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Review article

Insight into Drug Production Cost Estimation

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Abstract
The pharmaceutical industry is committed to innovating high-quality products that address medical demands globally. In this industry, the production costs constitute a significant portion of overall expenditures, where in 2016, the sector generated approximately $1 trillion in annual revenue, which increased to around $1.6 trillion by 2023. Product costing involves calculating all expenses associated with product development, covering both direct costs—such as raw materials and labor—and indirect costs, including administrative overhead. As a result, numerous studies have analyzed trends across various expense and income categories, with a particular focus on production costs. These studies seek to analyze the connections and variations in cost across various pharmaceutical companies, such as brand-name, generic, and biotech companies. Manufacturers estimate production expenses using current data to identify and mitigate hidden costs resulting from inefficient practices. This study conducted a detailed analysis of drug production costs, presenting two practical examples: Entecavir® and Orlistat®. The production costs of these drugs were examined based on the methodologies outlined in the study.
Keywords. Pharmaceutical Industry, Production Cost, Cost Optimization, Drug Cost Estimation.

Introduction

In the pharmaceutical industry, manufacturing costs represent a substantial portion of a company's overall expenses, generating approximately $1 trillion in 2016 and in 2023 approximately 1.6 trillion U.S. dollars in revenue, dedicated to developing performance-driven products that meet the healthcare needs of people worldwide [2, 3]. Consequently, numerous studies have examined trends in various expense and income categories, particularly focusing on manufacturing costs, to understand their relationships and differences among different types of pharmaceutical companies, such as brand-name, generic, and biotech firms (1) . In this context, reducing manufacturing costs without compromising quality presents an opportunity for social benefit, especially in a climate where significant investment is needed to discover new therapies for unmet medical needs while also controlling the rising prices of prescription drugs. Importantly, there are strong connections between manufacturing efficiency, drug pricing, and public health. It is anticipated that decreases in manufacturing costs could result in consumer surplus gains worth trillions of dollars, highlighting a critical economic measure of social welfare (1).

Moreover, pharmacoeconomic has a critical role for pharmaceutical industry by guiding the allocation of Research and Development (R&D) resources. Furthermore, evaluations demonstrate the value of pharmaceutical products to key stakeholders such as payers, prescribers, and patients, thereby supporting regulatory and reimbursement approvals. Additionally, improves the efficiency of R&D investments, strengthens likelihoods for market access and reimbursement and increasing the probability of regulatory approval (2).

Production cost involves calculating all expenses related to developing or acquiring a product, encompassing both direct costs and indirect costs. Four common production costing methods used in manufacturing of pharmaceutical products, job costing to evaluates the costs of producing a specific product, process costing to calculate the costs involved in producing a large quantity of identical product, standard costing which uses predetermined costs to compare actual costs against these standards and activity-based costing allocates indirect costs to specific products based on the activities (3).

Achieving cost-effectiveness in pharmaceutical manufacturing requires a careful balance between efficiency and quality, often by utilizing advanced strategies. One of main strategy is strategic sourcing, which can reduce raw material costs by optimizing the procurement process and carefully selecting suppliers. Another important strategy is lean manufacturing, which enhances manufacture efficiency by eliminating waste by tools such as value-stream mapping help identify waste in manufacturing processes. Additionally, supply chain optimization is third strategies that lowering costs through better inventory management can minimize issues like stock outs and overstocking. Lastly, yield improvement that increasing product output from the same raw materials, thereby costs are minimized, this can be achieved through process optimization, technological advancements and data-driven approaches (4). The aim of current analyzing review is to explore the production and operational costs in the pharmaceutical industry, with a focus on identifying cost-saving strategies and few examples of real cost is presented. This review focusing on performing a precise step to estimate drug production costs and identify key factors affecting costs, where data collected from different resources including journal article, public report, and databases, which has published in Joep Jacobs research group work (5), and others (6).

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Based on mathematical and statistical model to quantify costs required for drug production. The production cost in pharmaceutical industry is estimated in two steps, where is total manufacture cost and R&D).

