



Research Article

Procedure for Applying Predictive Analysis in the Development of Generic Drugs

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Abstract

The Pharmaceutical Industry faces the challenge of reducing the development time of new products, especially generic drugs. Predictive analytics is a category of analyzing historical data to make predictions about future outcomes based on statistical and machine learning techniques. The objective of this work is to design a procedure to incorporate predictive analysis in decision making during the development of generic medicines supported by scientific and economic arguments. The study was divided into two phases. Phase 1 will characterize the development value chain of generic medicines using the weighted SWOT Matrix to determine its status and the Delphi method to evaluate agreement between experts. Phase 2 detailed analysis of the techniques and tools to be used in the design of the procedure. The SWOT matrix showed that the chain has weaknesses in that the culture and knowledge of this work tool is not developed, but its strength is that it has a culture of good practices and quality management, as well as an adequate infrastructure. to make effective use of information technology. The procedure has 5 stages where the actions, resources, risk analysis and indicators to evaluate the impact are collected. The designed procedure contributes to streamlining decisions, improving quality, reducing costs and accelerating time to market, offering a significant competitive advantage.

Keywords

Predictive Analytics, Value Chain, Generic Drug Development

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1. Introduction

Emerging markets, characterized by their high variability and competitiveness, pose significant challenges for the pharmaceutical industry, especially in the development of generic drugs. This sector plays a key role in ensuring access to more affordable treatments but faces challenges such as cost pressure, intense competition and the need to reduce time to market [1, 2]. Being the first to market a new product after the innovator's patent expires is a key to success, as it can achieve a higher number of sales, which translates into a faster return on investment [1].

In the business world, characterized by constant evolution, competitiveness and uncertainty, the ability to anticipate changes in the environment has become critical for the success and survival of organizations [3].

According to recent data, the development of generic drugs takes an average of four years of research and also involves significant investments to be able to enter the international market. Generic laboratories invest an average of between 6% and 16% of their annual income in research and development, reaching 30% in some cases [3-5].

The pharmaceutical industry, in its areas of innovation and development, has historically used predictive and incremental project management methodologies, which have proven effective in coordinating complex processes and complying with strict regulatory standards [1, 2].

This is a sector that uses a large amount of data on generic drugs at an exponential rate, as it can help companies find the most suitable drug with the desired therapeutic effect [6].

However, in the current context, where commoditization and intense competition put pressure on costs, it is imperative to incorporate innovative approaches that optimize the value chain (VC) and enhance flexibility and efficiency in the development of generic drugs [7, 8].

The ability to accurately predict the time and cost required to bring a drug from the research stage to commercialization can help to better plan and manage resources, as well as reduce development times and increase the accessibility of generic drugs [6].

In this sense, predictive analysis emerges as a key tool. This approach, which uses historical data, algorithms, machine learning and advanced statistical techniques, allows for predicting trends, optimizing processes and reducing development times [9-11].

Predictive analysis in the pharmaceutical industry refers to the use of historical data and advanced analysis techniques, such as machine learning and artificial intelligence to predict future trends and clinical outcomes and optimize business processes. This approach allows pharmaceutical companies to make decisions and improve efficiency in various areas, from drug research and development to production and marketing. In the case of generic drug development, this analysis helps to optimize its life cycle from its conception to its arrival on the market [4-6].

The evolutionary process of the VC for its improvement is fundamentally based on the development of the product, the productive processes and the business models, where education, innovation and promotion are decisive to guarantee competitive advantages in the market [12-14].

The general objective of this work is to design a procedure based on predictive analysis that allows improving decision-making in the development of generic drugs, supported by scientific and economic arguments. To achieve this, the following specific objectives are established:

- 1) Characterize the value chain of the generic drug industry and identify the main areas for improvement.
- 2) Develop a structured procedure that integrates predictive analysis in the development of generic drugs by ensuring decisions based on data and scientific arguments.

2. Materials and Methods

To carry out the research, a structured protocol was followed to identify and retrieve relevant information on the prediction of time and cost of development of generic drugs. The data sources consulted include recognized databases such as: Dialnet, IEEEExplore, ArXiv, Pubmed, Oatd.org, OpenGray, Redalyc, Google Scholar, which guarantees a multidisciplinary approach and an exhaustive analysis of the literature.

The research was divided into two phases: A first phase related to the characterization of the VC for the development of generic drugs, and a second phase in which, based on the analysis of the consulted bibliography, the procedure to follow to implement the predictive analysis was developed.

2.1. Phase 1: Diagnosis of the VC of Generic Drug Development

2.1.1. Weighted Strengths, Weaknesses, Threats and Opportunities (SWOT) Matrix

The weighted SWOT Matrix was applied to assess the Generic Drug Industry's willingness to implement predictive analytics as a decision-making tool.

- 1) Participation and data collection method:
 - a) 10 experts representing different key players in the generic medicines sector were consulted, ensuring a comprehensive view.
 - b) To ensure the validity of the responses, the Delphi method was used, which allows for consensus to be obtained among experts through iterative rounds of consultation.
- 2) Data consolidation and analysis:
 - a) The experts were given a consolidated list covering internal and external factors identified in the VC.
 - b) The results were processed to calculate the Coefficient of Concordance using the following expression:

$$Cc = [1 - (Vn \div Vt)] * 100$$

Where:

Cc: Coefficient of concordance expressed as a percentage.

