereby reflecting a drug's social responsibility.

The subsequent criterion is CTD / dossier readiness. Before reaching the market, any medicinal product undergoes bioequivalence testing to confirm that the generic has the same pharmacologic action and effect as the original. Records of these tests are contained in the registration dossier, which is a document detailing the manufacturing process and all specifications, from formulation to equipment models. Then, this document is sent to the relevant regulatory body for verification in order to get a marketing authorization, which is a permit to legally release the medicine in a specific country or region. Even though CTD has no expiry date, maintaining its relevance is a prerequisite for extending the MA and reducing regulatory risks. Repeated studies are necessary to update the dossier, which requires additional investments, whereas the transfer itself is a significant expenditure on behalf of the company. Apart from updating, international companies mainly translate CTD's in order to distribute finished goods abroad. In the case of Ukraine, translating the rest of the dossiers, which don't have English versions is inevitable because the transfer is planned to be performed abroad. The process

is really time consuming because a medical product dossier may be from hundred to thousand pages. Accordingly, transferring drugs with outdated dossiers is financially and regulatorily disadvantageous.

The ultimate parameter is manufacturing complexity of a drug. This factor reflects the level of production effort when reproducing a drug at the production facilities of CMO's. From a technological point of view, the manufacture of medicines is classified according to complexity and number of stages involved. Modified-release or wet-granulated products are considered highly complex, since they require expertise, special equipment, and enhanced process control. Solid dosage forms typically have an additional film coating, or alternatively omitted. Tablets that undergo film coating require specialized equipment, additional control, and extended processing time, thereby increasing the complexity of transfer. Furthermore, the drug formulation may contain a varying number of APIs, ranging from one ingredient to combinations of two or three. Multi-component medicines primarily require advanced mixing equipment that ensures the homogeneity of the mixture, preventing segregation. Products containing one active ingredient are more technologically standardized. Therefore, the number of technological stages processes directly influence the resource intensity of pharmaceutical transfer. The components and its description are summarized below *(see Table 1.4)*.

Table 1.4. Drug selection components

Criterion	**Components**	**Key consideration**
Marginality	Pre-transfer gross margin percentage	≥ 50% to ensure financial feasibility and compensate for a CMO's manufacturing price markup
Social responsibility	Uninterrupted access to medicines for prolonged or lifelong therapy	Priority is given to medicines prescribed for patients requiring long-term therapy
Dossier readiness	Registration dossier completeness, bioequivalence testing records, marketing authorization status	Fully prepared dossier with valid marketing authorization reduces transfer timeline and regulatory risks

Manufacturing complexity	Number of manufacturing steps, equipment requirements, process control level	Modified-release and wet granulated drugs considered highly complex, requiring additional resources at CMO

1.4 COMPARATIVE ASSESSMENT SYSTEM FOR MEDICAL PRODUCTS

To obtain a comprehensive integrated score, taking into account the different nature of the indicators, it is necessary to bring them into a unified measurement system. To do this, a ranking method will be applied, which allows selecting the most priority drugs for external transfer. This method makes it possible to rank the criteria by importance, assigning weighting coefficients, in order to select the best alternatives. Note that the use of this tool, with its scoring and weighting coefficients, is based on experts' opinions.

The next step is to assign a score from 1 to 3 for each criterion, where 1 is the worst and 3 is the best. Further filtering indicates that at the stage of assessing the financial feasibility of transferring drugs to contract manufacturing, products with a gross margin of < 50% are rejected, as this is a prerequisite for the transfer to be cost-effective.

- Gross marginality

1 (low) – 50 - 55%, the drug meets the minimal acceptable financial threshold;

2 (mid) – 56 - 65%, the drug covers transfer expenses, maintaining acceptable level of profitability;

3 (high) – ≥ 66%, the drug has the highest profitability, while covering transfer costs.

- Social responsibility

1 (low) – symptomatic or short-term treatment, substitutes available on the market;

2 (mid) – has a clinical relevance, but short-term shortage doesn't result in critical consequences;

3 (high) – chronic or life-sustaining treatment, shortage may lead to disease exacerbation, hospitalization or risk to patient's life.

- CTD readiness

1 (low) - the dossier is not relevant, requires update;

2 (mid) - the dossier is relevant, but requires english translation;

3 (high) - the dossier is relevant and translated in english.

It should be noted that the scoring for the manufacturing complexity criterion slightly differs. Since higher technological complexity is characterized by a larger number of production stages, additional barriers arise during the transfer implementation. Therefore, inversion is applied to the scoring, where 1 corresponds to high complexity and 3 to low complexity.

- Manufacturing complexity

1 (low) – 2 or more APIs and/or modified-release and/or wet granulation and/or film-coating;

2 (mid) - 1 or 2 API and/or film-coating and/or wet granulation;

3 (high) - 1 API and direct mixing.

Regarding the assignment of weights, the highest priority is assigned to the criterion of marginality, so it receives the highest coefficient of 40% or 0.4. The next criterion is social responsibility, which receives 30% or 0.3, followed by the readiness of the registration dossier, which receives a coefficient of 20% or 0.2. The last criterion in terms of importance is production complexity, which gets 10% or 0.1. The results are presented in *Table 1.5*.

Table 1.5. Assigned weight coefficients

Criterion	**Weight coefficient**

Marginality	0,4
Social responsibility	0,3
CTD readiness	0,2
Manufacturing complexity	0,1

Based on the values obtained for each of the coefficients and assigning them specific weights, an integral estimate is calculated for each of the drugs:

$Xi = W1*Y1 + W2*Y2 + ... Wn*Yn,$ where

Wi - score of criterion i;

Yi - weight coefficient of criterion i;

Xi - composite score of the drug.

It should be noted that since the sum of the weight coefficients is equal to 1, and the highest score for the criterion is 3, the value of the integral evaluation will not exceed 3, as 1*3 = 3, and cannot be less than 1. The threshold values for drugs prioritised for transfer will be:

- ≥ 2.5, high priority for transfer;
- 2 - 2.4, transfer is acceptable, but requires additional revision
- < 2, transfer is not recommended.

1.5 MCDA FRAMEWORK FOR TRANSFER DECISION-MAKING

For the purpose of applying the MCDA tool with a two-stage analysis of drugs suitable for transfer to contract sites, it is necessary to compile all data into a single consolidated table. The first

phase begins with a financial assessment of the feasibility of the transfer. In order to filter out non-priority medicines and make the analysis consistent, a table is created with a list of drugs and their gross margin percentages, using a filter to separate products with a margin > 50% *(see Table 1.6)*. For the sake of confidentiality, the trade names of drugs are hidden.

Table 1.6. GM% of Drugs

Name	**Therapeutic area**	**GM %**
Product 1	Neurological	71%
Product 2	Psychiatric	73%
Product 3	Pain/Symptomatic Therapy	69%
Product 4	Neurological	67%
Product 5	Sleep Regulation	36%
Product 6	Neurological	61%
Product 7	Neurological	54%
Product 8	Cardiovascular	62%
Product 9	Neurological	37%
Product 10	Neurological	64%
Product 11	Cardiovascular	67%
Product 12	Cardiovascular	65%
Product 13	Cardiovascular	64%
Product 14	Psychiatric	70%
Product 15	Neurological	35%
Product 16	Psychiatric	68%
Product 17	Cardiovascular	69%
Product 18	Pain/Symptomatic Therapy	58%
Product 19	Cardiovascular	58%
Product 20	Cardiovascular	44%
Product 21	Neurological	65%
Product 22	Neurological	41%
Product 23	Neurological	60%
Product 24	Neurological	50%
Product 25	Neurological	30%
Product 26	Anti-inflammatory	68%
Product 27	Neurological	68%
Product 28	Psychiatric	72%
Product 29	Pain/Symptomatic Therapy	30%
Product 30	Pain/Symptomatic Therapy	45%
Product 31	Neurological	76%

Product 32	Neurological	68%
Product 33	Psychiatric	39%
Product 34	Psychiatric	68%
Product 35	Anti-infective	40%
Product 36	Cardiovascular	58%
Product 37	Neurological	64%
Product 38	Cardiovascular	57%

Source: internal data of Acino Ukraine

After applying the filter, 10/38 drugs are found to not meet the marginality criterion, therefore are excluded from further analysis.

Next, all medicines should be integrated with the defined evaluation criteria, assigned scores and corresponding weighting coefficients *(see Table 1.7)*.

Table 1.7. Scoring Breakdown of Drugs

Name	**Therapeutic area**	**Gross margin**	**Gross margin (0.4)**	**Social responsibility (0.3)**	**CTD readiness (0.2)**	**Manufacturing complexity (0.1)**
Product 1	Neurological	71%	3	2	2	2
Product 2	Psychiatric	73%	3	2	3	2
Product 3	Pain/Symptomatic Therapy	69%	3	1	2	2
Product 4	Neurological	67%	3	1	3	2
Product 6	Neurological	61%	2	1	2	3
Product 7	Neurological	54%	1	3	2	1
Product 8	Cardiovascular	62%	2	3	2	2
Product 10	Neurological	64%	2	1	2	3
Product 11	Cardiovascular	67%	3	1	3	1
Product 12	Cardiovascular	65%	2	1	3	2
Product 13	Cardiovascular	64%	2	1	3	1
Product 14	Psychiatric	70%	3	1	3	2
Product 16	Psychiatric	68%	3	2	2	2
Product 17	Cardiovascular	69%	3	1	3	2
Product 18	Pain/Symptomatic Therapy	58%	2	1	2	1
Product 19	Cardiovascular	58%	2	1	2	2
Product 21	Neurological	65%	2	3	3	3
Product 23	Neurological	60%	2	3	3	2
Product 24	Neurological	50%	1	3	2	2

Product 26	Anti-inflammatory	68%	3	1	1	3
Product 27	Neurological	68%	3	1	3	3
Product 28	Psychiatric	72%	3	2	3	2
Product 31	Neurological	76%	3	3	3	2
Product 32	Neurological	68%	3	2	3	3
Product 34	Psychiatric	68%	3	2	3	2
Product 36	Cardiovascular	58%	2	2	3	2
Product 37	Neurological	64%	2	2	2	2
Product 38	Cardiovascular	57%	2	2	2	1

Based on the collected data integral scores for each drug can be calculated by applying the defined weighting coefficients to the evaluation criteria *(see Table 1.8).*

Table 1.8. Composite Scores

Name	**Therapeutic area**	**Composite score of the drug**
Product 1	Neurological	2.4
Product 2	Psychiatric	2.6
Product 3	Pain/Symptomatic Therapy	2.1
Product 4	Neurological	2.3
Product 6	Neurological	1.8
Product 7	Neurological	1.8
Product 8	Cardiovascular	2.3
Product 10	Neurological	1.8
Product 11	Cardiovascular	2.2
Product 12	Cardiovascular	1.9
Product 13	Cardiovascular	1.8
Product 14	Psychiatric	2.3
Product 16	Psychiatric	2.4
Product 17	Cardiovascular	2.3
Product 18	Pain/Symptomatic Therapy	1.6
Product 19	Cardiovascular	1.7
Product 21	Neurological	2.6
Product 23	Neurological	2.5
Product 24	Neurological	1.9
Product 26	Anti-inflammatory	2
Product 27	Neurological	2.4
Product 28	Psychiatric	2.6
Product 31	Neurological	2.9

Product 32	Neurological	2.7
Product 34	Psychiatric	2.6
Product 36	Cardiovascular	2.2
Product 37	Neurological	2
Product 38	Cardiovascular	1.9

Based on the results of MCDA, 7 drugs received an integral score of 2.5 and belong to the high priority group for transfer to contract manufacturing organizations. 12 drugs received integral scores ranging from 2 to 2.4, which places them in the medium priority category for transfer. 9 drugs received scores below 2 points, placing them in the low priority sample and not recommended for transfer.