Total manufacture cost

The total manufacture cost is related to all process used in formulation of finished products. There are three essential constituents of total manufacturing cost. Direct materials, direct labor and manufacturing overheads as presented in the following equation (6).

Total manufacture costs = Direct material + Direct labor + Manufacture over head

Direct material cost

The cost of direct materials is related directly to the production process. If not precisely calculated for, it leads to too low estimating and too high estimating the costs, which causes serious money-flow difficulty (7). The cost of direct materials is determined based on the purchasing process. Where the steps involved in purchasing process of direct materials in two forms the local purchase and import of materials. Moreover, includes raw material (active ingredient and excipient) and packaging material (primary and secondary) (8).

Raw material cost

The raw material gives the therapeutic effect, aiding recovery or improving the condition (9). The cost of raw material depends on several factors includes batch size, country where it was manufactured, quality system the manufacturer has, what their gaining money margins are, and also if the purchaser of the raw materials possibly is a well-known customer to them who frequently also purchases other raw materials from them leading to a discount (9). Their cost can importantly affect the total cost of pharmaceutical manufacturing, which calculated by the following equations.

Stage cc= input raw material / stage output.
*Pharma cc= stage cc * API key starting material*
*Cost per pharma cc = price * pharma cc*
Then summation of cost per pharma cc to find the total raw material cost.

Stage cost contribution (stage cc) is quantity of Raw Material needed for manufacturing of one Kg of output. While, pharma cost contribution (pharma cc) is particular quantity of raw material which is needed to manufacture one Kg of active pharmaceutical ingredient material (10).

Excipients cost

In 2018, the global market for functional and multifunctional excipients in the pharmaceutical industry was valued at $8,076.4 million. Changing to different excipients can lead to a decrease in production cost if the other choice is cheaper or more easily available, as in generic drugs, which often involve excipients changing, is a common cost-reduction measure that can significantly lower costs, as calculated by the following steps (11).

1. *Determine the excipients required for batch formulation.*
2. *Determine the quantity of each excipient in kg.*
3. *Determine cost = quantity of each excipient in kg * cost of each excipient.*
4. *Total cost of excipients= summation of all excipients cost.*

Cost of quality

The cost of this activity is executing proactively to avoid defects and failure to deliver products with better quality and calculated by the following equation (12).

Cost of quality = Cost of good quality + cost of poor quality

Cost of good quality known as cost of conformance. Their cost is significantly high and primarily allocated to two categories, prevention and appraisal. While, cost of poor quality called as cost of non-conformance and divided into two types, internal and external failure (13). This is summarized in table 1.

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Table 1. Major categories for cost of quality.

Category	Definition
Prevention cost	The expenses involved in creating, executing, and sustaining a quality management system.
Appraisal cost	The costs related to inspecting, testing, and auditing products, components, and purchased materials to ensure they meet quality standards and performance requirements.
Internal failure cost	The costs incurred due to defective products, components, or materials that do not meet quality standards and result in manufacturing losses.
External failure cost	The costs resulting from defective products being delivered to customers.

Packaging material cost

Packaging is surrounding or protecting drug products for purpose distribution, keep, sold and use (14). The cost of packaging materials, include the cost of any kind using for the aim of packaging drug product. Where, the cost of primary packaging material shall form part of the production cost**.** While, the cost of secondary packaging material forms part of distribution overheads (14). Therefore, the pharmaceutical packaging market globally values around 71.0$ billion in 2018 and around 105.01 billion in 2023 (15, 16).
The total costs depend on certain requirements, the sum of the cost of all these requirements gives us the cost of medication packaging. Where, includes the package size, material types, material thickness, request quantity, instruments, quality control, and manufacture environment (17).

Labelling costs

Pharmaceutical labelling involves establishing and presenting necessary information on drug products. This information is printed on label and packaging inserts (18). Generally, the pharmaceutical labelling market reach 3.8 billion $ US in 2023. Thus, the pharmaceutical labelling changes based on some factor. Raw material is one of main factor which include paper, plastic film (polyethylene, polypropylene), adhesives (acrylic or rubber), ink (thermal transfer or uv resistance). Moreover, security feature, volume and regulatory requirements. The cost of high-quality materials and advanced features is more than basic label (19).