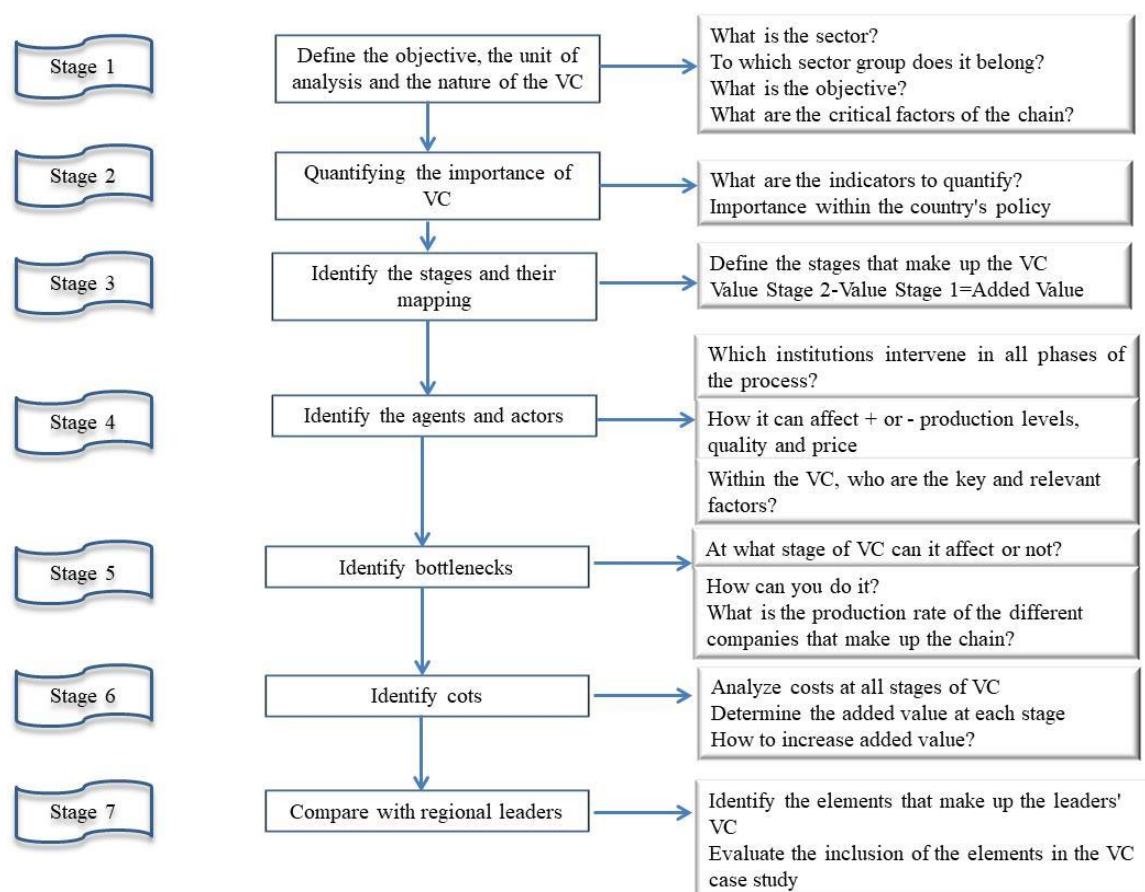
Vn: Number of experts against the prevailing opinion.

Vt: Total number of experts.

Empirically, a level of concordance of $Cc \geq 60\%$ was considered acceptable. This threshold ensures that the results reflect sufficient consensus among experts.

2.1.2. Characterization of the VC of Generic Drug Development

A specific methodology was applied that allowed the identification and evaluation of the main stages and processes of the VC, as well as the areas susceptible to improvement. Figure 1 describes the methodology used to carry out the characterization.



Source: Oña, N y Col, 2021 [15].

Figure 1. Methodology for Evaluating the CV of Generic Drug Development.

The methodology includes:

- 1) Identification of key stages: From initial research to commercialization.
- 2) Detection of critical points: Factors that impact time and cost.
- 3) Optimization proposal: based on the strengths and weaknesses detected in the SWOT Matrix.

2.2. Phase 2 Development of the Procedure for the Application of Predictive Analysis

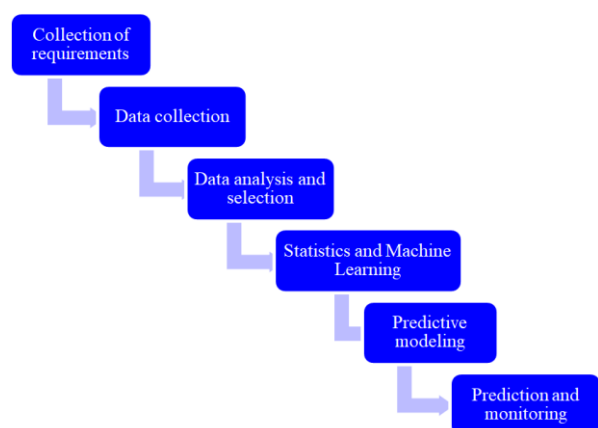
Selection of relevant literature related to predictive analysis.