1.6 RISK IDENTIFICATION RELATED TO SINGLE-SITE MANUFACTURING

Production concentration within a single plant creates increased structural vulnerability for the entire business operations. Given the military uncertainty, the risks associated with having a sole production site for the entire CIS region transforms any local disruption into a shock and requires comprehensive analysis. The absence of geographic and operational diversification causes high reliance on external challenges and limits the ability of ensuring uninterrupted production for the region. This section will analyze cumulative risks that can potentially arise from concentrating production capacity at a single plant during martial law.

First of all, it is important to mention the backup capacity of production lines. At the beginning of the full-scale invasion, the company faced the problem of rapidly increasing production volumes. Before leaving Ukraine, patients with long-term or lifelong medication treatment protocols started buying large quantities of drugs, leading to massive shortages in pharmacy chains. The mad demand

makes it difficult to rapidly increase production, as the physical limits of production capacity are being reached. A scenario in which production is completely halted for an indefinite period of time should be considered. Without a backup site, the company actually loses the ability to sell products continuously, which encourages distributors looking for new suppliers, whereas patients need to stop and change their treatment, negatively impacting the company's reputation as a socially responsible entity. Unlike increased demand, which can be compensated by redistributing production and making additional changes, such a development implies zero production of medicines.

In addition to the previous risk, during the period of martial law, the company is constantly in a geographical risk category. Diversification is going to improve the pace of increasing drug volumes, but the main plant, Pharma Start, should provide the majority of product batches according to the production plan. Its location in the Solomyanskyi district of Kyiv implies constant dependence on the security situation in the capital. Therefore, any missile attacks, prolonged water shortages, massive blackouts, and staff movement restrictions may cause repeated delays in the restoration of the production process.

Currently, the restoration of the plant poses an additional regulatory risk to the company. After the completion of scheduled repairs, it is necessary to reconfirm that all systems are functioning steadily and in compliance with regulatory requirements, undergo inspection by the relevant authorities, and renew GMP certificates. Only then commercial production can be resumed at the plant. Until this is done, additional contract manufacturing sites are improving the situation and continuing to produce drugs, compensating for lost volumes.

Besides that, the company faces high financial risks. During downtime, sales volumes quickly drop, which causes a cash flow gap for the company, as well as failure to meet the financial revenue plan for investors — top management from the headquarters in the United Arab Emirates. At the same time, fixed costs remain: employee salaries, security, taxes, while additional capital expenditures arise: purchase of new equipment, major repairs, installation of ventilation and cleaning systems, restoration

of engineering and energy systems. Thus, a forced break in production becomes not a short-term disruption, but a long-term financial burden, which, in the absence of an alternative site, affects the stability of the company.

The last risk to be considered in this section is logistical risk. The state of war in Ukraine creates conditions for delays in the import of API's to the Pharma Start plant. Customs delays, complications or changes in supply routes, or simply delays due to congestion at customs checkpoints occur. If raw materials for drug manufacturing are not delivered on time, production series are delayed, and drug shortages arise. Having an alternative site outside Ukraine provides additional protection and increases supply stability by using alternative raw material supply channels and reducing dependence on customs controls.

Each outlined risk is assessed across two dimensions: probability and impact. The probability shows the likelihood of the risk occurring and the impact - the severity of consequences for business operations of the company. The column named level reflects the criticality of the risk and is determined by the higher of two aspects *(see Table 1.9)*. In order to get quantitative results, scores are assigned to three levels: 1 - Low; 2 - Medium; 3 - High. The risk level is calculated by multiplying the probability number on impact one. The threshold values for risks will be:

- 1 - 2, Low;
- 3 - 4, Medium;
- 6, High;
- 9, Critical.

Table 1.9. Probability - impact assessment of risks associated with single-site manufacturing

Risk	**Probability**	**Impact**	**Level**
Backup capacity	3 - High	3- High	9 - Critical
Financial risk	2 - Medium	3 - High	6 - High
Geographical risk	3 - High	3 - High	9 - Critical

Logistical risk	2 - Medium	2 - Medium	4 - Medium
Regulatory risk	1 - Low	3- High	3 - Medium

The assessment reveals that Backup capacity; Financial and Geographical risks are classified as Critical and High Level, indicating severe vulnerability. Logistical and Regulatory risks are in the category of Medium Level. Overall, concentrating the production cycle on a single site in the state of war creates significant risks, requiring strategic measures to mitigate them.

1.7 RISK MITIGATION THROUGH CONTRACT MANUFACTURING ORGANIZATIONS

The effective solution of the problem associated with the concentration of production capacities on a single site is the diversification of production to the plants of other pharmaceutical companies or contract manufacturing organisations. Considering the above-mentioned risks, such as the lack of medicines on the market, a decrease in revenue, and rocket attacks, this approach, primarily, reduces the company's geographical and operational dependence on a sole plant, secondly, ensures the continuity of manufacturing and selling new batches of medicines under its own trademarks. It guarantees Acino Ukraine presence on the Ukrainian market, maintains ratings in certain therapeutic segments, and also helps to minimise financial losses associated with generating revenue. Therefore, diversifying production to contract organisations fulfills the company's obligation to ensure access to essential medicines and creates a resilient supply chain strategy with a multi-source manufacturing and sourcing model *(see Table 1.10)*.

Table 1.10. Expected Risk Mitigation Assessment Following Diversification Strategy

Risk	**Probability**	**Impact**	**Level**
Backup capacity	1 - Low ↓	3 - High	3 - Medium ↓
Financial risk	1 - Low ↓	2 - Medium ↓	2 - Low ↓
Geographical risk	3 - High	2 - Medium ↓	6 - High ↓
Logistical risk	1 - Low ↓	1 - Low ↓	1 - Low ↓
Regulatory risk	1 - Low	2 - Medium ↓	2 - Low ↓

The assessment demonstrates contract manufacturing strategy implies significant mitigation of risks. All five risks show improvement at least in one of the dimensions. Overall, diversification of production facilities through engaging with contact manufacturers positively affects company's operation and serves as a mitigating tool for the risk management.

1.8 CMO'S SELECTION REQUIREMENTS AND DESK RESEARCH

Engaging contract manufacturing organisations primarily serves as a method of strategic management for operational and regulatory risks, expanding production capacity in wartime conditions. Given the complexity of the technology transfer process and the high levels of regulation in the pharmaceutical industry, selecting potential partners cannot be done intuitively. This requires comprehensively defined parameters for suitable organizations and a step-by-step selection process. However, the limitation of the analysis is the inability to obtain certain information from open sources in advance, such as the final cost of the transfer or the workload of the contract manufacturer's production lines. Applying a sequential selection model, excluding real-time access to final transfer

costs and production line capacities, will ensure transparent and gradual identification of potential partners.

First of all, it is necessary to form a general description of the market for contract development and manufacturing organisations. The description is based on MAI CDMO, a B2B platform for finding partnerships in the field of pharmaceutical contract manufacturing (CDMO Directory). The website lists approximately 60 companies with production sites spanning North America, Europe, and Asia, thereby indicating global market demand. The companies offer a wide range of services, from the development and production of API's to the manufacture of sterile solutions for injections, solid dosage forms, creams, syrups, etc. Equally important, contract manufacturers provide services not only for the direct production of drugs but also for packaging, logistics, regulatory inspections, and quality assurance services. Diversity in production generally provides an opportunity to rapidly increase production capacity and output without significant capital investment and fixed costs, however, within the scope of this consulting work, diversification is a risk management tool and a way to maintain continuity in the supply of finished products.

Moving on to the step-by-step formation of a list of companies according to the list of criteria for selecting contract organizations. At the initial stage, applying the basic criterion inherent in responsible companies in the pharmaceutical industry, namely the presence of regulatory certificates, specifically EU GMP, since Acino Ukraine itself operates in compliance with European standards. Manufacturers who do not have valid supporting documents of the European standard or those who operate only according to national practices are automatically excluded from the list. For this purpose, a page from the MAI CDMO website featuring 60 contract organisations is analysed *(see Appendix B)*. After applying this filter, 12/60 producers are found to not meet the EU GMP criterion and are eliminated from the list.

Another criterion to consider is the location of the production site. It’s important to evaluate locations of potential contract organisations, as this directly affects delivery times, complexity, and

distance of transport routes. A large distance between the sending and receiving sites increases the risk of prolonged customs procedures and delays in the delivery of finished goods. The location of a potential partner also affects the financial component of the transfer. When assessing transfer costs, consider the cost of services, which is determined not only by the desired volume of drugs for the customer company but also by the level of wages, the cost of energy resources, the tax burden, and, in general, operating costs at production facilities. Typically, the cost of services in Western European countries will be higher than in Central and Eastern European countries, and therefore the final cost of the transfer ends up to be greater. To illustrate the formation of service costs, it's worth looking at the average salary of a chemical engineer in pharmaceutical manufacturing in Spain and in Poland *(see Appendix C and Appendix D)*. The average salary of a chemical engineer in Spain in 2026 is ~ €67,000, while in Poland it is ~ €53,000. Concerning logistic prices, Acino already allocates 4% of gross margin to cover logistic expenses. Given this fact, selecting CMOs nearby Ukraine allows them to operate within the budget or even save. However, engaging organisations located in such countries like Spain or France, which are geographically distant from Ukraine, where air transportation is likely to be engaged, put additional risk of overcoming the assigned threshold of 4%. Thus, the factor of logistical proximity to Ukraine becomes significant in the selection of contract organisations. Based on this evidence, a list of priority countries can be formed. These will be Poland, the Baltic states, Hungary, Slovakia, Romania and Moldova. Out of the 48 contract organisations that were initially considered suitable, 13 production sites meet the criterion of geographical proximity to Ukraine, of which 4 are located in Poland, one each in Lithuania, Latvia, Estonia and Slovakia, 2 in Hungary, and 3 in Romania *(see Table 1.11)*.

Table 1.11. Prioritized locations of CMO/CDMO's

Country	**CMO/CDMO's quantity**
Poland	4
Lithuania	1

Latvia	1
Estonia	1
Hungary	2
Slovakia	1
Romania	3
	13

As for political and trade agreements aspects, however, Hungary and Slovakia demonstrate political tension towards Ukraine, their membership in the EU provides institutional framework and guarantee for business operations regardless of individual member state political views. Furthermore, under the Association Agreement between Ukraine and the EU, medical products imported to Ukraine are subjected to zero custom duty, which has been in force since 2023 (Код Товару 3004 20 00 00). Consequently, selection of a CMO within EU member states reduces import costs associated with delivering finished goods to Ukraine, positively affecting financial feasibility of transfer.

The last criterion to be applied at this stage of analysis and selection of potential contract organisations is compliance with the forms of drug release at the Pharma Start plant. This refers to the manufacture of solid oral dosage forms - tablets and hard gelatin capsules. The necessary information about the possibility of manufacturing drugs in the same dosage forms should be sought on the companies' websites and looks something like this *(see Appendix E)*. So it's good to start searching the production capacities of companies in each country separately *(see Table 1.12)*.

Table 1.12. Forms of release

Country	**Name of CMO/CDMO's**	**Type of the product**		
		Uncoated tablets	**Film-coated tablets**	**Hard capsules**
Poland	Company 50	+	+	+
	Company 53	+	+	-
	Company 55	+	+	+
	Company 56	+	+	+
Lithuania	Company 49	-	-	-
Latvia	Company 52	+	+	+
Estonia	Company 54	-	-	-

Hungary	Company 51	+	+	+
	Company 60	-	-	-
Slovakia	Company 57	+	+	-
Romania	Company 15	-	-	-
	Company 58	+	+	+
	Company 59	+	+	+

Starting with Poland, the data shows that 3/4 of the pharmaceutical manufacturers are identified specializing in the production of all three required forms of medication, and one site does not produce hard gelatin capsules, but this deviation is acceptable, as the transfer portfolio includes not only capsule-based formulations. As for Lithuania, the only contract manufacturer that met the preliminary conditions, unfortunately, does not have experience in manufacturing the required forms of drugs and is therefore excluded from the list. Unlike Lithuania, Latvia meets all three release form requirements. The same cannot be stated about Estonia, where, unfortunately, the contract manufacturer does not produce tablets and hard capsules. Hungary shows a more promising trend: one of the plants manufactures all three forms, the second site specialises only in hard capsules, and the third, unfortunately, does not meet the specified criteria for the required drug format. In Slovakia, the potential partner is only engaged in the manufacture of tablets, but still in accordance with the format. Finally, considering Romania, where three contract manufacturers are found. Only one of the three plants does not specialise in manufacturing tablets and hard capsules, but the other two do. Therefore, according to the defined parameters and the results of the sequential selection model, 9/13 companies are currently the priority contract manufacturers for the production of Pharma Start portfolio products *(see Table 1.13)*.