Direct Labor costs

Direct labor refers to any employee that is directly associated in product manufacturing**.** Direct labor costs are the costs incurred by paying the salary of direct labor employee**,** they are continually variable costs (20). The direct labor costs together with direct raw materials cost known as prime costs, and with manufacture overheads as conversion cost (21). Hence, the labor costs calculated depend on the number of employ days needed to manufacture batch (22). Direct labor cost is calculated in three steps [9] as the following:

1. *Step one is gross wages rate are the entire cost of salaries or hourly wages that pay to all of employees*

   *Gross wage rate = Pay rate * Gross hours*

2. *Step two is annual payroll labor cost it is the actual amount paid to employees annually*

   *Annual payroll labor cost = Gross pay * Other Annual costs*

3. *Step three is hourly direct labor cost to calculate the net hour is employee work*

   Hourly direct labor cost=Annual payroll labor cost / Net hours worked

Cost of manufacture overhead

It is the sum of indirect expenses associated with the factory incurred in the manufacture of a product. They can be fixed or variable costs based on the status, known as factory overhead (23). They include indirect labor which employees that are not directly related to product manufacturing (24). Moreover, indirect materials are used to aid the manufacturing process (8). Moreover, cost related to manufacturing factory which include, utilities, rent, marketing and advertising for instance in January 2023 the pharmaceutical industry in US spend about 1.1billion dollars for advertising (25, 26). Moreover, training program by apply effective ways to train staff without spending a lot of money, like wise prioritize training, use online resource, encouraging peer to peer learning, utilize in-house expertise, and community resources (27). Furthermore, insurance, cafeteria expense and fire insurance (8).

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Besides, maintenance and repair cost of equipment, by implementing predictive and preventive maintenance (28). Depreciation of equipment and machinery calculated by straight line depreciation formula [32] as the following;

Depreciation = (Asset cost -salvage cost) / useful life.

Research and Development cost

The estimation of industry R&D costs for novel drug development involves inputs and multiple stages, including basic research, drug discovery, preclinical studies, pre-approval clinical trials, and post-approval clinical trials. These stages incur direct costs, such as materials, labor, and supplies; indirect costs, like overhead; and opportunity costs, reflecting the time value of invested capital (29).

R&D cost in manufacturing name as initial cost. Price water house Coopers in 2012 estimated that the average research and development (R&D) cost per new drug molecule was USD 2.8 billion in the period from 2002 to 2006, and USD 4.2 billion between 2007 and 2011. Over the past decade, the Deloitte Center for Health Solutions has published annual reports on pharmaceutical R&D expenditures. The most recent report (Deloitte, 2019) estimates the average cost of developing a new drug at USD 1,981 million for the original cohort and USD 2,422 million for the extension cohort, factoring in the expenses associated with unsuccessful attempts. The original cohort consists of the 12 largest biopharmaceutical companies, while the extension cohort includes four mid-to-large specialized companies. Additionally, the 2019 report provides a historical overview of cost estimates from previous reports. These estimates are derived from the total R&D expenditures of the cohort companies, which in 2019 amounted to USD 79 billion (30)**.** The total research and development (R&D) costs associated with bringing a new drug to market comprise several components, the direct costs incurred for the successful product, failed attempts, and the cost of capital. Calculated by the following equation (31), and presented in table 2.

$$Total\ R\&D\ costs = OOP\ suc\ costs + OOP\ fail\ costs + Cost\ of\ capital.$$

$$OOP\ suc = (OOP\ suc\ PC) + (OOP\ suc\ ph1) + (00P\ suc\ ph2) + (OOP\ suc\ ph3) + (OOP\ suc\ ph\ appr).$$

$$OOP\ fail = (OOP\ fail\ PC) + (OOP\ fail\ ph1) + (OOP\ fail\ ph2) + (OOP\ fail\ ph3) + (OPP\ fail\ ppr.$$

$$OOP\ fail\ PC = OOP\ suc\ PC * \frac{1}{Ppc*Pph1*Pph2*Pph3*Pappr} - OPP\ suc\ PC.$$

$$COC = COC\ pc + COCph1 + COCph2 + COCph3 + COCappr.$$

$$COC\ pc = (OOP\ suc\ pc + OOP\ fail\ pc) * (1 + WAAC)^{Tpc+Tph1+Tph2+Tph3} - 1$$

