

# Cost of Goods Sold (COGS) Analyses: FAQ Brief



This primer outlines how COGS analyses can inform product introduction planning.

## KEY TAKEAWAYS

- **When a drug is produced in India by a generic manufacturer, costs are generally lower** than originator manufacturing in Europe or the US.
- **Cost of Goods Sold (COGS) is defined as the direct cost to manufacture a product.** COGS do not include research and development (R&D), product development expenses, or fixed costs to set up the manufacturing processes because these are not part of the ongoing manufacturing costs.
- Injections are a widely used administration form and many **generic manufacturers have extensive experience producing them at low cost.** For injectables, per person per year (PPPY) production costs can, in some cases, be lower than for oral tablets, in part because long-acting products usually require lower amounts of active pharmaceutical ingredient (API) over the course of a year.

## What is the difference between originator and generic drugs and why are their costs different?

**Originators and Generics:** Pharmaceutical companies are called “originators” or “innovators” when they hold the patents for a drug, either as a result of discovering it during research and development (R&D) or buying the compound from a university or another company. The patent holder has the exclusive right to manufacture and sell the product in the territory covered by the patents. These products are often referred to as “patented” drugs. Patented drugs sometimes sell at very high prices based on their clinical benefits and the fact that only one company makes the product.

When drugs are licensed to be manufactured by other companies or are manufactured by other companies after coming off patent, they are referred to as “generic products.” Generic products often compete primarily on price because many companies are in the market with the same formulation.

Drugs currently used for HIV include both patented and generic products. Many HIV drugs have been voluntarily licensed to generic firms. These licenses, often issued through the Medicines Patent Pool, grant permission for a company to manufacture the product

and sell it only in the licensed territory (which typically excludes all high-income and some upper middle-income countries where the originator sells their product). Generics could also be available in countries outside the voluntary license territory where there are no patents or patent barriers have been removed.

**Cost Differences:** Some costs do not differ between generics and originators. For products that require specific equipment or machinery that can only be purchased from a single source, generic and originator suppliers would pay the same price. For example, in the case of long-acting injectable cabotegravir (CAB-LA), generic suppliers will need to procure a Netzsch mill and wet beads.

However, drug production costs (such as raw materials, labor, manufacturing facilities, packaging, and overheads) for both patented and generic drugs are much greater when production facilities are located in high-income countries as compared to production costs in India or other low-cost settings, where many generic manufacturers are based. Since most patented HIV drugs are produced in high-income countries, whereas most generic HIV drugs are produced in lower cost manufacturing environments, such as India, patented HIV drug costs are generally higher.

Patented drugs may also have higher production costs because there is less competition and less need for cost optimization. For many high-volume HIV drugs, generic companies have built up highly efficient manufacturing capacity. Thus, generic HIV products, such as tenofovir disoproxil fumarate, lamivudine, and dolutegravir (TLD), benefit from manufacturing and supply chain cost optimization, as well as economies of scale compared to similar drugs manufactured in high-income countries.



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In addition to licensing their products, some originators sell their branded products in low- and middle-income countries (LMICs) at a “not-for-profit” or “access” price. While the “access” price includes minimal or no margin, it does still include full recovery of direct costs and overheads, as recovering these costs is critical for manufacturing sustainability. This includes cost categories that donors will, on occasion, cover or share with generic developers to keep generic prices low. Since the cost of producing a drug in a facility located in a high-income country, like the US or Europe, is much higher than in India, even the ‘not-for-profit price’ is often 3-5 times greater than the price offered for the same product by a generic firm with production in India. [1]

Due to the potential for lower costs with a licensed generic product manufactured outside of the US or Europe, conducting Cost of Goods Sold (COGS) analyses to estimate generic production costs is often an important early step in access planning. The COGS analysis helps determine what costs and prices might be for a licensed product and whether these lower costs and prices could translate into greater public health impact.