For the design of the procedure, a review of the literature related to predictive analysis in the pharmaceutical industry was carried out. This review focused on identifying:

- 1) Predictive analysis techniques: Advanced statistics, machine learning algorithms and artificial intelligence.
- 2) Application cases: Previous studies that demonstrate the effectiveness of predictive analysis in similar areas.
- 3) Key implementation factors: Technical, operational and regulatory requirements.

Several analysts agree with the elements shown in Figure 2 (Kumar V, Garg, M. L, 2018) [9], (Espino, C, 2017) [10], (Principe, J. A and Sanavedra, J. C, 2021) [16], (Apalay, C. H y Espinosa, A., 2018) [17], (Fernandez, R., Costa, J., Oviedo

de la Fuente, M., 2024) [18], (Faroukhi et al, 2020) [19].



Source: own elaboration.

Figure 2. Predictive Analytics Process.

It should be noted that the literature retrieved from the different databases on the application of predictive analysis was found primarily in the fields of medicine, medical services, and industrial maintenance in different sectors, as well as in the development of new molecules. A few publications were identified for the topic of this research, which is why it is considered to be a novel topic and a significant contribution to improving efficiency and effectiveness in the creation of new generic drugs.

Based on this information, a procedure was structured that details the steps necessary to integrate predictive analysis in the development of generic drugs, optimizing decision-making based on historical and current data.

3. Results

The links in the VC of generic drugs were identified in which predictive analysis can be applied more efficiently to optimize critical processes.

3.1. Diagnosis of the VC of Generic Drug Development

Table 1 shows the main weaknesses, threats, strengths and opportunities identified in the VC of generic drugs. A weighted matrix was created from these variables.

Table 1. Weaknesses, Threats, Strengths, Opportunities.

Weaknesses	Threats
Lack of funding that does not allow for timely acquisition of resources. There is no qualified and experienced personnel to develop predictive analysis. There is no culture of decision-making through prediction of the future. Fragmentation in the integration of processes within the VC. Low adoption.	Accelerated technological changes. Outflow of qualified personnel to other sectors of the economy or to other countries. Impacts of the tightening of the blockade. Strict regulations that slow down the arrival in the market. Intense competition that reduces profit margins.
Strengths	Opportunities
Culture of Good Practices and Quality Management. Accounting that reflects economic facts. There is an investment plan for the development of companies. The entities have the infrastructure to make effective use of information technology. Consolidated experience in generic development. Availability of historical and robust data and regulatory records.	Work is being done to promote the computerization of society and the use of electronic government. The biopharmaceutical industry is a priority sector. Integration of the group's companies with better use of their resources and capabilities. Integration of the industry with other sectors of the economy. Growing demand for generic drugs in emerging markets. Progress in predictive analysis and machine learning tools.

Source: own elaboration.

The weighted SWOT Matrix, table 2, reveals that the predominant quadrant is the first one, suggesting a favorable environment for formulating offensive strategies that capitalize on strengths and opportunities. One could mention the availability of robust historical data (S6) and advances in machine learning tools (O6) can be integrated to implement predictive analysis in the generic development phase.

Furthermore, the existing technological infrastructure (S4) allows these tools to be adopted without the need for large additional investments.

Table 2. Weighted SWOT Matrix.

	O1	O2	O3	O4	O5	O6	TOTAL	T1	T2	T3	T4	T5	TOTAL
S1	2	3	3	3	3	2	16	3	3	2	3	3	14

	O1	O2	O3	O4	O5	O6	TOTAL	T1	T2	T3	T4	T5	TOTAL
S2	3	2	2	2	2	3	14	2	3	1	2	2	10
S3	3	3	2	2	3	3	16	3	1	3	3	3	13
S4	3	3	2	2	2	3	15	3	3	3	2	2	13
S5	2	3	3	3	3	3	17	3	2	2	3	3	13
S6	3	2	2	2	2	3	14	3	2	0	2	2	9
TOTAL							92						72
W1	3	3	2	2	3	3	16	3	3	3	3	3	15
W2	3	3	3	3	3	3	18	3	3	2	2	2	12
W3	3	2	2	2	0	3	12	3	2	2	2	3	12
W4	1	1	2	3	3	2	12	3	3	1	3	3	13
W5	3	2	2	3	1	3	14	3	2	3	1	3	12
TOTAL							72						64

Source: own elaboration.

3.2. Characterization of the VC of Generic Drug Development

Stage 1

Sector: Pharmaceutical industry, strategic to guarantee the basic list of medicines.

Unit: Generic drugs. They represent a key component to reduce health system costs and improve accessibility to essential

treatments.