Table 2. Equation for calculation R&D (31)

OoP: Out-of-pocket	**PC: pre-clinical**	**Phx: Phase 1, 2 or 3**	**Appr: Approval**
Px: success rate for phase x	Px = 100% – failure rate for phase x	Tx: Duration of phase x (years)	T: Time of development in years
WACC: Weighted average cost of capital	Suc: success cost	Fail: failure cost	CoC: Cost of capital

R&D costs opportunities for reductions, the capital cost (53%) and failure cost (40%), on average represents about 93% of total R&D cost as demonstrated in figure 1, therefore considered as the appropriate cost class that may be targeted for decreasing R&D costs. Moreover, costs impacted by four cost drivers**,** trial size, trial duration, success rate and weighted average cost of capital which presented in figure 2 (31).

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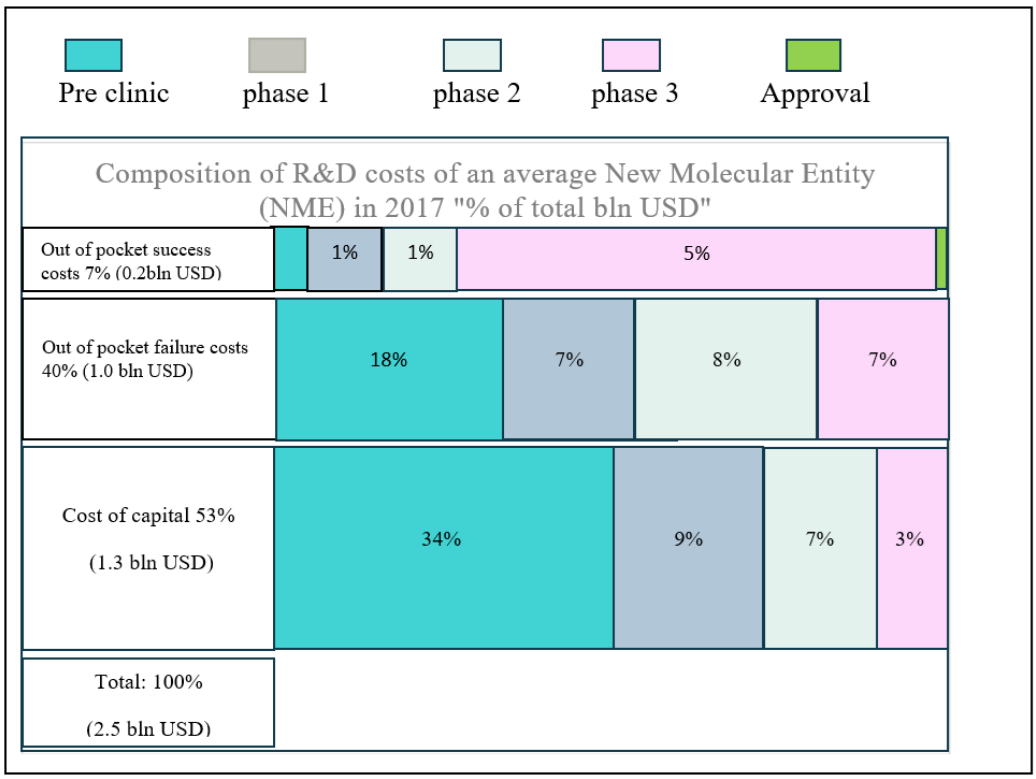

Figure 1. Composition of R&D costs of an average New Molecular Entity in 2017.