Table 1.13. Potential list of CMO/CDMO's

Country	**Name of CMO/CDMO's**	**Type of the product**		
		Uncoated tablets	**Film-coated tablets**	**Hard capsules**
Poland	Company 50	+	+	+
	Company 53	+	+	-
	Company 55	+	+	+

	Company 56	+	+	+
Latvia	Company 52	+	+	+
Hungary	Company 51	+	+	+
Slovakia	Company 57	+	+	-
Romania	Company 58	+	+	+
	Company 59	+	+	+

Such a method of selecting potential partners helps to evaluate the overall offer on the pharmaceutical market of contract organisations and, with the help of the gradual introduction of regulatory, technological and geographical criteria, together with filtering, it allows the selection of the most attractive manufacturers that demonstrate potential compatibility with the product portfolio of the Pharma Start plant. It should be noted that the list of production sites is not final, but rather serves as a basis for further commercial evaluation by the company's internal experts.

CHAPTER 2. RECOMMENDATION SECTION

2.1 MULTI - CMO MODEL AS A STRATEGIC RISK MANAGEMENT TOOL

This part of the consulting thesis contains justification of the choice of cooperation with several contract manufacturing organisations, and is also aimed at providing practical recommendations on the list of drugs recommended for transfer to external production sites according to the results obtained from applying MCDA and directly implementing the algorithm for the process of transferring the portfolio to potential contract firms, which are determined according to a sequential selection model.

As a result of the analysis, the reasonable question may arise as to why not transfer the entire list of medicines to one potential site, which may even be a financially sound decision on the part of Asino Ukraine, since large volumes can encourage partner companies to offer corporate discounts. However, the purpose of the transfer is not just a financial gain, but developing a strategic risk management solution related to the concentration of production at one plant in a state of martial law. It is the implementation of cooperation in the multi-CMO format that provides an opportunity to diversify operational, regulatory and financial risks in the case of cooperation with only one contract manufacturer. To better justify the decision, the advantages and disadvantages of this solution need to be considered.

To begin with, it's better to focus on the advantages. First and foremost, it is necessary to highlight the continuity of production. As mentioned in the analytical section, the Pharma Start plant manufactures medicines necessary for long-term or lifelong therapies, particularly in the cardiology, neurology and psychiatry sectors. If this sole contract manufacturer, whose capacity covers the entire transferred portfolio, faces a temporary halt in production, for example due to technical failures, a

shortage of all relevant drugs will occur. The described case directly contradicts one of the company's most important missions: to ensure uninterrupted access to quality medicines where and when they are needed. In the pharmaceutical market, drug shortages are quickly detected and are quite critical for patients, doctors, distributors, and pharmacy chains, which negatively affects the company's reputation as a reliable and socially responsible supplier. In addition to losing market share, this situation can lead to a deterioration in relations with existing contractors. Diversifying production across several external sites is a strategic solution to minimise this risk, allowing potential shortages to be partially or fully offset by redistributing volumes. Thus, such a cooperation model reduces concentration risk and increases the company's resilience to external shocks.

In addition to the above, a cooperation model with several contract manufacturers helps to reduce the potential financial burden. If only one external site is involved in the transfer, then all future revenue depends on it, namely on the volume of finished products received. Even if product deliveries are suspended for a short period of time, Acino Ukraine faces an overall decline in revenue, while fixed costs remain. Meanwhile, the concentration of transferred production at a single site can create cash flow gaps. The termination of revenue from product sales can lead to a situation where the company does not have the funds to cover current obligations. In this case, the company will be forced to attract additional financing, which increases the debt burden. Therefore, from a financial point of view, diversification of production ensures a more stable cash flow and preserves at least partial profit in emergency situations related to the shutdown of production at one of the sites.

Moving on to the disadvantages of this solution, it is important to note that restrictions related to the diversification of production capacities may apply not only to the multi-CMO cooperation model, but also to the general format of cooperation. Therefore, collaboration with several contract manufacturers requires significant investments in the transfer process itself, which includes the transfer of manufacturing technologies, the supply of raw materials, process validation, equipment qualification, and, if necessary, professional training for the host party's employees. Duplicating this

process across different production sites means that the company incurs the same costs for each procedure, which creates an additional investment strain.

The next point that needs to be discussed is the inevitable reduction in gross margins for each drug. The company will be faced with paying for the finished products and transfer service itself, which increases the cost of the medicines and, consequently, the overall cost structure of each drug, thereby reducing margins. This restriction applies to both the model of cooperation with a single contract manufacturer and multi-CMO.

There are negative aspects that are external by nature, making it impossible to resolve them promptly. An example of this is delays of trucks with products at the border. Unfortunately, such unpredictable events can affect the timely delivery of medicines, which cannot be resolved either by the customer company or by the manufacturing site.

The last thing to add in the section on the limitations of this type of cooperation is the increasing complexity of process control and management. Differences in the operational processes of each of the potential contract sites, in the internal regulations of companies, coordination of production batches of manufactured drugs and coordination of production schedules require more precise and coordinated control on the part of Acino Ukraine, namely the quality control, supply chain and project management/business development departments.

Therefore, the cooperation model involving the use of external contract manufacturers, whether one or several, involves elements of managerial complexity and increased costs, but the nature of these shortcomings is controllable. On the other hand, diversification of production in conditions of sustained increased risk in wartime demonstrates long-term security of uninterrupted supply and preservation of partial profitability, and forms a kind of shield against the negative consequences associated with the concentration of production in a single plant.

2.2 PRIORITIZED DRUG PORTFOLIO FOR MANUFACTURING TRANSFER

In this section, it is necessary to form a recommended list of priority drugs for transfer, with justification of the integrated assessments obtained for each of them, as well as to explain why other drugs are not recommended for transfer to external production sites.

The analytical section determined the threshold for the integral evaluation, which will indicate the high priority of the drug for transfer - 2.5, with a minimum possible value of 1 and a maximum of 3. This defined threshold is higher than the average of 2, and therefore outlines the truly strong positions in the portfolio, the criteria of which satisfy the conditions for transfer. The three-point rating scale promotes more transparent evaluation of drugs and maintains a balance between sufficient differentiation and minimization of subjectivity, as opposed to the introduction of a five-point scale or higher.

7/12 products received a rating of 2.5, indicating high priority for transfer. These products are: Product 2 with a rating of 2.6, Product 21 with a rating of 2.6, Product 23 with a rating of 2.5, Product 28 with a rating of 2.6, Product 31 with a rating of 2.9, Product 32 with a rating of 2.7, and Product 34 with a rating of 2.6 *(see Table 1.8)*.

After obtaining the finalized integrated assessments, it is clear that, first of all, 5 out of 7 products have the highest score for the gross margin criterion, which makes these drugs feasible for transfer from a financial point of view. Almost the entire pool of drugs is accompanied by a high level of social responsibility, which is determined by the level of social responsibility on the part of the company. All 7 recommended drugs have updated dossiers translated into English, which simplifies the regulatory aspect of the dossier. Finally, these drugs are characterized by a low or medium level of manufacturing complexity, which also makes them attractive for transfer to external sites.

Moving on the products that received a medium level of priority for transfer. These are: Product 1 with a score of 2.4, Product 3 with 2.1, Product 4 with 2.3, Product 8 with a score of 2.3, Product 11 with 2.2, Product 14 with 2.3, Product 16 with 2.4, Product 17 with 2.3, Product 26 with a score of 2, Product 27 with 2.4, Product 36 with 2.2, and Product 37 with an integral score of 2 *(see Table 1.8)*.

The table, as a result of MCDA, reveals that drugs with a medium score are actually characterized by high ratings in terms of marginality, which is the criterion with the highest weight. However, the ratings in the social responsibility category, which is the second criterion for prioritizing drugs for transfer, define this selection of products as medicines that do not significantly affect the company's social responsibility image, indicating the existence of analogues on the market. Medium threshold values also determine the need to update or translate dossiers, as well as the availability of items whose manufacturing technology is multi-stage and difficult.

Lastly, attention should be given to the drugs with integrated scores below 2. These are: Product 6 , Product 7, Product 10 and Product 13 with integral score of 1.8; Product 12, Product 24 and Product 38 with 1,9; Product 18 with 1,8 and Product 19 with 1,7 *(see Table 1.8)*.

The table shows that almost all of these drugs share low social responsibility for the company, technological complexity of reproduction, and medium or low percentage of marginality, which jointly form low scores and therefore do not make these drugs a priority for transfer.

Thus, the highest recommendation for transfer is assigned to drugs: Product 2 - Psychiatric drug, Product 21 - Neurological drug, Product 23 - Neurological drug, Product 28 - Psychiatric drug, Product 31 - Neurological drug, Product 32 - Neurological drug and Product 34 - Psychiatric drug. They are characterized by a combination of high scores on all four criteria, making them attractive for transfer in the first round. Drugs that fall into the medium priority category for transfer can be included in the long list of drugs for transfer. Given their high scores on the marginality criterion, they can generate additional profitability for the company, so they can be considered in terms of production diversification if CMOs have the necessary production capacity. Drugs classified as low priority for

transfer will not be recommended for further transfer. This decision is based on the high complexity of reproducing these drugs, their medium to low gross margins percentage, and the availability of analogues on the pharmaceutical market. The transfer of such drugs could potentially be more expensive due to production complexity, which is not a financially beneficial decision for Acino Ukraine.

2.3 SELECTION OF CONTRACT MANUFACTURERS

After applying a sequential selection model of potential plants that meet geographical, technological and economical criteria, 9 mainly recommended contract factories were identified: Companies 50, 53, 55 and 56 in Poland; Company 52 in Latvia; Company 51 in Hungary; Company 57 in Slovakia; Companies 58 and 59 in Romania.

The listed companies specialising in contract manufacturing primarily meet the condition of geographical proximity to Ukraine. 4/5 border Ukraine, which reduces the risks of both transport time and logistics. It is important to add that due to the increased cost of production caused by a number of factors, which are described in more detail in section 2.8 of the Analytical section, preference is given to the regions listed in the table. After screening out the companies that do not meet the first two conditions, these contract sites are equipped with the capacity to manufacture uncoated tablets, film-coated tablets and hard gelatin capsules, which corresponds to the forms of release of medicines at the Pharma Start plant.

2.4 ALLOCATION OF TRANSFER PORTFOLIO

Since at the stage of selecting potential contract manufacturers, the customer company does not possess any quantitative information regarding prices or, in general, the possibility of relocating production to external facilities, it is necessary not to distribute the preparations among contract sites, but to propose an algorithm for strategy implementation.

Moving on to the creation of an algorithm for initiating cooperation with contract manufacturers:

- **Recommendation 1** -> determining the planned transfer volume.

Since the Pharma Start plant is undergoing renovation along with the plan to resume production of drugs for sale, it is not interested in transferring the entire volume of manufactured tablets and capsules, which is practically impossible given the workload of external plants, manufacturing their own products and is not a financially feasible solution, since the essence of any business is to maximise profits. In this case, it is necessary to set a limit on the planned volume of drugs to be transferred. The most optimal solution is 20% of the planned volume of tablets in 2026. The 80/20 distribution, with 80% going to production at the Pharma Start, ensuring stable high revenues, while 20% serves as a security buffer in case of another production shutdown. 20% from the total volume production was determined internally in the company based on its strategic priorities. However, in the event of unpredictable external incidents, the possibility of increasing the total volume from should be discussed additionally.