## What are COGS?

Cost of Goods Sold (COGS) is defined as the direct costs and expenses required to manufacture a product assuming a given volume of production. CHAI estimates COGS at several different volumes of production that would be typical for the top 2-3 manufacturers over a period of 3-5 years. CHAI COGS estimates may change as we learn more about the product. COGS estimates may also change as manufacturers themselves learn more about the product, and how best to manufacture it. CHAI teams use publicly available sources for data inputs, as well as the expertise of sourcing and product manufacturing specialists. CHAI teams have visited over 50 manufacturing facilities in the past five years to understand the latest technologies and verify approaches to estimating COGS.



### COGS ANALYSES ARE AN ESSENTIAL INPUT FOR INTRODUCTION PLANNING

For COGS analyses, CHAI includes the costs of raw materials, labor, packaging materials, and other direct factory operating costs. In principle, this approach to COGS aims to capture the total variable costs of making the product. CHAI teams include an allowance for direct factory overhead charges but do not include allocations of “above the factory”-level costs *allocated* to products from departments such as quality assurance, production management, regulatory affairs and corporate departments such as IT and HR. The basis for allocating these fixed costs varies within each company and cannot reliably be estimated from publicly available sources.

COGS analyses are an essential input for product introduction planning. In CHAI’s experience, the COGS for drugs and diagnostics used in LMICs tend to decline over time and, in particular, decline as production volumes increase by 5, 10 or 20-fold. This is due to improvements in production efficiency (which take place over time) and to economies of scale. When used effectively, COGS can help donors and other partners estimate costs at product launch as well as future production costs if demand, sales, and use increase. Understanding future costs and prices is essential for undertaking market-shaping interventions to ensure affordable and quality-assured supply of new products.

## Do COGS include capital expenditure and product development costs?

Capital expenditures (often referred to as “CapEx”) for equipment and facilities needed in the production process contribute to the cost of production via a depreciation charge that is usually included in a facility’s overhead cost allocation. Since equipment and facilities last for many years, only a portion of their purchase cost is expensed each year, and this is called the “depreciation charge.” CHAI includes these costs as part of API and formulation costing via the depreciation charge.

### KEY TERMS

**Active Pharmaceutical Ingredients (APIs):** APIs are the main components of drugs, and often account for a large portion of the COGS. For example, cabotegravir is the API in CAB-LA while tenofovir disoproxil fumarate (TDF) is one of the two APIs in TDF/FTC (a formulation of oral PrEP).

**Cost of Goods Sold (COGS):** COGS refer to production costs, or the sum of the direct costs needed to manufacture a product, including elements like raw materials for APIs and costs associated with making APIs into the administration form (e.g., liquid for injection).

**Price:** Price refers to the amount paid to procure or purchase a commodity. The way companies set prices is often complex and can depend on laws that regulate drug prices or whether there are similar products on the market.

**Capital Expenditure (“CapEx”):** Capital expenditure is the money a company spends to buy or maintain fixed assets, such as equipment and facilities.

1. Note: Different pharmaceutical companies may approach “not-for-profit” or “access” pricing differently. As an example of not-for-profit prices in the marketplace, the originator “not-for-profit” price of generic dolutegravir (DTG)(30 tablets) is \$20.11 ([USAID GHSC-PSM e-Catalog 2021](#)) while the generic benchmark price is \$2.35 ([USAID GHSC-PSM e-Catalog 2022](#))

CHAI also does not include the costs of potential new upfront expenses (e.g., purchasing a nano mill), product development, or R&D (which may vary among generic manufacturers) in our COGS analyses. These costs are expensed as incurred, regardless of whether a product is ever fully developed or commercialized. CHAI and partners may also consider financial support for these costs via product development risk-sharing agreements with firms willing to invest in making new HIV drugs and selling them at affordable prices.

## What is the difference between COGS and price?

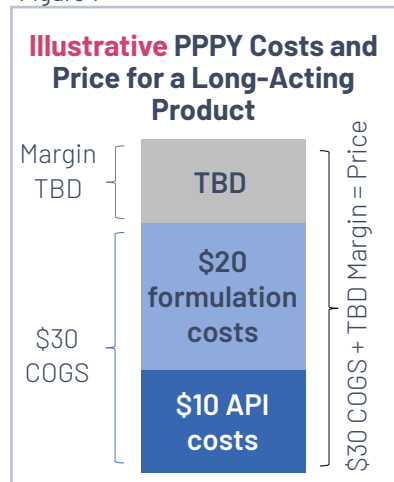
COGS analyses estimate the costs of manufacturing a product. While COGS can inform pricing, COGS do not estimate the price at which a product will or could be available. The price of a product will almost always be higher than the COGS because companies add a margin (see Figure 1). The margin is generally higher for originators than generics as a result of several factors, including higher R&D costs that must be recovered. All companies aim to recover their investment costs through pricing.