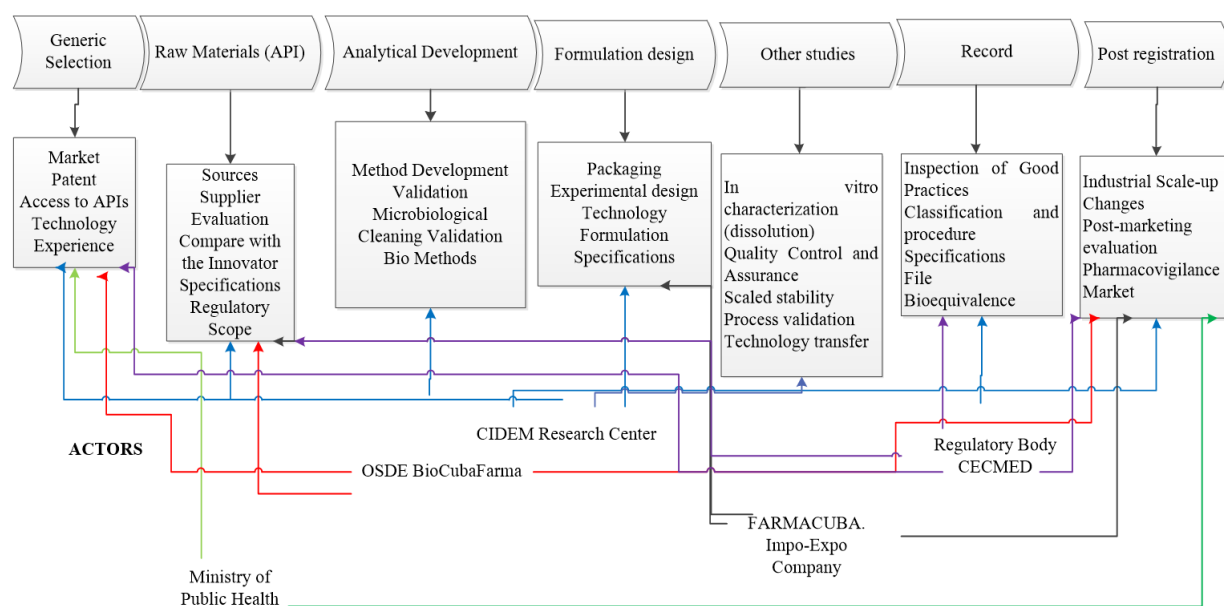
Generic drug development stage.

Stage 2

Generic drugs make up 95% of the country's Basic List of Medicines; more than 405 are sold to the National Health System.

Stage 3 and 4

Figure 3 illustrates the key stages in the development of generic drugs from the research phase to market. The mapping allows to visualize the critical processes within the VC.



Source: own elaboration.

Figure 3. Mapping of the CV of Generic Drug Development.

The main links of the VC are:

Generic Selection

- 1) Generic medicines are identified based on the market, patents, access to active ingredients (API) and accumulated experiences.
- 2) Analysis of the regulatory and technological context to select products with high development and commercialization potential.

Actors: Ministry of Public Health (MINSAP), Higher Organization of Business Management (OSDE) BioCubaFarma, Center for Drug Research and Development (CIDEM), Center for State Control of Drugs and Medical Devices (CECMED).

Raw Materials (API)

- 1) Identify the source of raw material acquisition and supplier evaluation.
- 2) Compare the API specifications with the innovator and validate the regulatory environment.

Actors: CIDEM, FARMACUBA, CECMED.

Analytical development

- 1) Design and validation of analytical methods, including microbiology, cleaning validation and development of bioanalytical methods.
- 2) Quality control of initial formulation processes.

Actors: CIDEM, FARMACUBA.

Formulation Design

- 1) Experimental design of the formulation and packaging.
- 2) Technological optimization to meet regulatory specifications.

Actors: CIDEM, FARMACUBA

Other studies

1. In vitro characterization (dissolution).
2. Process validation, quality assurance and stability studies.
3. Technology transfer to ensure scaling and regulatory compliance.

Actors: CIDEM, CECMED

Record

1. Inspection of Good Manufacturing Practices.
2. Classification, review and processing of specifications.
3. Preparation of the regulatory file and bioequivalence studies.

Actors: CIDEM, CECMED.

Post-registration

1. Industrial scaling of medicines.
2. Post-marketing evaluation, including pharmacovigilance and market monitoring.
3. Incorporation of improvements derived from experience in the use of the product.

Actors: CIDEM, CECMED, MINSAP, OSDE BioCubaFarma.

Step 5 Identify bottlenecks.

Bottlenecks in VC are points where the workflow slows down or is interrupted due to resource, process or capacity limitations, [Table 3](#) reflects the bottlenecks identified in the study chain.

Table 3. Identifying Bottlenecks.

VC Link	Bottleneck
Generic selection	API access, there are funding issues.
	Lack of market information, difficulties in predicting demand and analyzing competition.
Raw Materials (API)	Supply chain problems due to shortage or lack of raw materials or active ingredients.
	Dependence on a few suppliers, concentration of supply in a limited number of suppliers.
Analytical development	Availability of equipment and qualified personnel to perform the tests.
	Lack of integration of historical data, although there is a database, it is not fully accessible to perform predictive analysis.
Formulation design	Mismatch between development lab and production, lack of communication between formulation development and production capacity.
	The necessary resources for experimentation are not available.
Other studies	Bioequivalence validation, these studies are one of the most critical phases.
	There is no adequate infrastructure to simulate large-scale production before commercialization.
Record	The documents to be submitted to CECMED do not meet all the established requirements.
Post-registration	Continuous market evaluation, there is no efficient feedback system.

Source: own elaboration

Stage 6 Identifying costs.

Table 4 presents a cost-benefit analysis broken down by link in the VC of generic medicines in Cuba. The associated costs, achievable benefits and the main value leaks at each stage are identified. This analysis reveals critical bottlenecks

and opportunities for improvement in coordination between actors and in the allocation of resources, which are essential to strengthen the sustainability and competitiveness of the system.

Table 4. Cost Benefit Analysis.