- **Recommendation 2** -> one drug per contract manufacturer.

This decision is reasonable from the perspective of minimising the risks associated with manufacturing a single drug at several external sites. Firstly, the transfer portfolio consists of only 7

drugs. Secondly, it is related to ensuring the quality of production. After manufacturing, medicines undergo three stages of stability testing, i.e. studies are conducted to ensure that API/s remains within the acceptable range in the medicine. Diversifying the production of the same drug across different plants increases the risks associated with compliance with such conditions, as different sites operate under varying conditions, such as: equipment, environment, technological parameters, making it more difficult to control quality across batches in multiple plants. From the expenditure perspective, such a decision positively influences costs associated with quality audits and regulatory submissions required, since each production site requires separate amendments in registration dossier, involving regulatory fees and administrative costs, thereby increasing overall expenses. Although merging the production of several medicines on one site may positively influence administrative expenses, this decision creates a potential operational dependence on a single plant. Any disruption in the manufacturing process will simultaneously affect multiple drugs transferred.

- **Recommendation 3** -> sending short drug profiles

Since at the stage of selecting potential contract manufacturers, the customer company does not have commercial information about the actual cost of services and the workload of production lines, the optimal solution in such a situation is to send out profiles containing information about the active pharmaceutical ingredient(s), the necessary equipment, manufacturing methods, planned production volume, as well as a request for price and manufacturing/delivering time. Depending on the production capabilities of contract manufacturers, the distribution of drugs will be carried out in accordance.

This process may appear chaotic, but it is a realistic way to obtain reliable information about production capabilities and transfer costs. If there are no matches, it is necessary to contact other potential partners about the possibility of locating production.

2.5 CONTRACTUAL MECHANISM FOR COOPERATION WITH CMOs

In order to ensure structured interaction between the company ordering the transfer and the company performing it, it is necessary to conclude a cooperation agreement, which serves as a mechanism for regulating collaboration and a protective tool in the event of disputes or violations of the terms and conditions. For this purpose, a real legal agreement of Acino Ukraine will be analysed *(see Appendix F)*.

The first section to be considered is the block on general terms and conditions of the contract for the provision of contract manufacturing services of pharmaceutical products *(see Appendix G)*.

- Terms and conditions of the contract:
  - The parties of the agreement are the ordering company, hereinafter referred to as the Buyer, or Acino Ukraine, and the executing company, hereinafter referred to as the Manufacturer.
  - The subject of the agreement is the Manufacturer's obligation to manufacture products from the Pharma Start factory portfolio and supply them to the Buyer, which in turn obliges the Buyer to accept and pay for them;
  - The products manufactured at the Manufacturer's production facilities and subsequently sold in Ukraine;
  - The term of the contract is the Contract Year, which begins on the Date of the product's release on the Ukrainian market and ends on 31 December of the same calendar year in which the Date of Entry into Force of the agreement falls, and thereafter each subsequent year for a period of 12 months, unless otherwise agreed by the parties.

The next step is the consideration of the range of services provided by the Manufacturer.

- Services:

- The manufacturer carries out the full cycle of product development, including the purchase of API/s and raw materials, production, quality control, certification, serial production, labelling, packaging and storage of products on the territory of the Manufacturer's production site.

The definition of a management model between the parties is an important stage of cooperation. To visualize the departments responsible for the transfer process, the following RACI Matrix is used *(see Fig. 1)*. The matrix is generated by Chat-GPT.

Figure 1. RACI Matrix for Contract Manufacturing Agreement

Particular attention should be paid to the section on acceptance and quality of finished products within the contract manufacturing agreement.

- Acceptance and quality:
  - Upon delivery, the Product shall have ≥ 85% of its shelf life remaining;
  - The Product must comply with the requirements specified in the GMP, Registration Certificate, Additional Technical Agreement on Quality and the current legislation of the territory where it is manufactured;

- It must not have any defects that prevent the sale of the Product in Ukraine.

The contract is supposed to set out the financial terms that regulate the pricing mechanism *(Appendix H)*.

- Prices:
  - The price of the products, apart from manufacturing, includes packaging, fees for the use of the Buyer's intellectual property (Trademark), fees for the use of the Buyer's intellectual property (Dossier);
  - The price for the Products is fixed for a term of two contract years;
  - The fixed price is subject to revision in the event of an increase in the cost of API from the supplier and in the event of a devaluation of the hryvnia against the dollar by more than 10%.

Since the Products will be sold in Ukraine, the agreement must contain clauses on the organization of logistics and the supply of API and raw materials to the Manufacturer.

- Equipment:
  - Equipment is purchased by Acino Ukraine;
  - The cost of equipment is reflected as capital expenditure in the financial model of Acino Ukraine;
  - Equipment is located and operated on the Manufacturer site;
- Supply and logistics:
  - The initial purchase of raw materials is carried out by the Pharma Start plant, whose affiliate is Acino Ukraine LLC, and the Manufacturer purchases raw materials from the Supplier (Pharma Start LLC);
  - Delivery of ordered products is carried out on the terms of Incoterms 2020;
  - Products must be shipped no later than 30 working days from the date of order confirmation.

The contract manufacturing agreement must contain provisions on the terms of termination of cooperation and resolution of disputes in order to protect the interests of both parties.

- Termination of cooperation and resolution of disputes:
  - The agreement extend automatically for a period of 1 year, unless otherwise specified by the parties;
  - The agreement may be terminated in the event of a material breach by one of the parties of the terms and conditions governing the contract; infringement of intellectual property rights related to the Product; breach of quality by the Manufacturer during production or other situations not defined as force majeure;
  - Disputes, disagreements or claims shall be resolved through negotiations between the parties;
  - If the parties fail to reach an agreement through negotiations within 30 calendar days from the date of the dispute, the further resolution shall be carried out in accordance with the current legislation of Ukraine.

Consequently, an agreement serves not only as a management element of cooperation, but also as a clear distribution mechanism for cooperation, combining the distribution of responsibilities, financial, logistical, production and intellectual components. It establishes the boundaries of cooperation and coordinates the resolution of disputes within the legal framework, which is a necessary component for the stable functioning of both parties *(see Fig. 2)*. The scheme was generated by Claude.AI.

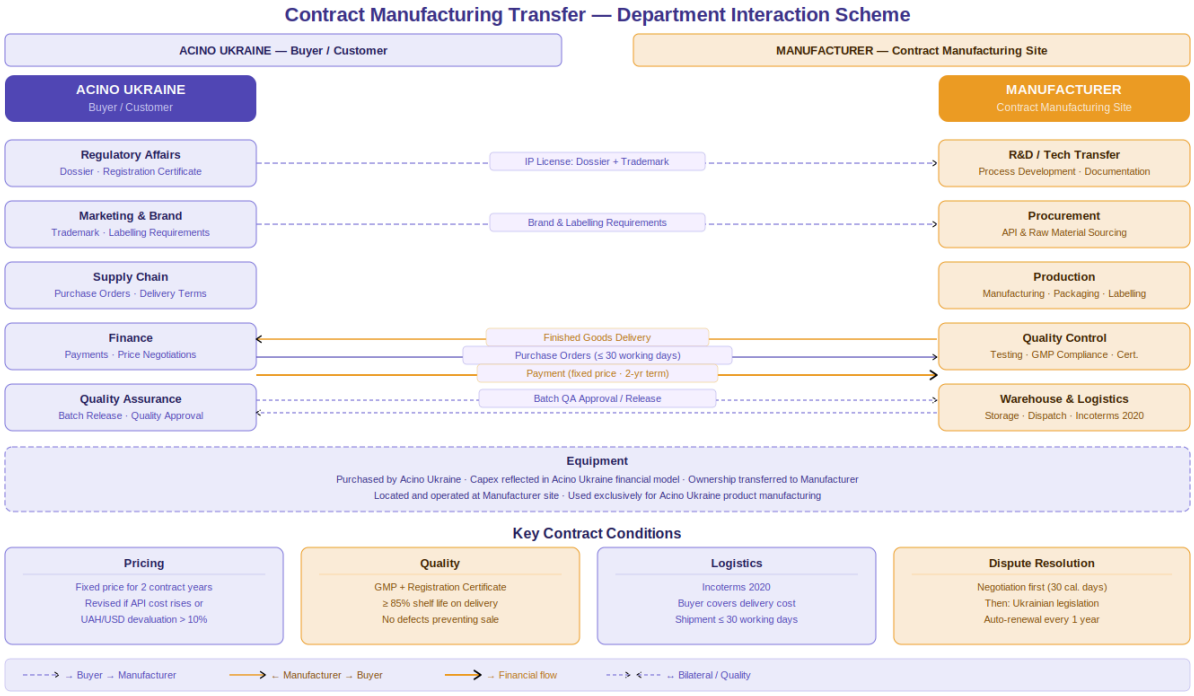

Figure 2. Scheme Of Interaction Between Two Parties During Contract Manufacturing

CHAPTER 3. ECONOMIC JUSTIFICATION SECTION

3.1.CASH FLOW ANALYSIS OF THE OUTSOURCING STRATEGY

An integral part of any project is determining its financial value to stakeholders. Financial analysis within this consulting case helps to assess the actual financial benefits of partially diversifying production, providing economic evidence of the validity of the transfer.

The calculations are based on three drugs that have been classified as high priority for transfer, namely Product 2, Product 21 and Product 28.

The financial model is based on the 20% from the absolute gross margin value generated by the drug at Acino's own manufacturing site. 20% is the investment boundary, assigned internally in the company, representing the strategic priorities of Acino. The baseline of 20% reflects not the projected gross profit from contract manufacturing, but the opportunity to cover transfer-related costs, accounting for CapEx,OpEx, logistics, regulatory and validation costs. The selection of own-generated gross margin is driven by several factors. Firstly, commercialization of finished products is expected to start only after second or third years from the transfer initiation, and volumes along with COGS are under negotiation process, thus making impossible to calculate the forecasted gross profits from contract manufacturing. During building the forecasted financial metrics the only credible source for the basis of calculation is in-house gross margin. The model will test whether the company is able to finance the transfer costs from existing funds. Positive NPVs will confirm the hypothesis that 20% is a sufficient amount allocated to cover expenses associated with manufacturing transfer and start generating financial gain, therefore the transfer of the drug is financially feasible.

The forecast horizon is five years – from 2026 to 2030. Year 0 represents the initial investment period for launching outsourced production, specifically 2026.

A discount rate of 16% is applied to discount the cash flows, which corresponds to the weighted average cost of capital for the company's branches in the CIS region. Additionally, a cost of capital of 19% has been calculated manually for the company, taking into consideration presence in Ukraine, under martial law *(see Appendix I)*. This calculation serves as a comparative basis for the project valuation.

The Payback Period is calculated for each of the three products – the length of time required for the income generated by the investment to start covering the investment costs, with no consideration of the time value of money.

Internal Rate of Return - is the financial indicator that measures the annual profitability of an investment project by determining the rate at which net present values of cash flows equals to zero.

Description of cost line components:

1. Gross margin (20% base) - the share from the absolute gross margin of the specific drug generated at its own manufacturing site in Ukraine, allocated as the internal investment for the transfer.
2. Machinery - one-time cost of manufacturing equipment purchased by Acino for the CMO.
3. Project management - internal personnel of Acino dedicated to coordinating and managing the project execution during the active phase.
4. Manufacturing, raw materials and testing batches - costs for active pharmaceutical ingredients, packaging materials and excipients, as well as for batch production and analytical testing of pilot batches.
5. Method transfer - costs for the transfer of analytical methods, including documentation, personnel training and method verification.