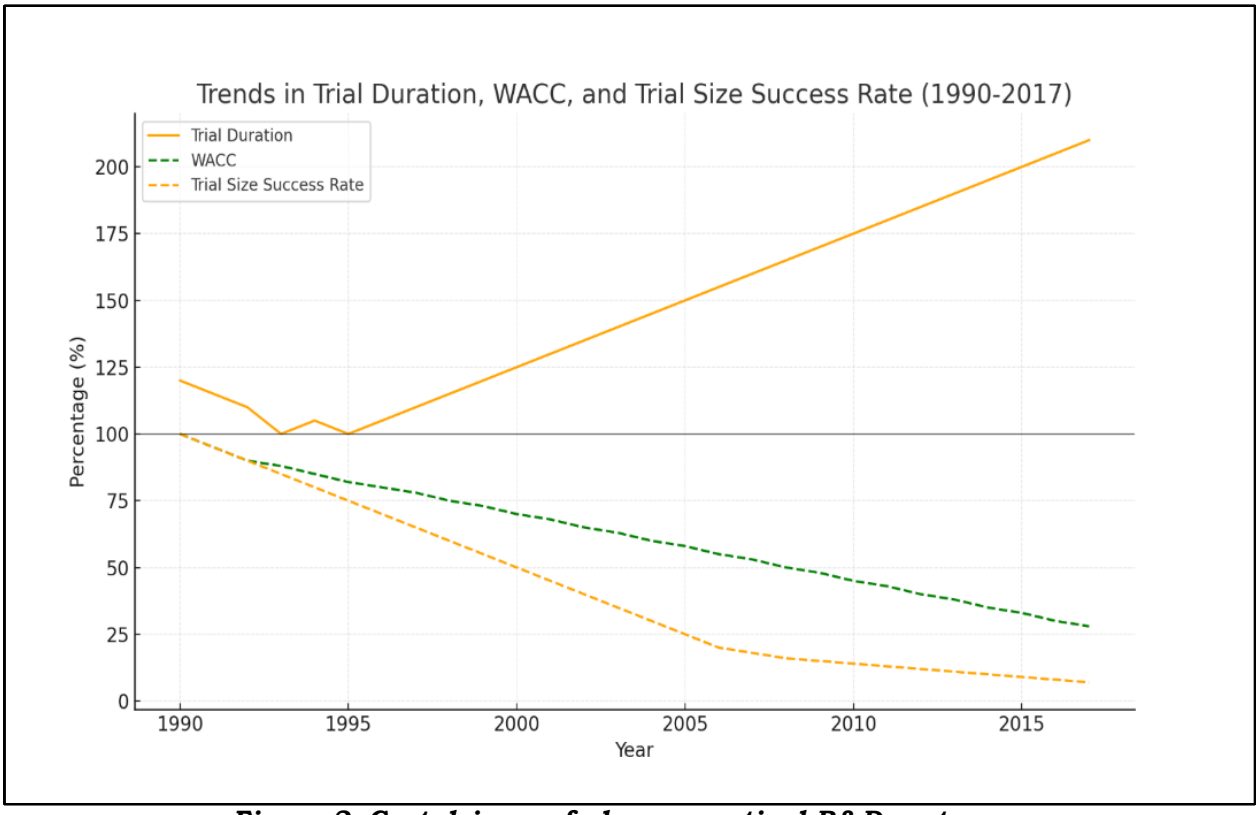

Figure 2. Cost drivers of pharmaceutical R&D costs.

Results

The current evaluation is reflecting pharmaceutical manufacturing cost estimation to the drug “Entecavir® tablet and Orlistat® capsule”. Entecavir®, a nucleoside analog with strong activity and specificity against the hepatitis B virus (HBV), was approved by the U.S. FDA in 2005 (32). With a daily dose of 0.5 mg, a one-year supply of entecavir® requires under 0.2 grams of active pharmaceutical ingredient (25) per person, manufactured by direct compression. Including $20 for formulation and packaging and a 50% profit margin, the minimum estimated treatment cost is $36 per person per year, their cost summarizes in figure 3 (33, 34).