Pricing also depends on volumes – if low volumes are expected, a company will usually set a higher price to ensure they recover costs over the first few years after launch. If a company expects competitors to reach the market, they may try to recover costs over a shorter period of time, leading to further increases in pricing. For example, assuming production costs for a drug are \$34 PPPY and a company has spent \$10 million on start-up expenses, if the company anticipates 350,000 annual users and wishes to recover initial expenses in the first year, they will set a margin of almost \$30 PPPY, resulting in a price over \$60 PPPY:

*Illustrative calculation of margin for companies to recover start-up expenses:*

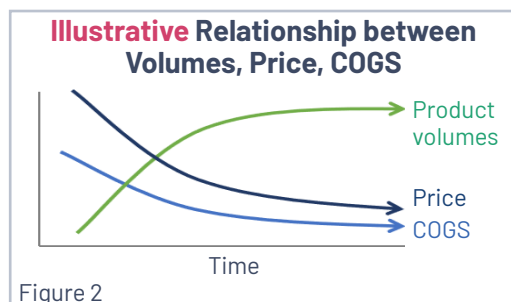
$$350,000 \text{ annual users} \times 6 \text{ vials per user per year} = 2.1 \text{ M vials} \rightarrow \frac{\$10 \text{ M start-up expenses}}{2.1 \text{ M vials}} = \text{\$4.76 per vial or } \text{\$28.57 PPPY margin needed to recover start-up expenses}$$

Figure 1



Conducting a COGS analysis can help increase transparency because it enables a comparison between a product's ultimate price to the purchaser versus the company's production costs to manufacture it. COGS can, therefore, help consumers or buyers understand whether companies are including a large margin or whether they are offering the product at a price close to the COGS, or production costs.

## What does a sustainable market look like and what role does price play?



To ensure clients have uninterrupted access to the products they need, a sustainable supplier market is critical. In a sustainable market, suppliers can continue manufacturing a product to meet demand over time. A pricing strategy that enables suppliers to recoup upfront investments, as well as cover ongoing production costs is critical to ensure sustainability and long-term access. If a product's price were equal to production costs (COGS), the supplier would not be able to continue manufacturing the product, which would ultimately limit access. See illustrative view of relationship between volumes, price, and COGS in a sustainable market in Figure 2.



### Application of COGS Analyses to Long-Acting Injectable Cabotegravir (CAB-LA)

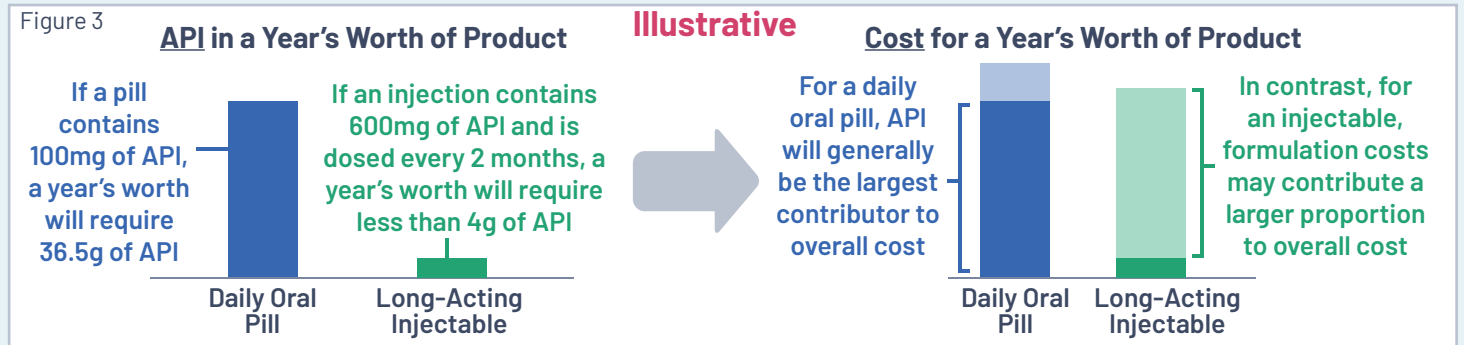
#### Can an injectable be inexpensive to manufacture?