6. Registration fees - disposable regulatory fee for obtaining marketing authorization required to add CMO's production site as an additional location.
7. Validation fees - technical fees for validation protocol development, execution and reporting according to GMP standards.
8. Logistics - costs for transportation of finished goods from the CMO site back to the Ukraine storage facility.
9. Regulatory Affairs FTE - costs for one full-time worker assigned for regulatory control and support of the transfer, including dossier updates and authority submissions
10. Quality Assurance FTE - costs for one full-time worker assigned for quality control of the manufacturing process at CMO's site.
11. Supply Chain FTE - costs for one full-time worker assigned for purchasing finished products and delivery coordination.

The detailed calculations are provided below *(see Tables 3.1, 3.2, 3.3, 3.4, 3.5).* All figures are in EUR.

Table 3.1. Financial Feasibility Model for Product 2

P&L block	**2026F**	**2027F**	**2028F**	**2029F**	**2030F**
Gross margin 20% base	***0***	***0***	***700,473***	***756,176***	***813,662***
CapEx	***(144,000)***	-	-	-	-
Machinery	*(144,000)*	-	-	-	-
Operational expenses	***(179,000)***	***(17,000)***	***(143,019)***	***(145,247)***	***(147,546)***
Project management	*(5,000)*	*(5,000)*			
Manufacturing, raw materials and testing batches	*(100,000)*	-	-	-	-
Method transfer	*(74,000)*	-	-	-	-
Registration fees	-	*(12,000)*	-	-	-
Validation fees	-	-	*(10,000)*	*(10,000)*	*(10,000)*

Logistics (4% of GM)	-	-	*(28,019)*	*(30,247)*	*(32,546)*
Regulatory Affairs (1 FTE)	-	-	*(35,000)*	*(35,000)*	*(35,000)*
Quality Assurance (1 FTE)	-	-	*(35,000)*	*(35,000)*	*(35,000)*
Supply Chain (1 FTE)	-	-	*(35,000)*	*(35,000)*	*(35,000)*
EBITDA	***(179,000)***	***(17,000)***	***557,454***	***610,929***	***666,115***
Depreciation expense	***(28,800)***	***(28,800)***	***(28,800)***	***(28,800)***	***(28,800)***
EBIT	***(207,800)***	***(45,800)***	***528,654***	***582,129***	***637,315***
Tax rate	*0%*	*0%*	*18%*	*18%*	*18%*
NOPAT	***(207,800)***	***(45,800)***	***433,496***	***477,346***	***522,598***
Cash Flow block					
Depreciation	***28,800***	***28,800***	***28,800***	***28,800***	***28,800***
CapEx (cash outflow)	***(144,000)***	***-***	***-***	***-***	***-***
Net Cash Flow	***(323,000)***	***(17,000)***	***462,296***	***506,146***	***551,398***

Source: internal data of Acino Ukraine

Table 3.2.Financial Feasibility Model for Product 21

P&L block	**2026F**	**2027F**	**2028F**	**2029F**	**2030F**
Gross margin 20% base	***0***	***0***	***416,684***	***452,354***	***489,423***
CAPEX (cash outflow)	***(70,000)***	-	-	-	-
Machinery	*(70,000)*				
Operational expenses	***(182,446)***	***(17,000)***	***(131,667)***	***(133,094)***	***(134,577)***
Project management	*(5,000)*	*(5,000)*	-	-	-
Manufacturing, raw materials and testing batches	*(97,446)*	-	-	-	-
Method transfer	*(80,000)*	-	-	-	-
Registration fees	-	*(12,000)*	-	-	-
Validation fees	-	-	*(10,000)*	*(10,000)*	*(10,000)*
Logistics (4% of GM)	-	-	*(16,667)*	*(18,094)*	*(19,577)*
Regulatory Affairs (1 FTE)	-	-	*(35,000)*	*(35,000)*	*(35,000)*
Quality Assurance (1 FTE)	-	-	*(35,000)*	*(35,000)*	*(35,000)*
Supply Chain (1 FTE)	-	-	*(35,000)*	*(35,000)*	*(35,000)*
EBITDA	***(182,446)***	***(17,000)***	***285,017***	***319,260***	***354,846***

Depreciation expense	***(14,000)***	***(14,000)***	***(14,000)***	***(14,000)***	***(14,000)***
EBIT	***(196,446)***	***(31,000)***	***271,017***	***305,260***	***340,846***
Tax rate	*0%*	*0%*	*18%*	*18%*	*18%*
NOPAT	***(196,446)***	***(31,000)***	***222,234***	***250,313***	***279,494***
Cash Flow block					
Depreciation	***14,000***	***14,000***	***14,000***	***14,000***	***14,000***
CapEx (cash outflow)	***(70,000)***	**-**	**-**	**-**	**-**
Net Cash Flow	***(252,446)***	***(17,000)***	***236,234***	***264,313***	***293,494***

Source: internal data of Acino Ukraine

Table 3.3. Financial Feasibility Model for Product 28

P&L block	**2026F**	**2027F**	**2028F**	**2029F**	**2030F**
Gross margin 20% base	***0***	***0***	***509,158***	***525,511***	***546,089***
CAPEX (cash outflow)	***(66,500)***	***0***	***0***	***0***	***0***
Machinery	*(66,500)*	-	-	-	-
Operational expenses	***(130,000)***	***(13,000)***	***(131,667)***	***(133,094)***	***(134,577)***
Project management	*(5,000)*	*(5,000)*	-	-	-
Manufacturing, raw materials and testing batches	*(91,000)*	-	-	-	-
Method transfer	*(34,000)*	-	-	-	-
Registration fees	-	*(8,000)*	-	-	-
Validation fees	-	-	*(10,000)*	*(10,000)*	*(10,000)*
Logistics (4% of GM)	-	-	*(16,667)*	*(18,094)*	*(19,577)*
Regulatory Affairs (1 FTE)	-	-	*(35,000)*	*(35,000)*	*(35,000)*
Quality Assurance (1 FTE)	-	-	*(35,000)*	*(35,000)*	*(35,000)*
Supply Chain (1 FTE)	-	-	*(35,000)*	*(35,000)*	*(35,000)*
EBITDA	***(130,000)***	***(13,000)***	***377,491***	***392,417***	***411,512***
Depreciation expense	***(13,300)***	***(13,300)***	***(13,300)***	***(13,300)***	***(13,300)***
EBIT	***(143,300)***	***(26,300)***	***364,191***	***379,117***	***398,212***
Tax rate	*0%*	*0%*	*18%*	*18%*	*18%*
NOPAT	***(143,300)***	***(26,300)***	***298,636***	***310,876***	***326,534***
Cash Flow block					

Depreciation	***13,300***	***13,300***	***13,300***	***13,300***	***13,300***
CapEx (cash outflow)	***(66,500)***	***-***	***-***	***-***	***-***
Net Cash Flow	***(196,500)***	***(13,000)***	***311,936***	***324,176***	***339,834***

Source: internal data of Acino Ukraine

Table 3.4. Discounted Cash Flows

PRODUCT	**INDICATOR**	**Year**				
Product 2		0	1	2	3	4
	Net Cash Flow	***(323,000)***	***(17,000)***	***462,296***	***506,146***	***551,398***
	Discounted CF	***(323,000)***	***(14,655)***	***343,561***	***324,266***	***304,532***
	Cumulative CF	***(323,000)***	***(340,000)***	***122,296***	***628,442***	***1,179,841***
Product 21						
	Net Cash Flow	***(252,446)***	***(17,000)***	***236,234***	***264,313***	***293,494***
	Discounted CF	***(252,446)***	***(14,655)***	***175,560***	***169,334***	***162,094***
	Cumulative CF	***(252,446)***	***(269,446)***	***(33,212)***	***231,101***	***524,595***
Product 28						
	Net Cash Flow	***(196,500)***	***(13,000)***	***311,936***	***324,176***	***339,834***
	Discounted CF	***(196,500)***	***(11,207)***	***231,820***	***207,686***	***187,687***
	Cumulative CF	***(196,500)***	***(209,500)***	***102,436***	***426,612***	***766,447***

Table 3.5. Investment Performance Metrics

METRIC	**PRODUCT**		
	Product 2	**Product 21**	**Product 23**
WACC	**16%**	**16%**	**16%**
NPV	**634,705**	**239,888**	**419,486**
Payback Period	**1 years 9 months**	**2 years 2 months**	**1 year 8 months**
IRR	**69%**	**45%**	**73%**

Therefore, the financial analysis conducted on the basis of three drugs shows positive NPVs for Products 2, 21 and 28 drugs at a base discount rate of 16%: EUR 634,705; EUR 239,888 and EUR 419,486 respectively. This means that a strategy to diversify even 20% of the expected gross margins is financially viable.

Assuming a discount rate of 19%, which values capital in the Ukrainian segment, all three drugs generate positive NPVs of EUR 564,491; EUR 203,292 and EUR 374,690 respectively.

As for internal rates of return, the picture differs across three products. Products 2, 21 and 28 generate IRR's at 69%, 45% and 73% respectively. Such high IRR's are achieved relatively through small investments compared to the projected gross margins, indicating a significant margin of safety in capital gains before the projects become unprofitable.

Payback periods are relatively short for all three products: 1 year 9 months for Product 2; 2 years 2 months for Product 21 and 1 year 8 months for Product 28. It's important to note this is a model-based timeframe, not a calendar one. The investment recovery periods will begin after the start of commercialization.

3.2. SENSITIVITY ANALYSIS

Sensitivity analysis determines how resilient the model is when indicators deviate from the base case scenario. Two key parameters are used for this purpose: the WACC and the one-time investments, including OpEx and CapEx, i.e. the impact of their deviation on fluctuations in NPV *(see Appendix J,K,L)*. The ranges for the discount rate were 10%, 13%, 16%, 19% and 22%, incorporating the company's baseline regional cost of capital and the most negative author's scenario. The ranges for fluctuations in initial investment were -20%, -10%, the projected investment, +10% and +20%.

The first graph illustrates the sensitivity of NPV to fluctuations in one-time investments at a base discount rate of 16% *(see Fig. 3)*. Immediately, a gentle slope can be observed in all three lines, representing the products selected for analysis. NPV values remain positive across the entire range of

investment assumptions. Consequently, such a tendency confirms that even significantly exceeding the base scenario of investments doesn't affect the feasibility of transferring these drugs.