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Orlistat® is a saturated derivative of lipstatin, a powerful natural inhibitor of pancreatic lipases derived from the bacterium Streptomyces toxytricini (35). The FDA approved Orlistat® 120 mg in 1999 as a prescription medication for managing obesity (36). The manufacturing process involves several steps, granulation, extrusion and spheronization, drying, lubrication, and final encapsulation (37). The calculation accounts for various factors, including a 5% loss during tablet formulation, a cost of $0.01 per tablet for formulation, the excipient cost (averaging $2.63 per kg of finished product), an average Indian taxation rate of 27% on profits, and an overall 10% margin for profit, their cost summarizes in figure 3 (38).

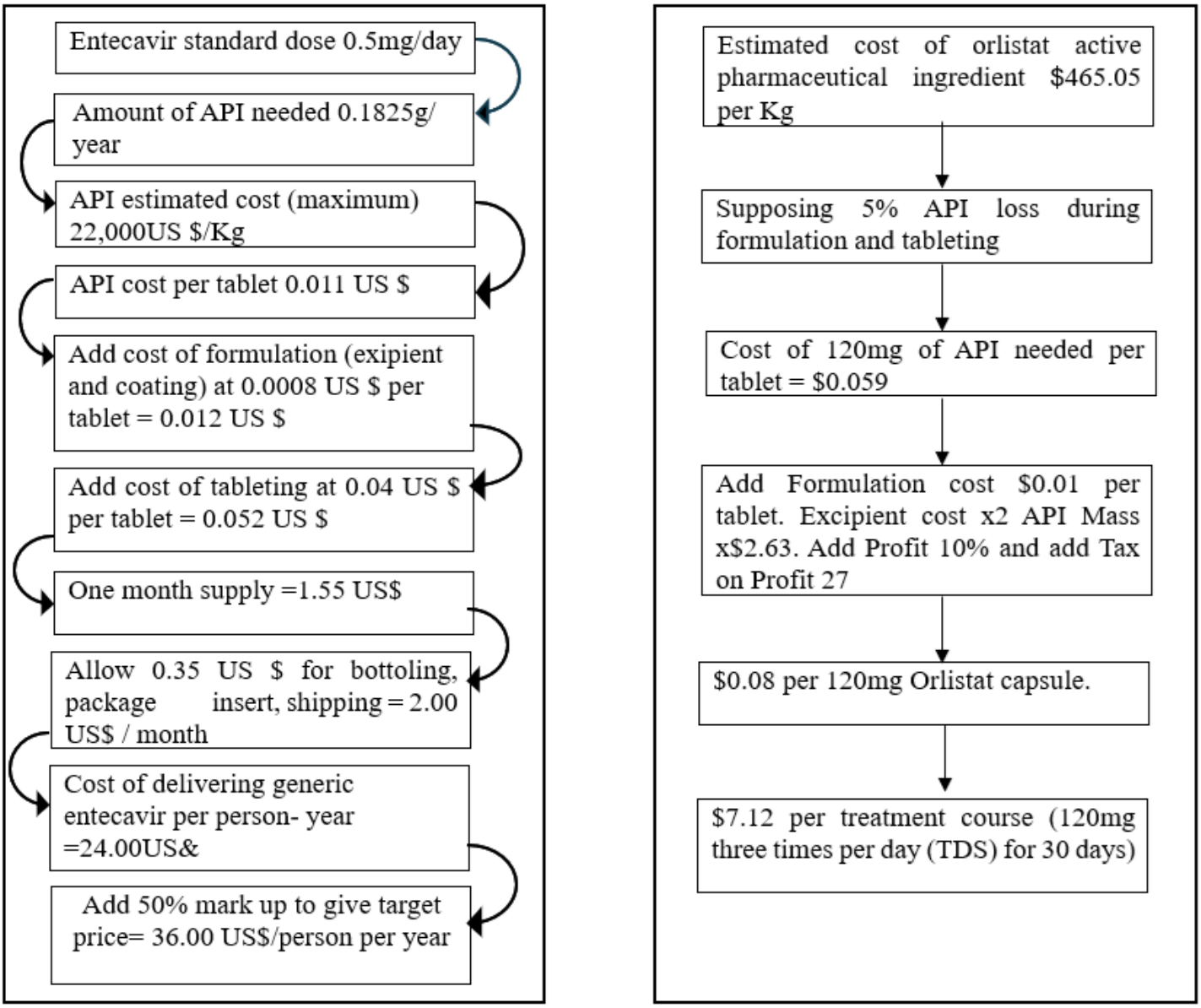

Figure 3. This is a two flowchart to summarizes the manufacturing cost for Entecavir® and Orlistat® (33, 38).

Conclusion

Manufacturers estimate production costs using current data, addressing hidden costs caused by poor practices (39). R&D is cornerstone in the pharmaceutical industry, especially in developing markets, where improving R&D efficiency is crucial (40). Pharmaceutical, biotechnology, and healthcare sectors should maintain a strong security posture to avoid financial losses due to intellectual property theft. In 2011, the UK government estimated that intellectual property theft caused £1.8 billion in losses (41).

Manufacture opportunity based economic considerations includes, the contract manufacturing outsourcing (CMO) this approach offers several advantages, including reduced costs, enhanced production capacity, and the ability to concentrate on core functions such as drug research, development, and marketing(42) . Moreover, Integration laboratory information management system (LIMS) streamlines repetitive activities, enabling scientists and researchers to concentrate on advancing their work, LIMS reduces overhead and maintenance costs, boosts productivity, and minimizes errors (43).