Link	Actors	Cost (Miles CUP)	Benefit	Value Chain and Risk
Generic selection	Ministry of Public Health (MINSAP), OSDE BioCubaFarma, CIDEM, CECMED	From 130.00 to 300.00	Products with prices slightly cheaper than those in the region.	A loss of added value is identified due to the lack of involvement of all actors in the chain.
Raw materials (API)	CIDEM, FARMACUBA, CECMED	From 140.00 to 200.00	Have the API specifications, the evaluated suppliers and their availability.	A VC leak is identified due to having few suppliers, due to problems in the supply chain.
Analytical development	CIDEM, FARMACUBA	From 300.00 to 1000.00	Have validated analysis techniques and validated processes.	Leaks identified in the VC due to availability of personnel and equipment.
Formulation design	CIDEM, FARMACUBA	From 260.00 to 1000.00	Having the product until its stability.	Leakage in the VC is identified due to lack of communication between the processes.
Other studies	CIDEM	From 3000.0 to 3500.0	Having the product ready for registration, production and prompt commercialization	Leakage in the VC is identified due to not having all the resources to carry out the bio-equivalence studies and, if applicable, the technology transfer.
Record	CIDEM CECMED	From 1500.0 to 20000.0	Commercialization of the product	Registration is not granted in a timely manner due to poor quality of the documentation.
Post-registration	CIDEM FARMACUBA CECMED	1% de las ventas para realizar esta etapa	Having consumer studies and continuous evaluation of the market	Leakage of added value is identified due to not being involved in all the actors in the chain.

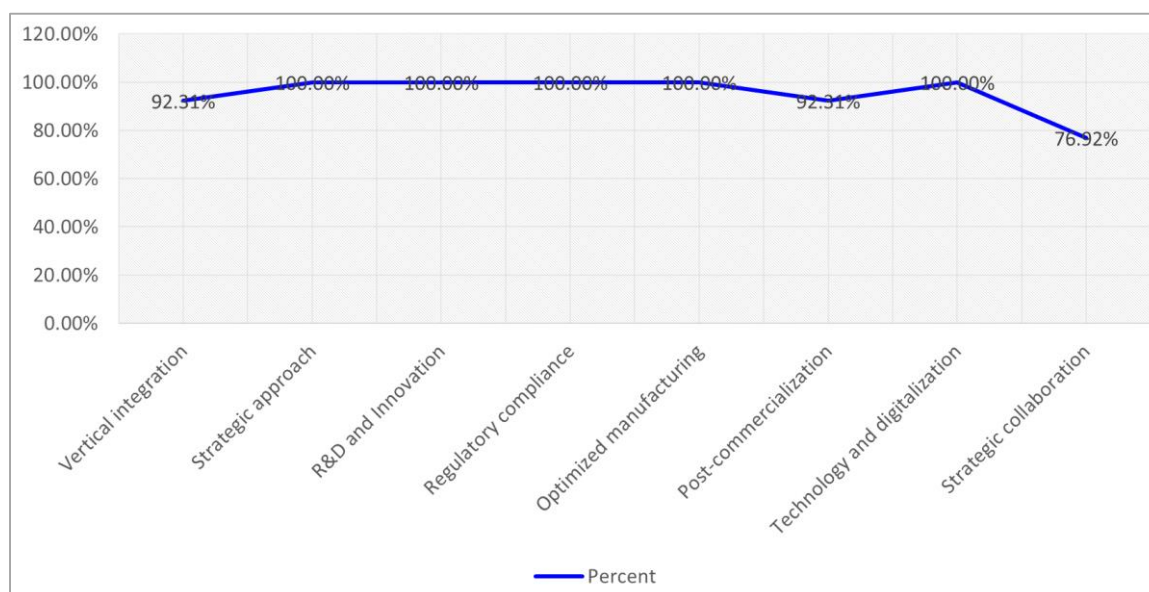
Source: own elaboration.

Stage 7 Compare with leaders.

The producer leaders analyzed were: Teva Pharmaceutical Industries (TEVA), Mylan NV (Holland), Novartis (Sandoz a Novartis Division), Sun Pharmaceutical, Lupin Pharmaceutical, Sanofi Aventis, Novo Nordisk Pharma, Dr. Reddy's Laboratories, Cipla, Zydus Lifesciences, Hikma Pharmaceuticals, Fresenius Kabi, Aurobindo Pharma, STADA Arzneimittel, Endo International, Endo International, Glenmark Pharmaceutical.

For the development of the evaluation, elements such as vertical integration, strategic focus, R&D and innovation, regulatory compliance, optimized manufacturing, post-commercialization, technology and digitalization, and strategic collaboration were considered.

Leaders incorporate into the VC of generic drug development the elements, Figure 4, that differentiate them and that should be part of the study chain.



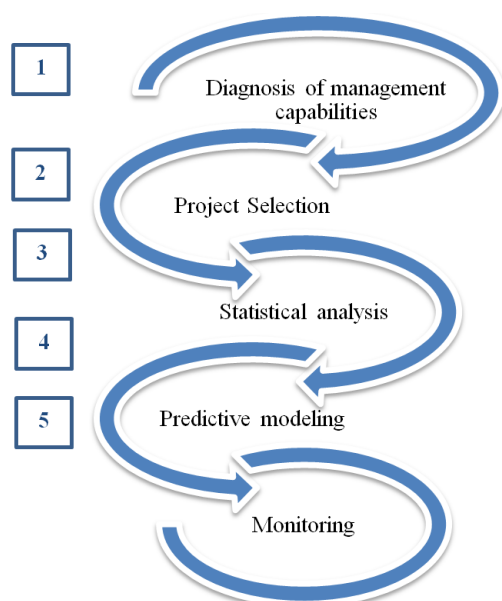
Source: own elaboration.