Injections are a common and widely used drug delivery form. They are used to administer contraceptives, vaccines, and many other therapies. As a result, many pharmaceutical companies have significant experience manufacturing quality-assured injectable products and can make them cheaply and efficiently. For example, generic depot medroxyprogesterone acetate (DMPA), a three-month injectable contraceptive which was first introduced for contraception in the 1990s, costs \$0.77 per injection, translating to just \$3.07 per year (4 injections per year). Injectable contraceptives make up a significant (and increasing) share of the contraceptive market, with shipment volumes totaling 84 M across 69 FP2020 countries in 2020. [2]

2. CHAI, 2021. Family Planning Market Report. [Link](#). Acc. August 2022




## How could an injectable HIV product be cheaper than a daily oral pill?

Long-acting products require fewer doses per year than daily oral pills because the active pharmaceutical ingredient (API) in long-acting products is more potent and is maintained at a therapeutic level in the body for a much longer period of time. Since APIs often make up a large proportion of a product’s total COGS, this can, in some cases, translate to a cheaper product over the course of a year. As shown in the illustrative visual (Figure 3), the amount of API needed for a year of daily oral tablets (365 pills) is much more than the amount needed for a year of a long-acting injectable product.



### The Building Blocks of the CAB-LA COGS Estimate

To estimate generic CAB-LA COGS, experts first determine how the product is made. Most of this information is gathered from the public domain via patents, as well as consultation with experts in academia and industry. After establishing the manufacturing steps, experts add up the costs from each step to estimate total COGS, or production costs. Estimating COGS often requires review of costs associated with similar products or processes, as these data points can inform accurate assumptions for new products. The key production steps for the COGS analysis of CAB-LA include:

 <b>Making APIs</b>	The API is the active ingredient in the product. Some APIs (like cabotegravir and dolutegravir) have similar chemical structures so their production costs are comparable. Drugs can contain multiple APIs.
 <b>Making the product formulation</b>	Formulation refers to making the product form, such as an oral tablet or injection. Both oral tablets and injections are widely used for many different drugs. As such, costs for new tablets or injectables can be estimated by comparing costs for similar products in the market. However, for novel delivery forms, such as microarray patches or inserts, estimating costs may be more challenging.
 <b>Sterilization</b>	Sterilization refers to the process of ensuring a product does not have any biological impurities or contamination. The costs required for sterilization depend on approach (two types are gamma irradiation and steam sterilization), how frequently it is needed, and when the sterilization is needed.

## What did CHAI’s COGS analysis for generic CAB-LA find?

The production costs to manufacture CAB-LA in India at one of the larger firms supplying ARVs is estimated to be \$30-40 PPPY during early generic introduction, or “launch,” when there may be a small number of users. Based on estimates for supplying CAB-LA to 800,000 annual users (lower than current oral PrEP annual initiation rates in LMICs), CHAI estimates generic CAB-LA COGS at \$14-18 PPPY. COGS for API synthesis are expected to decrease as volumes increase. However, the impact of volume on the costs of milling and some formulation costs will be more limited as additional equipment will have to be added to increase capacity.

CHAI also estimates that upfront investments would be needed for generic companies to begin manufacturing CAB-LA, including purchase of a nano mill, as well as drug development and bioequivalence study costs, both of which are expected to be more expensive than what is needed for daily oral ARVs. These upfront costs are not factored into the COGS analysis – if they are not covered by donor support, product pricing would likely be higher in order to recover these costs. This analysis was conducted by a team of technical experts, led by PhD scientists and industry experts with decades of experience in drug development and process chemistry. For more information, please see CHAI’s [full analysis](#).