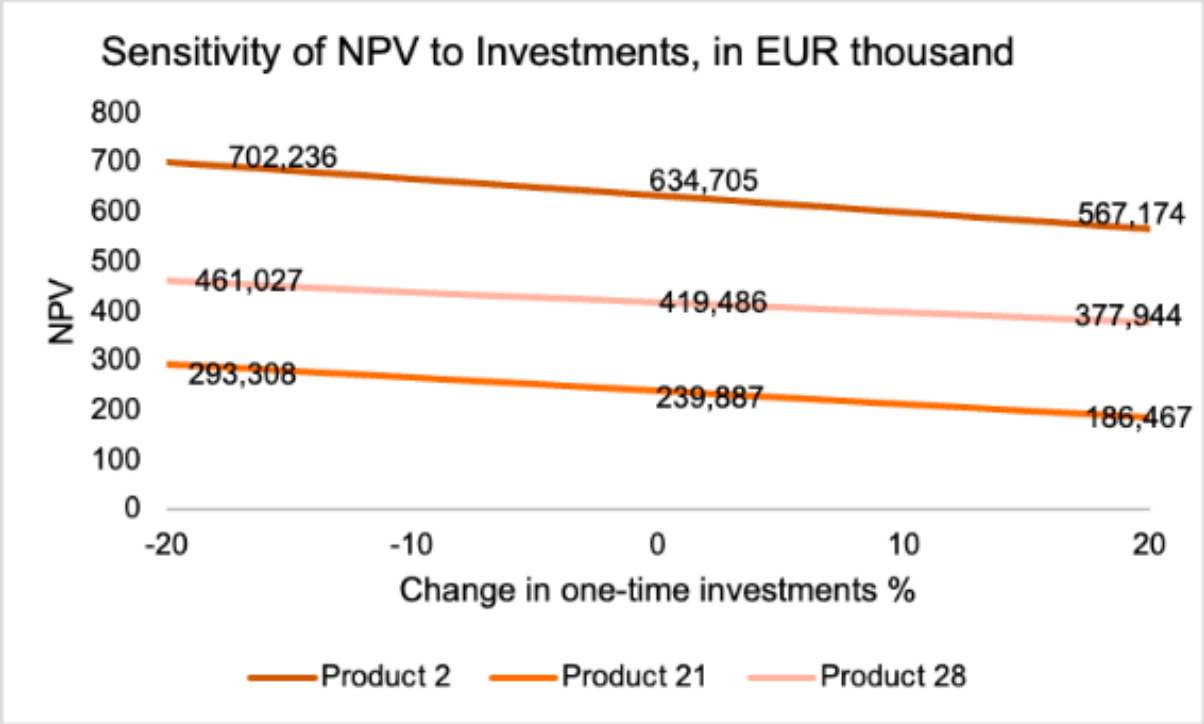

Figure 3. Sensitivity of NPV to One-Time Investments

The second graph to be examined shows the sensitivity of NPV to changes in WACC, assuming a base scenario amount of one-time investments *(see Fig. 4)*. In this case, the situation has a bit of a different pattern. It can be seen that slopes are steeper than in the previous illustration, especially for Product 2 and Product 28. But still all three drugs demonstrate positive NPV values across WACC range of changes, confirming that cost of capital increase is not a factor that determines the financial feasibility of manufacturing transfer.

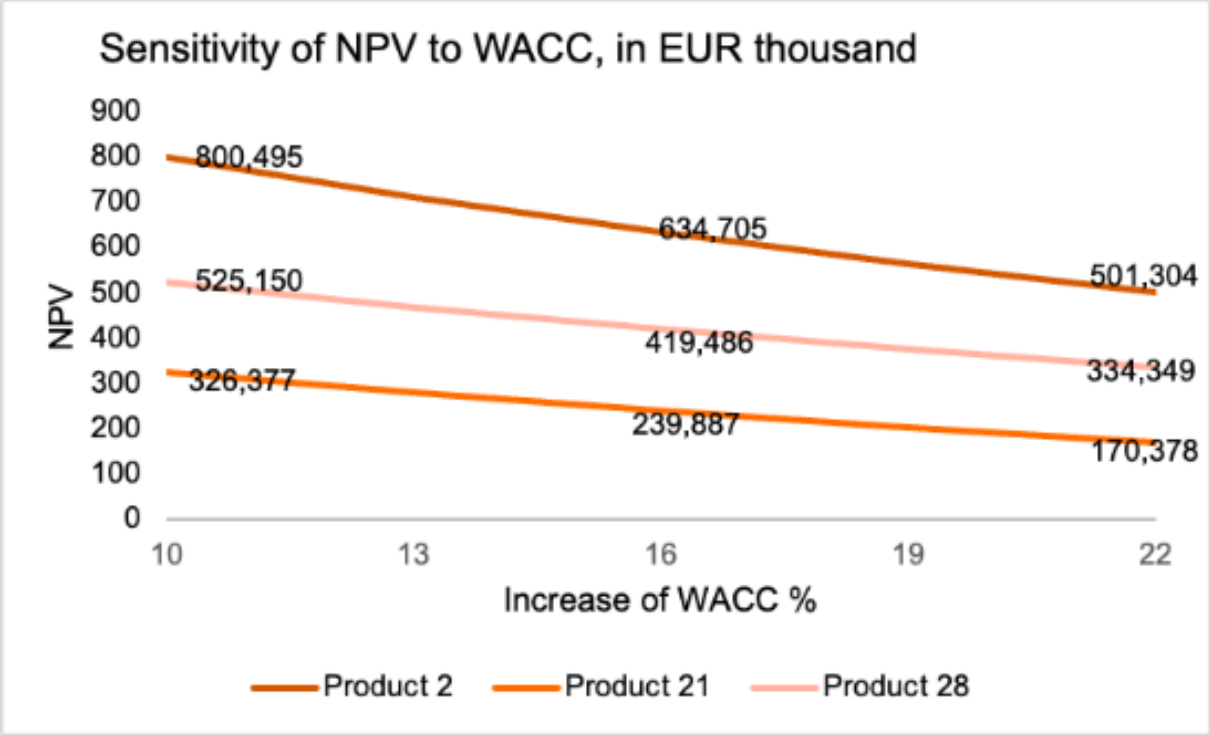

Figure 4. Sensitivity of NPV to WACC

To conclude, the sensitivity analysis confirms the financial resilience of the model, demonstrating positive NPV values across varying changes in two main assumptions: change of one-time investments and change of WACC. This suggests that the project will remain financially stable even under a range of unpredictable changes.

CHAPTER 4. IMPLEMENTATION SECTION

4.1 BUILDING A WORK BREAKDOWN STRUCTURE

The implementation of pharmaceutical technological and manufacturing transfer is a versatile process that requires clear structure of phases in order to ensure the clarity and efficiency of results. To achieve operational excellence project management tools such as work breakdown structure (WBS) are highly recommended to use. Decomposing the project through WBS serves as a step-by-step foundation for the transition of manufacturing.

The initial phase of transfer is the Definition Phase. By the end of the given phase sending unit (Acino Ukraine) obtains the results from CMO/CDMOs' researchers, selects potential partners based on commercial proposals, sings CDAs and conducts Business Case and Due Diligence procedures so that validating the alternative sites and the appropriate drugs. It involves a comprehensive audit of price quotes, partners' capacity for manufacturing and CapEX requirements associated with additional machinery for CMO. That is also a perfect opportunity to observe and mitigate financial and operational risks associated with transfer, because on the stages of DD and BC the sending unit receives precise data about expenses, payback period, expected revenues, GMP compliance and technical capability of the receiving company. Therefore, the Definition Stage shows the alignment with sending unit requirements and provides a foundation for Go/No-go decision.

1. **Definition Phase**
    - **1.1.** CMO/CDMO search
    - **1.2.** CDA negotiation and signing
    - **1.3.** Drug transfer feasibility assessment

1.4. Receiving a price quote

1.5. Business case evaluation, validation and approval

1.6. Due Diligence

1.7. Contract signing for contract manufacturing

The approved Business Case and completed Due Diligence serve as transition to the next phase of the project - Transfer Phase. The described stage focuses on the integration of specialised knowledge of manufacturing and technological processes from the sending unit site to the receiving company. The phase is characterised by the two main activities: documentation preparation from both parties and production execution of pilot batches, which subsequently leads to the validation process and commercial manufacturing by CMO. Given that Acino Ukraine aims to produce transferred drugs at its own plant, maintaining identical medical characteristics is essential to ensure product quality, bioequivalence indicators and similar control results from different plants, which is also a strict requirement from regulatory authorities.

2. Transfer Phase

2.1. Documentation preparation

2.2. CMO/CDMO technical documentation preparation

2.3. Samples and substances preparation

2.4. Control methods verification

2.5. Batches manufacturing and validation of technological process

2.6. Stability studies

2.7. Documentation preparation for dossier

While the Transfer Phase implies the direct manufacturing of medicines, the commercialization is impossible without approval from regulatory authorities leading to the third phase of the project - Registration Phase. The process involves gathering each piece of data associated with the production as about machinery characteristics as well as the dissolution profile of the drug - elements of a dossier.

This ensures that the transferred medicine, especially produced on the site of contract organization, meets quality and safety standards. Given that Acino Ukraine operates the only pharmaceutical plant within CIS region, where the company is present, dossier synchronization across different countries is a registration necessity to mitigate the legal barrier for the commercialization on various markets.

3. **Registration Phase**

    3.1. Variation submission in Ukraine and UBA region

    3.2. Variation procedure in Ukraine and UBA region

Once the dossier has gone through the variation procedure - in a regulatory authority - Acino Ukraine is empowered to place the order for the transferred drug. Upon purchase placement by Acino, the contract manufacturing site initiates a commercial production of the transferred drug, which involves conducting quality control procedures, and releasing finished dosage form for subsequent delivery to Ukraine. The described phase represents the final stage of the full-cycle CMO manufacturing process and transforms the project into a long-term supply model.

4. **Commercial Phase**

    4.1. PO placement by Acino Ukraine

    4.2. Order processing

    4.3. Delivery to Ukraine

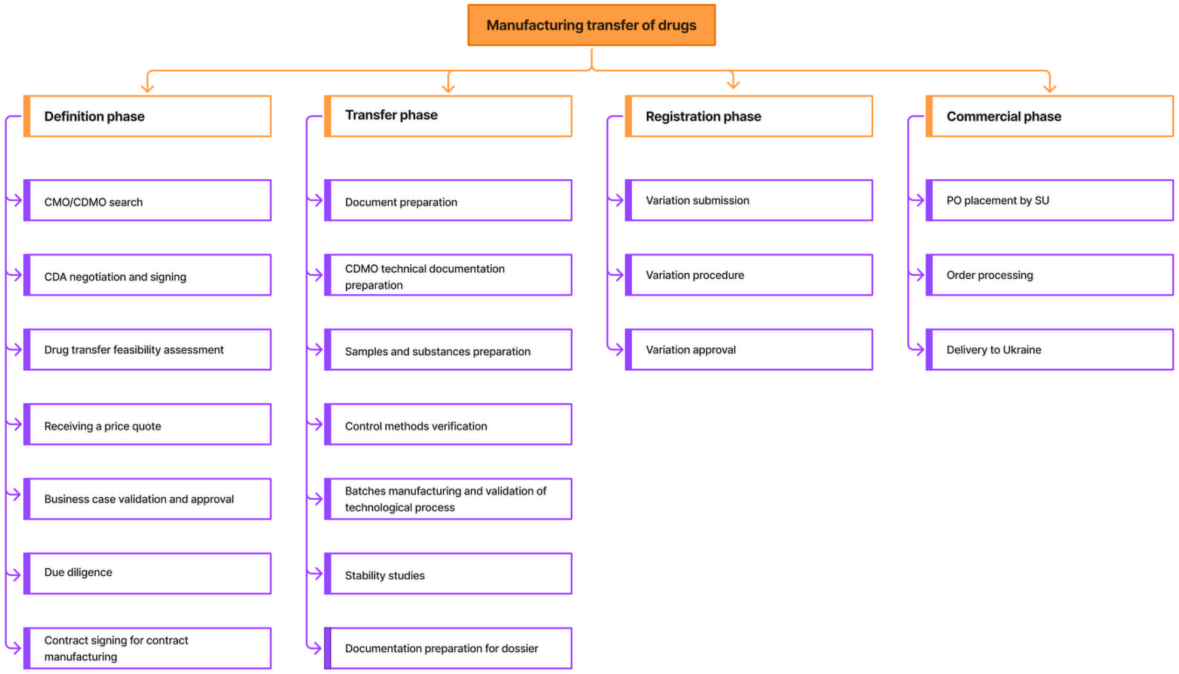

Figure 5. Work Breakdown Structure for Contract Manufacturing Transfer
Source: Work Breakdown Structure (WBS) Template | The Conference Room (Community), https://www.figma.com/community/file/1238441376887122918/work-breakdown-structure-wbs-template-the-conference-room.

4.2 EXECUTION PLAN OF THE DRUG TRANSFER

Drug transfer project is a huge and time-consuming project with a duration up to 2-3 years. Successful management of the set of activities can be reached by building Gantt Chart - a project management visualization tool, which serves as a working calendar and breaks tasks into sequential steps defined by duration and dependencies. While WBS decomposes a total scope of work into a group of tasks and subtasks, Gantt Chart creates a sequential step-by-step execution plan through the entire project with defined milestones, timelines and dependencies.