Figure 4. Elements Present in the Evaluated Chains.

3.3. Development of the Procedure for the Application of Predictive Analysis (PAAP)

The procedure is composed of 5 stages as shown in Figure 5. This procedure aims to identify the opportunities that the generic drug industry has to reduce development time and more effectively insert itself into the VC.

For each stage, the actions, necessary resources, risk analysis, as well as indicators to evaluate the impact were designed.



Source: own elaboration.

Figure 5. Procedure for Applying Predictive Analysis (PAAP).

Stage 1 Conduct a diagnosis of management capabilities by identifying the dimensions to evaluate the performance of organizations.

Dimensions: General Management, Development, Personnel, Marketing, Financial Economy, Logistics and Operations.

Skills to be assessed:

General Management: Environment, direction, organization, security, managers and legal.

Development: R&D+i cycle, information technology, R&D+i investments, quality management, knowledge management, product design, business and management.

Personnel: training, work organization, education, remuneration, health and safety, suitability.

Marketing: market analysis, commercial analysis, customer service, negotiation, contracting, product, price, distribution, promotion.

Economic-Financial: accounting cycle, cost management, analysis, financing, working capital, planning.

Logistics: supply chain integration, negotiation and contracting, procurement, storage, inventory management, transportation and distribution.

Operations: internal processes, capabilities, planning, organization, maintenance and repair, discipline, technology and metrology.

Diagnostic technique: checklist, survey of experts and workers.

Stage 2: Project Selection.

With the result of the diagnosis of the capabilities, especially those identified in the Development dimension, the project or projects are selected to apply the predictive analysis and build the models.

At this stage the following steps are deployed:

1) Data sources: What do you want to improve? What are

the current limitations? What would be the benefit? What were the variations?

- 2) Data collection: data mining, databases, information and statistics, sensor collection.
- 3) Data management: data cleaning and validation, inspection and adjustment of information, identification of what is relevant.

Stage 3: Statistical Analysis.

In this stage, assumptions and hypotheses are validated and tested through the use of standard statistical models.

- 1) Descriptive statistics.
- 2) Behavioral probability.
- 3) Apply regression techniques.

Stage 4: Predictive modeling.

- 1) Selection of predictive models: classification, regression, clustering, forecasting, outliers, time series.

- 2) Selection of the analysis technique: regression, computational learning, Open Source environment.

- 3) Implementation: implementation of one or more models.

Stage 5: Monitoring.

Three important steps are developed in this stage to evaluate the effectiveness of the obtained models.

- 1) Validation of the predictive models.
- 2) Optimization of the predictive analysis process.
- 3) Evaluation of the impact and performance.

Table 5 is a summary of the application of PAAP in the generic drug industry.

Table 5. Application of PAAP.

Stages	Objective	Predictive technique applied	Result
Generic drug selection	Select the innovative drug whose patent is about to expire with high potential for market share.	Time series and regression models	Predicting patent expiration dates. Evaluating market trends to identify molecules with high demand.
Formulation design	Create a formulation equivalent in terms of bioavailability and bioequivalence to the innovative drug.	Machine learning and neural networks	Modelling of chemical interactions between excipients and the active ingredient. Formulations that meet stability, absorption and release requirements in the body are predicted. Reduction of the need for physical testing.
		Monte Carlo simulation	Generation of scenarios to evaluate the performance of different formulations under varying environmental conditions.
Raw materials (API)	Select raw materials (active ingredients) that guarantee quality and availability in the market.	Predictive analysis of suppliers and demand	Predicting potential supply chain disruptions. Identifying alternative sources of raw materials.
Analytical development	Develop analytical methods to evaluate the quality of the formulation.	Advanced statistical models, multivariate regression	Prediction of critical parameters in analytical methods by specification limits.
Bioequivalence testing	Demonstrate that the generic drug has the same therapeutic effect as the innovative drug.	Logistic regression	Predicting the probability of success in bioequivalence testing based on data from previous formulations.
		Bayesian networks	Modeling the probability of adverse events during testing.
Pilot scale production	Validate that the developed formulation can be produced on a large scale in compliance with quality standards.	Stochastic optimization	Optimal configuration of machinery and manufacturing process.
	Ensure that the drug meets the quality, safety and efficacy requirements imposed	Sensitivity analysis	Identification of critical variables that could affect quality
		Multivariate regression	Prediction of critical compliance areas based on historical regulatory

Stages	Objective	Predictive technique applied	Result
Regulatory compliance	by the regulatory agency.	Bayesian networks	audit data.
			Modeling the probability of approval based on drug characteristics and regulatory precedents
Supply chain optimization	Prepare the drug for global distribution.	Time series analysis	Demand prediction based on market trends and epidemiological data.
		Monte Carlo simulation	Modeling the impact of variables and scenarios.
Commercialization	Launch the generic drug on the market to quickly capture market share.	Linear regression	Predicting optimal prices to maximize market share.

Source: own elaboration.