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Besides, continuing manufacturing (CM) has attracted attention due to its potential for lowering manufacturing costs by enabling the continuous processing of inputs and materials throughout the development cycle, Net Present Value (NPV) to assess the economic viability of a potential investment (44). Furthermore, lab-on-a-chip technology, emerging these technologies offer significant economic benefits by reducing manufacturing costs and enhancing the efficiency and precision of product development (45)
The drug production costs are calculated in two steps involving R&D and total manufacturing which have three essential constituents, direct materials, direct labor, and manufacturing overheads, passing through packaging material cost, labeling cost, and costs required to ensure that the drug product meet specification. Two drug product examples Entecavir® and Orlistat® provide practical insights into drug production cost and detailed cost estimation. A comprehensive overview was successfully obtained of pharmaceutical production costs, evaluation of production costs across various stages, and exploring opportunities for cost optimization by economic considerations during manufacture.

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Conflicts of Interest
The authors declare no conflicts of interest.

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المستخلص

يُعدّ قطاع الصناعات الدوائية من المجالات الحيوية التي تسعى إلى تطوير منتجات مبتكرة وعالية الجودة لتلبية الاحتياجات الطبية العالمية. وتشكّل تكاليف الإنتاج نسبة كبيرة من إجمالي النفقات التشغيلية في هذا القطاع. تناول هذه الدراسة تكاليف إنتاج الأدوية في الصناعة الدوائية، حيث يتم حسابها من خلال مرحلتين رئيسيتين: البحث والتطوير والتصنيع الكلي، والذي يشمل المواد المباشرة، العمالة المباشرة والنفقات العامة للتصنيع. كما يتم تحليل تكاليف التعبئة والتغليف، ووضع العلامات، والاختبارات التي تضمن مطابقة الدواء إلى معايير الجودة. يسلط التحليل الضوء على التكاليف المباشرة وغير المباشرة للإنتاج، مع التركيز على تحسين الكفاءة التشغيلية، وكان الهدف من هذه الدراسة تقديم نظرة شاملة حول تقدير تكاليف الإنتاج الدوائي، وتحليل التكاليف عبر المراحل المختلفة، واستكشاف سبل تحسينها من خلال اعتبارات اقتصادية أثناء التصنيع. هذه الدراسة قد قدمت مثالين لتكلفة إنتاج دواء للمريض وهم دواء ®Entecavir ودواء ®Orlistat وقد قدمت ذلك بالتفصيل وفقا لأليات تكاليف الإنتاج المذكورة سابقا في هذه الدراسة.

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