The key advantage of the visualization approach is assigning milestones - critical steps, that point out the ending of the scaled task during each phase of the project with a duration of 0 days . These milestones allow the project management team to monitor the performance of execution, therefore ensuring timely implementation of transfer.

Moving forward with the duration of each phase and total project time. The first phase is the Definition Stage, taking 8 months to complete, with an approximate duration of 2 months for each task, execution of which often happens simultaneously. However, some of the tasks, typically signing SDEA, a Safety Data Exchange Agreement, takes 4 months to finish, because of technical complexity of aligning pharmacovigilance protocols between two companies. To prevent bottlenecks, the schedule provides overlap with the beginning of the transfer phase to ensure timely execution of the project. Several of the control gates are included in the phase. Firstly, signing CDA, therefore authorizing exchange of any sensitive data between parties, which is crucial to start cooperation. Forward milestones are Business case Due Diligence approvals. The final milestone is contract signing, which serves as a foundation for technical transformation of transfer.

Once administrative assignments are agreed, the next phase can be performed - Transfer phase, spanning around 27 months, but executing in parallel with subsequent phases. This stage focuses on analytical methods transfer, technical validation, manufacturing of pilot batches and stability studies of medicines. The prerequisite to start producing drug batches, is harmonisation of technical documentation. This begins with creation of Transfer Protocol, a road map for any manufacturing activities on CDMO’s plant. Then leading to preparation and translation of Quality Control and Cleaning Validation protocols. To optimize timelines, the preparation of documentation is executed in parallel. The stages ensure that receiving unit facilities standards are aligned with original specifications. Once the CMO’s documentation approval is reached as a milestone, the CMO plant is able to proceed with procurement of raw materials and manufacturing of two pilot batches. The main milestone there is when samples and substances are delivered to the receiving unit. After that

laboratory batches producing and subsequent quality control start. Before commercialization of batches, there is a requirement to study finished medicines according to regulatory standards, therefore the plant conducts stability studies at points 0,3,6,9,12,18,24,36 months. That's the explanation of the long duration of the whole phase. However, the baseline scenario allows monitoring for 6 or 9 mounts to study the profile of the drug. In case, next testing reveals deviations from normal characteristics, the batches are immediately recalled from the manufacturer. The last stage before moving to the registration phase is preparation of the dossier for regulatory affairs, where analytical and manufacturing data are organized for submission, taking approximately 2 months.

The phase described below marks the transition to registration phase. The phase includes variation procedures in Ukraine and the company's operating region, named UBA. The project prioritizes a procedure in Ukraine beyond the region, spanning around 8 months, which signalises that commercialisation of the medicine can be started while the drug undergoes approval in the region, thus optimizing timelines of the project and mitigating the risk of manufacturing stagnation. The variation procedure involves regulatory assessment of drug's characteristics between sending and receiving units, therefore approving the technology of manufacturing on an alternative site and authorizing the permit for distribution of the product.

Following the approval from regulatory authority, the project transforms into the Commercial Phase. The Acino places the order for manufacturing commercial batches of the medicine, then the contractor procures raw materials and packaging for a future drug. Subsequently, the receiving plant starts to produce the required number of batches for Acino, afterwards undergoing quality control. Once the stages are completed, the process moves to the transportation, involving the delivery of finished product to the central warehouse of the Acino in Ukraine. The critical point within the stage is when delivery is completed, meaning that the company is able to start sales in Ukraine.

To sum up, the project implementation takes approximately 36 months, starting from October 2025 ending in March 2028. The timeline is non-negotiable due to pharmaceutical nature, which is

highly regulated to comply with international practices and standards. Utilizing the parallel execution of steps and stages optimizes the transfer execution, ensuring manufacturing alternatives without compromising the quality of drugs for Ukrainian market.

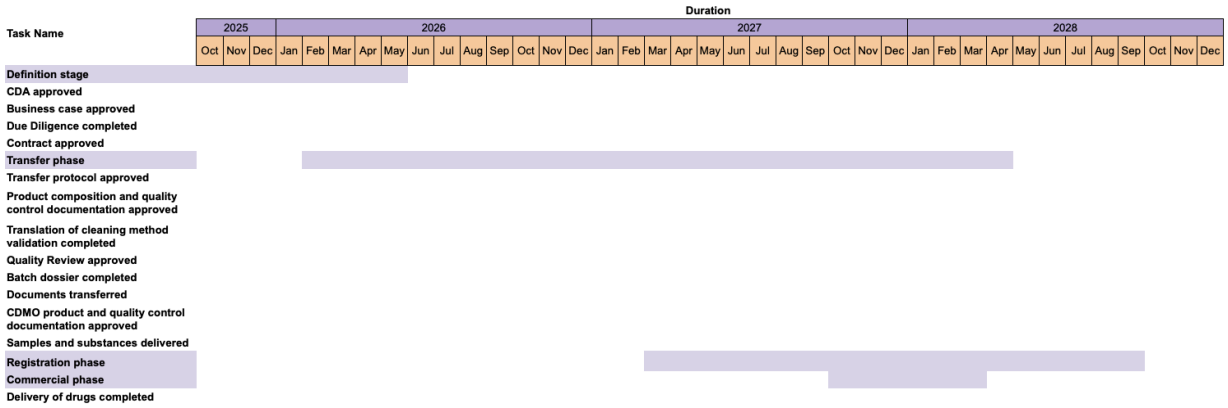

Figure 6. Gantt Chart Of Contract Manufacturing

CONCLUSION

Modern pharmaceutical business is undergoing significant changes driven by the full-scale invasion in Ukraine. One such company is Acino Ukraine, part of Arcera, whose manufacturing division - Pharma Start - was severely damaged by the russian massive missile attack at the end of July 2025. The incident resulted in a temporary shutdown of the plant, blocking the company's operating activities associated with producing medicines. The incident highlighted Acino's over-reliance on a single site and vulnerability to external shocks. This disruption calls for an urgent solution - to develop a diversification and risk mitigation strategy through collaboration with contract manufacturing organisations. This thesis develops and justifies such a strategy involving a consulting approach applied to a real pharmaceutical company case.

The Analytical section of the project was dedicated to a comprehensive selection model of the drugs for transfer and organizations that suit Acino partnerships criteria. In order to obtain the prioritised list of medicines, a Multi Criteria Decision Analysis framework was applied, providing the result of 7 out of 38 products with high level priority for transfer from Pharma Start portfolio. As for contract manufacturing organizations assessment, a sequential selection model was utilised with several main criteria. As a result, the step-by-step approach demonstrated that 9 out of 60 companies turned out suitable for potential collaboration. Risk identification confirmed that single-site concentration manufacturing exposed some key threats, such as: backup capacity, financial, geographical, logistical and regulatory, while diversification strategy serves as a mitigation mechanism.

The Recommendation section was primarily focused on developing proposals for the project implementation, including allocation of the transfer portfolio within selected sites and contractual mechanism to govern the relationship between sending and receiving units.

The Economic justification confirmed the financial feasibility of drugs selected for transfer. The Cash Flow analysis showed positive Net Present Values at 634,705, 239,888, 419,486 EUR for Products 2, 21 and 28 respectively, reflecting capital sufficient to cover the transfer - related expenses. The Payback periods are 1 year 9 months, 2 years 2 months and 1 year 8 months for three drugs respectively, indicating a rapid return on investments. Sensitivity analysis validated the robustness of the model towards changes in WACC and initial one-time investment values compared to NPV of all three products, proving the financial sustainability under different scenarios.

The Implementation section of the thesis described the project execution using project management tools as Work Breakdown structure and Gantt Chart. The project calendar involves four main phases: Definition, Transfer, Registration and Commercial, with the total duration of 36 months.

Overall, the findings provided in this thesis capstone project contribute both theoretically and practically for the pharmaceutical industry in Ukraine. The study delivers a practical diversification strategy to the client that strengthens its operational resilience. The methodology developed may serve as a foundation for Ukrainian pharmaceutical manufactures handling the challenges of war time production continuity.

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.

APPENDIX A

Statistics for leading pharmaceutical companies in terms of monetary sales as of June 2025

ЛЗ. Червень 2025

PROXIMA

Топ-10 маркетуючих організацій та брендів у грошовому вимірі

Маркетуюча організація	Питома вага, %	Рейтинг, 2025	Рейтинг, 2024	Рейтинг, 2023
Фармак АТ	5,53	1	1	1
Тева Фармасьютікалз Індастріз	4,05	2	4	3
Асіно	3,73	3	3	4
Дарниця ФФ ПрАТ	3,58	4	2	2
КРКА	3,56	5	7	6
Київський вітамінний завод АТ	3,48	6	6	8
Корпорація Артеріум	3,32	7	5	5
Берлін-Хемі АГ	3,26	8	8	7
Кусум Фарм ТОВ	2,63	9	9	9
Серв`є	2,46	10	10	10

Бренд	Питома вага, %	Рейтинг, 2025	Рейтинг, 2024	Рейтинг, 2023
КСАРЕЛТО	0,86	1	1	2
НУРОФЄН	0,83	2	3	6
ТРИПЛІКСАМ	0,80	3	6	8
ДЕТРАЛЕКС	0,69	4	5	3
НІМЕСИЛ	0,67	5	4	1
НАЛБУФІН	0,64	6	2	4
СИМБІКОРТ	0,61	7	9	11
СПАЗМАЛГОН	0,60	8	7	5
ДЖАРДІНС	0,54	9	25	97
СІНДЖАРДІ	0,50	10	18	31

Джерело: Система дослідження ринку «PharmXplorer»

Без урахування тимчасово окупованої території АР Крим, м. Севастополь та частини зони проведення ООС станом на 24.02.2022р.

APPENDIX B

The table listing contract manufacturing organizations on the website

Name of CMO/CDMO's	Country	EU GMP
Company 1	India	-
Company 2	Spain	+
Company 3	Italy	+
Company 4	US	-
Company 5	Italy	+

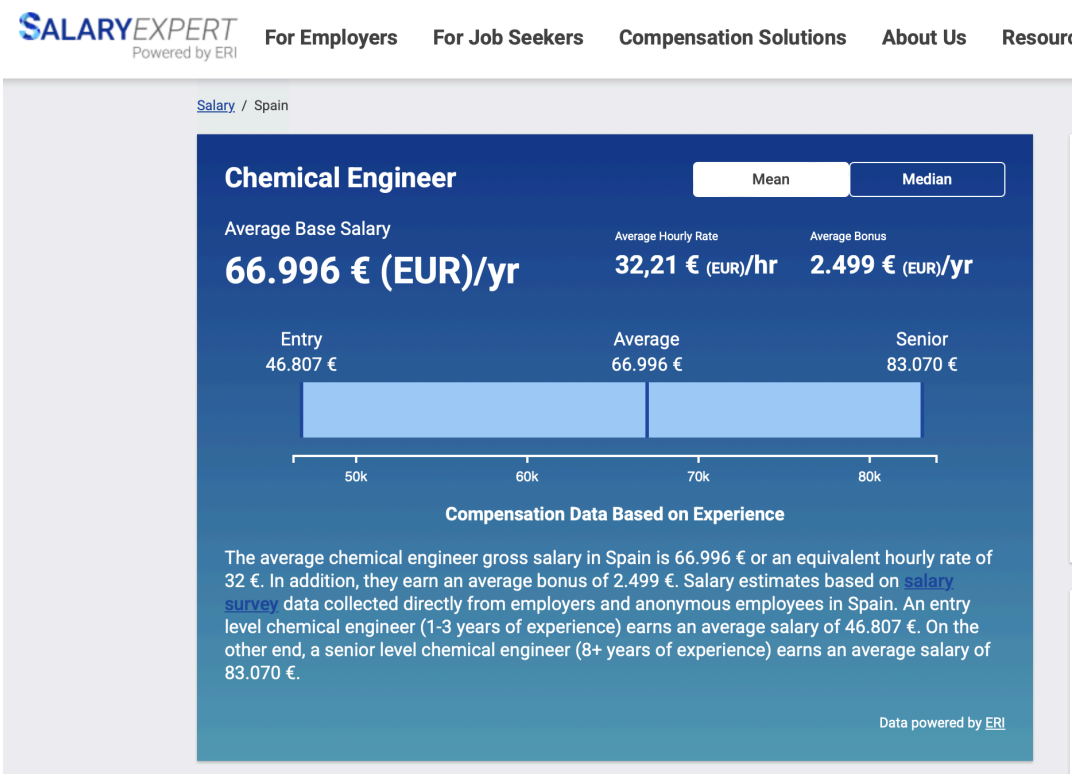
Company 6	France	+
Company 7	Germany	+
Company 8	Germany	+
Company 9	Switzerland	+
Company 10	Japan	+
Company 11	Horway	+
Company 12	France	+
Company 13	Germany	+
Company 14	Italy	+
Company 15	Romania	+
Company 16	Germany	+
Company 17	US	-
Company 18	Germany	+
Company 19	Ireland	+
Company 20	Switzerland	+
Company 21	Italy	+
Company 22	Germany	+
Company 23	Germany	+
Company 24	Germany	+
Company 25	Switzerland	-
Company 26	Germany	+
Company 27	China	+
Company 28	Switzerland	+