4. Discussion

During the characterization phase of the generic drug industry, clear opportunities to improve competitiveness by integrating historical data (S6) with advanced machine learning tools (O6) were identified using the SWOT matrix and according to the criteria of the consulted experts. This approach requires an initial investment in technological infrastructure and the systematization of available data. Since quadrant 1 predominates in the matrix, it is concluded that offensive strategies are the most appropriate to maximize internal strengths and take advantage of external opportunities.

Among the most relevant strengths are the existing technological infrastructure and the availability of historical data (S4, S6), which provide a solid basis for implementing predictive technologies. On the other hand, advances in predictive analysis tools and machine learning (O6) offer a clear path towards the modernization of VC. This analysis underlines the need to integrate these technologies to overcome bottlenecks and improve predictability in key processes.

As previously stated, generic drugs represent 95% of the Basic List of Medicines in Cuba, which demonstrates their fundamental role in health coverage and their impact on the sustainability and equity of the health system. However, VC faces multiple challenges that hinder its articulation and value generation.

There are bottlenecks that do not allow this CV to be articulated, among the most relevant are: access to APIS limited by financing problems and dependence on the international supply chain, limited capacities in advanced tests due to lack of specialized personnel and equipment; lack of systematization of historical data, although there is robust historical data, they are not structured for predictive analysis; insufficient infrastructure restrictions for bioequivalence studies and for simulation on an industrial scale, poor feedback the lack of adequate systems for monitoring and post-registration pharmacovigilance hinders continuous improvement..

To address these challenges, a set of key strategies is proposed, including: adopting predictive tools to improve demand prediction and drug selection, optimizing the supply chain by diversifying suppliers to minimize risks of dependency and shortages, making improvements in infrastructure and training: investing in specialized equipment and training personnel to conduct bioequivalence and simulation studies on an industrial scale, implementing training programs in predictive analysis and regulatory processes. Furthermore, post-registration feedback must be strengthened with the implementation of systems for continuous market monitoring and pharmacovigilance. In short, bottlenecks must be managed through process optimization and the integration of advanced technology to make each phase of the generic drug life cycle more efficient.

These actions must be aligned with the strategic objectives of the Health System to ensure effective integration of internal and external actors in the CV.

However, the cost-benefit analysis by link highlights how value leaks (fragmentation of actors or dependence on few suppliers) increase risks and limit competitiveness, especially in the initial stages of generic selection and API acquisition.

The highest costs in the chain correspond to the links of analytical development, formulation design and other studies, which range from 300.00 to 3500.00 MCUP. Despite these costs, the associated benefits, such as having validated analytical techniques, stable formulations and products ready for registration and production, do not translate into optimal use of the value generated. This is due to critical leaks, such as lack of specialized personnel, insufficient equipment and problems in communication between processes.

Bottlenecks and value leaks were identified at each link in the CV: Generic selection: The lack of integration between the different actors in the chain hinders a more efficient selection of the drug to be developed. Raw materials (API), the dependence on few suppliers and interruptions in the supply chain generate leaks, making it necessary to diversify API sources to guarantee availability. Analytical development: The leaks detected directly impact the capacity to validate analytical

techniques and processes, which slows down the CV. Formulation design: The lack of communication between processes prevents optimizing resources and accelerating product development. Other studies: Not having sufficient resources to carry out bioequivalence studies and transfer technology limits the capacity to register and produce drugs efficiently. Record: The costs associated with registration, as shown in Table 4, are highly variable and the value leak arises primarily from the quality of the documentation presented, which delays commercialization and affects the competitiveness of the product. Post-registration: Although this stage represents a small percentage of the cost, 1% of sales, the lack of integration of the actors in consumer studies and market evaluation generates value leakage. This problem affects the capacity for continuous feedback and improvement of the CV.

To optimize cost-benefit, the following strategies are outlined:

- 1) Generic selection: promote the effective integration of actors in the selection stage through collaborative platforms that facilitate data-based decision-making.
- 2) Raw materials: diversify suppliers, prioritize strategic alliances and use predictive tools to anticipate interruptions in the supply chain.
- 3) Analytical development and formulation design: invest in training and specialized equipment, as well as in the digitalization of processes.
- 4) Other studies: strengthen the infrastructure for bioequivalence studies through alliances and incentives for technology transfer.
- 5) Registration and post-registration: improve the quality of documentation through training programs in regulatory standards and consolidate post-registration monitoring systems to generate continuous feedback.

The comparison with leading companies highlights key practices that can be adapted to the Cuban context. Many companies rely on vertical integration to ensure a stable supply of APIs and improve cost control, the use of advanced technology: continuous production and predictive analysis systems have been shown to reduce costs and increase efficiency, they also apply specialized equipment and standardized processes that streamline compliance with rules and regulations in various markets, and proactive pharmacovigilance and post-marketing data analysis are crucial to ensure quality and provide feedback to the VC. These common elements are a reflection of how these companies manage to balance competitiveness, innovation and sustainability, ensuring their leadership in the global generic medicines market. In contrast, the VC analyzed in the Cuban case shows a vicious circle that limits its value generation, mainly due to the lack of technological articulation and modernization.

The PAAP is presented as a comprehensive solution to address the current limitations of the CV. Its focus on identifying projects by determining the opportunities for improvement integrates the necessary elements to go through the different stages of the PAAP and achieve the desired objective, which

is the projection of the possible results.

In the first stage, the diagnosis of the capabilities is carried out and for the purpose of this work, it is important to concentrate on the development capacity.