Company 29	Italy	+
Company 30	Belgium	+
Company 31	US	-
Company 32	Spain	+
Company 33	India	-
Company 34	US	N/A
Company 35	Germany	+
Company 36	Netherland	+
Company 37	Spain	-
Company 38	Spain	-
Company 39	China	-
Company 40	US	-
Company 41	US	+
Company 42	US	+
Company 43	UK	+
Company 44	US	+
Company 45	Sweden	+
Company 46	Belgium	N/A
Company 47	US	+
Company 48	Italy	+
Company 49	Lithuania	+
Company 50	Poland	+
Company 51	Hungary	+

Company 52	Latvia	+
Company 53	Poland	+
Company 54	Estonia	+
Company 55	Poland	+
Company 56	Poland	+
Company 57	Slovakia	+
Company 58	Romania	+
Company 59	Romania	+
Company 60	Hungary	+

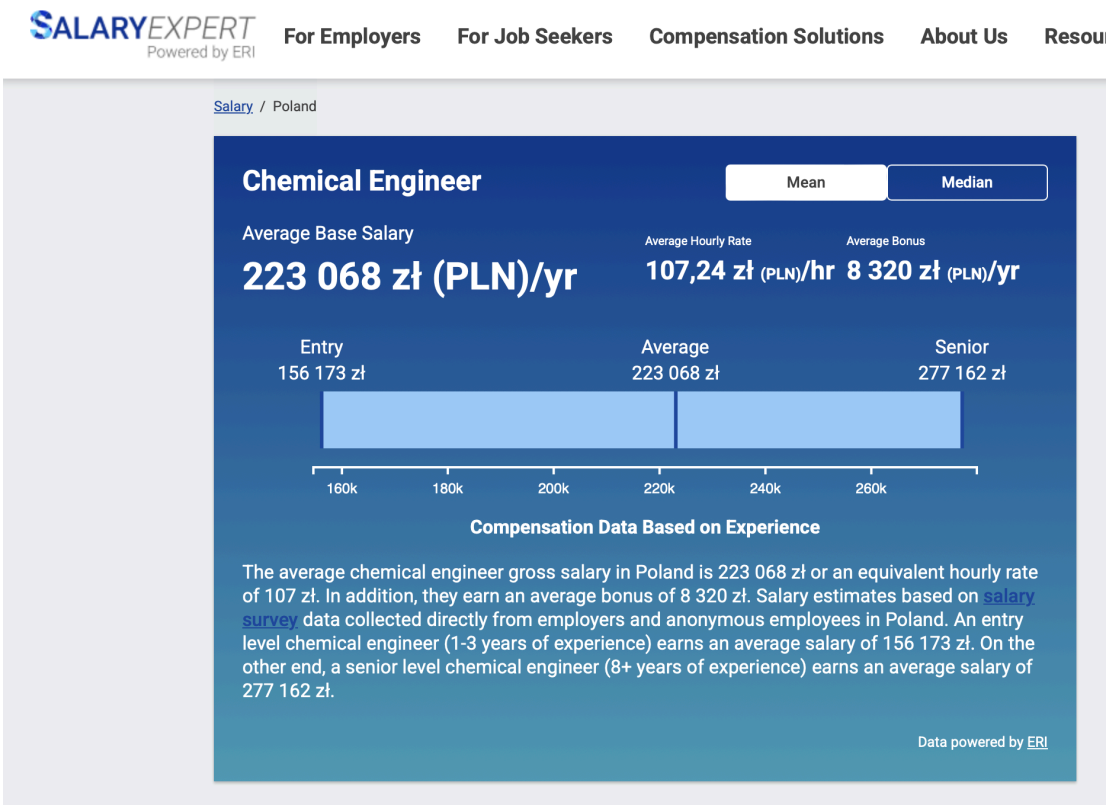
APPENDIX C

Example of salary range of a pharmaceutical employee in Spain



APPENDIX D

Example of salary range of a pharmaceutical employee in Spain



APPENDIX E

Example of company's capabilities for drug production on the official website

APPENDIX F

Insertion of legal agreement to manage the cooperation between two parties

ДОГОВІР КОНТРАКТНОГО ВИРОБНИЦТВА №

Київ Дата

Цей Договір Контрактного виробництва (надалі – “Договір”) укладено Дата («Дата Набрання Чинності») між:

Виробник, юридична особа, створена та зареєстрована відповідно до законодавства України, в особі _____які діють на підставі Статуту, надалі – “ ВИРОБНИК”,

та

ТОВАРИСТВО З ОБМЕЖЕНОЮ ВІДПОВІДАЛЬНІСТЮ “Назва”, юридична особа, створена та зареєстрована відповідно до законодавства України, в особі Генерального Директора ПІБ, який діє на підставі Статуту, надалі – «Покупець»,

ВИРОБНИК та ПОКУПЕЦЬ надалі іменуються окремо «Сторона», а разом — «Сторони».

Преамбула

ВИХОДЯЧИ З ТОГО, що Сторони уклали Ліцензійний договір;

ВИХОДЯЧИ З ТОГО, що ВИРОБНИК погодився виробляти та постачати Покупцю, а Покупець погодився купувати у ЛІЦЕНЗІАРА певні обсяги Продуктів для комерційного використання на Території.

APPENDIX G

Insertion of legal agreement terms to manage the cooperation between two parties

2. Предмет Договору

2.1. ВИРОБНИК зобов'язується за замовленням Покупця виготовити (контрактне виробництво) Продукти, зазначені у Додатку № 1 до цього Договору, на Схваленому підприємстві та поставити у власність Покупця згідно з умовами цього Договору, а Покупця зобов'язується приймати та оплачувати їх.

3. Контрактне виробництво

3.1. Контрактне виробництво Продукту здійснюється на підставі чинного Реєстраційного посвідчення, що на момент укладання Договору належать Виробнику та має бути передане в подальшому Покупцю відповідно до умов Ліцензійного договору, та відповідно до узгоджених матеріалів Реєстраційного досьє. В рамках виконання цього Договору ВИРОБНИК здійснює повний цикл виробництва Продукції, включаючи закупівлю необхідних сировини відповідно до Договору поставки сировини АФІ та матеріалів, виробництво, контроль якості, сертифікацію та випуск серій уповноваженою особою, маркування та пакування.А зберігання продукції.

3.2. Покупець зобов'язується купувати Продукти у ВИРОБНИКА відповідно до погоджених об'ємів та терміну згідно з Додатком 1 та іншими умовами цього Договору.

3.3. З метою виробництва Продуктів ВИРОБНИК закуповує сировину АФІ, визначений у Додатку 2 до цього Договору.

APPENDIX H

Insertion of legal agreement terms to manage the cooperation between two parties

4.2. **Період стабільності ціни та Перегляд**: ПОКУПЕЦЬ купує, а ВИРОБНИК продає Продукти за ціною, зазначеною в Додатку 1. Ціна фіксується на 2 (два) послідовні Контрактні роки («Період стабільності ціни»).

Надзвичайний перегляд ціни. Період стабільності ціни не застосовується у разі збільшення вартості сировини АФІ від його постачальника, який є афілійованою особою Назва компанії. У такому випадку, ВИРОБНИК дзеркально (у відповідній пропорції) збільшує вартість Ціни Продукту та застосовує нову Ціну щодо продукту, який буде виготовлено з відповідної партії сировини АФІ.

Період стабільності ціни також не застосовується до випадку суттєвої девальвації гривні до долара США на понад 10%.

У будь-якому такому випадку, ВИРОБНИК має надати ПОКУПЦЮ обґрунтовані докази та документацію, що підтверджують настання такого випадку. Обидві Сторони зобов'язані добросовісно проводити переговори для узгодження надзвичайного коригування ціни.

APPENDIX I

Insertion from google sheets to illustrate how the WACC was calculated

WACC	16%

WACC (EUR)	19%	
Risk-free rate (RFR)	2.95%	*Germany 10-Year Goverment Bond Yield, as of April 2026*
Equity Risk Premium (ERP)	4.23%	*Damodaran, as of April 2026, Germany ERP*
Ukraine Country Risk Premium (CRP)	15.54%	*Damodaran, as of April 2026*
Beta	0.41	*based on peer companies*
Cost of Equity	**20.22%**	
Risk-free rate (RFR)	2.95%	
Debt-risk premium (DRP)	5.00%	*Damodaran, defalt spread for Ukraine*
Pre-tax cost of debt	7.95%	
CIT for Ukraine	18%	
After Tax Cost of Debt	**7%**	
Weight of equity	**90.61%**	*based on peer companies*
Weight of debt	**9.39%**	

Levered beta	0.41
Sandoz	0.56
KRKA	0.43
Gedeon Richter	0.24

	Sandoz	**KRKA**	**Gedeon Richter**	
Market value of equity, EUR	27,883,000,000	7,120,000,000	5,581,000,000	*as of April 2026*
Market value of debt, EUR	3,155,890,168	586,750,000	648,000,000	*as of April 2026*
Weight of equity	89.83%	92.39%	89.60%	
Weight of debt	10.17%	7.61%	10.40%	
Debt/Equity	11.32%	8.24%	11.61%	
CIT	15.3%	18.6%	9%	*as of April 2026*
Unevered Beta	0.61	0.46	0.26	

APPENDIX J

Sensitivity analysis for Product 2

Product 2	WACC					
	634,705	10%	13%	16%	19%	22%
Initial investments	-20%	868,186	780,577	702,236	631,949	568,690
	-10%	834,341	746,773	668,470	598,220	534,997
	0	800,495	712,969	**634,705**	564,491	501,304
	10%	766,650	679,164	600,939	530,763	467,610
	20%	732,805	645,360	567,174	497,034	433,917

APPENDIX K

Sensitivity analysis for Product 21

Product 21	WACC					
	239,887	10%	13%	16%	19%	22%
Initial investments	-20%	379,957	334,201	293,308	256,639	223,654
	-10%	353,167	307,452	266,598	229,965	197,016
	0	326,377	280,703	**239,887**	203,292	170,378
	10%	299,587	253,954	213,177	176,619	143,740
	20%	272,797	227,205	186,467	149,946	117,102

APPENDIX L

Sensitivity analysis for Product 21

Product 28	WACC					
	419,486	10%	13%	16%	19%	22%
Initial investments	-20%	566,813	510,985	461,027	416,174	375,780
	-10%	545,981	490,184	440,256	395,432	355,065
	0	525,150	469,384	**419,486**	374,690	334,349
	10%	504,318	448,584	398,715	353,947	313,633
	20%	483,486	427,783	377,944	333,205	292,918