In the business context, development articulates different elements, seeking to lead an organization towards the achievement of its objectives. In turn, it is a process through which staff and managers acquire skills and capabilities to promote the efficient management of resources, implement product and process innovation to obtain sustainable growth in the organization.

Business development refers specifically to the progress experienced by the organization, as a consequence of its evolution over time; this leads to achieving an image, consolidating a certain competitive position, obtaining a good work environment, or satisfactorily meeting economic-financial indicators [19-21].

Innovation makes the difference between the survival or disappearance of a company. In a globalized world, innovation is a task to be developed daily, it is a continuous and dynamic process, not seasonal. Innovation must go hand in hand with Corporate Social Responsibility, as it must be an instrument that provides a competitive advantage for the company and at the same time a real benefit for all interest groups and for the environment [21]. Development and innovation programs in the company today are considered key to achieving competitive advantages, this translates into more flexible companies that manage to exploit existing opportunities and have a greater capacity to adapt and respond to changes that may exist. Therefore, more innovative companies will have greater adaptability to threats and opportunities that may arise.

It can be said that development is a process through which the company strengthens skills, both for the efficient management of resources and for implementation and innovation, as a consequence of its evolution. Achieving a certain competitive level or simply meeting financial economic indicators will be the result of the correct management and use of the learned skills.

Role of ICT in business development.

Information and communication technologies (ICT) are those technologies that facilitate the acquisition, storage, processing, evaluation, transmission, distribution and dissemination of information [22]. There is no doubt that the use and access to information are critical factors in the development of today's economy and it is ICT that has allowed access to large volumes of information to be relatively simple.

ICTs are a key element to make work more productive: streamlining communications, supporting teamwork, managing stocks, performing financial analysis, and promoting products in the market. ICTs allow companies to produce more, faster, of better quality and in less time [23].

The key to a modern organization is to generate and manage knowledge and facilitate learning preferably through electronic management; therefore, ICTs can store and disseminate useful knowledge for a company. Technology makes it easier

for management to implement and manage online communication and coordination, necessary to induce flexibility and adaptability in companies [24].

The important role played by ICTs in the modern company can be understood, being part of almost all the processes in which it intervenes when the technologies and software for its correct operation are available, they can be decisive when high levels of performance are to be achieved [25].

The above justifies that the diagnosis of the capabilities and especially the development of the capabilities is incorporated as a first stage or step in the PAAP.

Once the project or projects to be developed are available, an analysis of the sources that generate the data is carried out, the data is collected and the relevant data that will form part of the predictive process is identified.

In the statistical analysis stage, prediction can be grouped into regression and computational learning techniques. This will allow us to understand the nature of the data and to develop and validate the assumptions and hypotheses, in addition to testing them through the use of standard models [9-11].

Regression models are the pillar of predictive analytics by establishing a mathematical equation as a model to represent the interactions between the different variables, but it is convenient to select the regression model that best suits the study to be carried out: linear regression model, survival or duration analysis, decision trees, adaptive regression curves, among other techniques since there is a great variety [9, 10, 26].

Among the computational learning techniques, the following can be mentioned: neural networks, support vector machines, Bayesian networks, K-nearest neighbors, Monte Carlo simulation [10, 11, 26].

The predictive modeling stage will provide the possibility of selecting the predictive model according to the project to be developed, as well as the most effective analysis techniques and their implementation. Already in the monitoring stage, the models will be validated against other references, the process will be optimized and the impact and performance will be evaluated.

The PAAP addresses a crucial process in the pharmaceutical industry since it allows the reduction of the development time of generic drugs, improvement in the efficiency of the use of resources and improved access to drugs. The faster development of generic drugs can help guarantee faster access to effective treatments, contributing to improving public health.

5. Conclusions

The PAAP is revealed as a key strategic tool to overcome the current limitations of the pharmaceutical value chain in Cuba. Its comprehensive approach, from the diagnosis of capacities to the monitoring of results, provides a structured framework to promote technological modernization, improve operational efficiency and foster competitiveness in the global market.

The implementation of the PAAP can generate significant impacts in the pharmaceutical industry, such as:

Reduction of the development time of generic drugs, accelerating their availability to the population.

Increase in the efficiency of the use of resources, minimizing operating costs and improving economic sustainability.

Optimization of processes through the use of advanced analytical techniques and predictive models that promote decisions based on reliable data.

ICT and business innovation are essential elements for the transformation of the industry. These tools not only facilitate the collection and analysis of data, but also allow for more efficient and adaptable management in a highly competitive environment.

The adoption of PAAP not only has the potential to transform the Cuban pharmaceutical industry, but also represents a step towards greater technological sovereignty and autonomy in the production of medicines. By aligning itself with global trends in digitalization and innovation, the industry will be able to position itself as a relevant player in the region, contributing significantly to public health and the economic development of the country.

Abbreviations

VC	Value Chain
SWOT Matrix	Weighted Strengths Weaknesses Threats and Opportunities
API	Raw Materials
MINSAP	Ministry of Public Health
OSDE	Higher Organization of Business Management
CIDEM	Center for Drug Research and Development
CECMED	Center for State Control of Drugs and Medical Devices
R&D	Research and Development
PAAP	Development of the Procedure for the Application of Predictive Analysis
ICT	Information and Communication Technologies

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Conflicts of Interest

The authors declare that there is no conflict of interest.

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