

Cost of Goods Sold (COGS) Analysis: Generic Long-Acting Injectable Cabotegravir (CAB-LA)

February 2023



1. Background & Methodology

2. Generic CAB-LA COGS Analysis

3. Generic Capital Expenditure and Development Costs

4. Discussion & Conclusions

Background: Cost of Goods Sold (COGS) analyses estimate the total direct production costs to manufacture a product – this is a crucial input for introduction planning

What is a COGS analysis?

- A COGS analysis estimates the **total direct production costs** to manufacture a product
- A COGS analysis also assesses **how costs change under different volume scenarios**
- **COGS are not the same as price.** The price of a product will almost always be higher than the COGS because companies add a profit margin.
- **COGS do not include research and development (R&D) or product development expenses** because these are not part of the ongoing costs to manufacture the product

How is a COGS analysis used?

- COGS analyses are often conducted to understand whether **generic production could increase affordability.**
- A COGS analysis of generic production **does not estimate production costs for an originator.** Production costs between generics and originators vary widely depending on where manufacturing takes place, volumes, and overhead and supply chain costs.
- COGS analyses may also be used to **inform pricing discussions**, but COGS do not estimate the price at which a product will or could be available.

Note: For more information on how COGS are used and other FAQs, please see our [COGS FAQ Brief](#) (available online and in the appendix of this document, slides 19-30)



The aim of this COGS analysis is to estimate the **production costs of generic manufacture of CAB-LA** to understand opportunities for increasing affordability through generic production

Methods: CHAI estimates the COGS for generic CAB-LA by estimating the costs associated with each production step, assessing potential for reductions at higher volumes



CHAI's generic CAB-LA COGS 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. Estimates have also been **validated by independent, third-party analysis**.

1

CHAI first conducted a detailed **review of the manufacturing process** for CAB-LA.



2

CHAI then **estimated the costs associated with each production step** from data, largely in the public domain. Costs are estimated for both low and medium-scale volume scenarios to understand the potential for cost reductions.

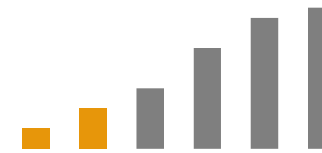
DATA & SOURCES:

- Most assumptions on costs come from data available in the public domain.
- Some cost assumptions come from direct consultation with industry stakeholders.
- The manufacturing process for CAB-LA also largely comes from the public domain via patents, as well as expert opinion from academia and industry.

Estimated Costs at Different Volume Scenarios

Annual CAB-LA Users

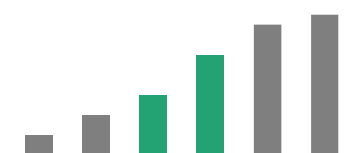
Illustrative



Launch volumes

Annual CAB-LA Users

Illustrative



Medium-scale volumes
(Approx. 800K annual users)

CHAI estimated capital expenditure and start-up costs separately from COGS, as these expenses do not impact the ongoing, direct production costs of manufacturing generic CAB-LA. In addition, these costs have, on occasion, been covered by donors.

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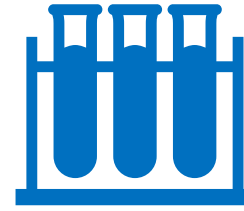
4. Discussion & Conclusions

CAB-LA production involves three main steps: API & synthesis, formulation, and sterilization; costs are estimated separately for each step



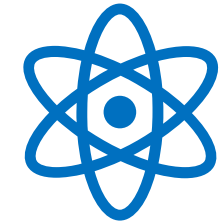
API & Synthesis

- CAB API is manufactured using the same starting materials as DTG with one exception.
- Process used to make CAB is similar to that used to make DTG.



Formulation

- CAB-LA requires a small and consistent particle size to achieve its long-acting properties. Milling to reduce particle size is a routine industry practice, though manufacturers will require a new type of mill (a nano mill) for CAB-LA.
- CAB-LA is a suspension of the CAB API in a water-based mixture. It must be formulated so that it is consistently administered via a syringe.
- With sufficient details, this formulation process can be reproduced. Generics make other suspended liquid formulations for the US and EU markets.



Sterilization

- Both the CAB API and CAB-LA formulation must be sterilized with gamma irradiation.
- Generics would likely contract with manufacturers with gamma irradiation capability for sterilization.

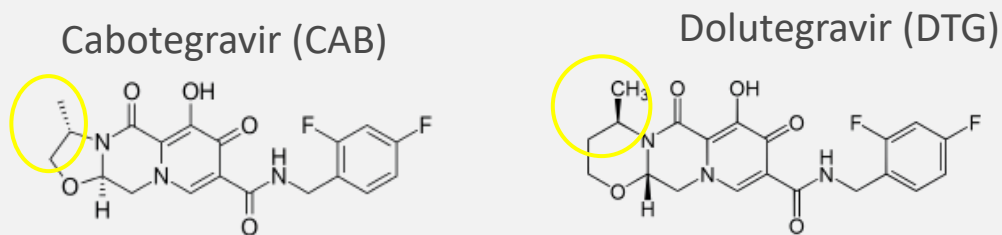


API & Synthesis: Based on similarities in chemical structures, the cost of DTG API is used as a proxy for CAB API

DATA & SOURCES:

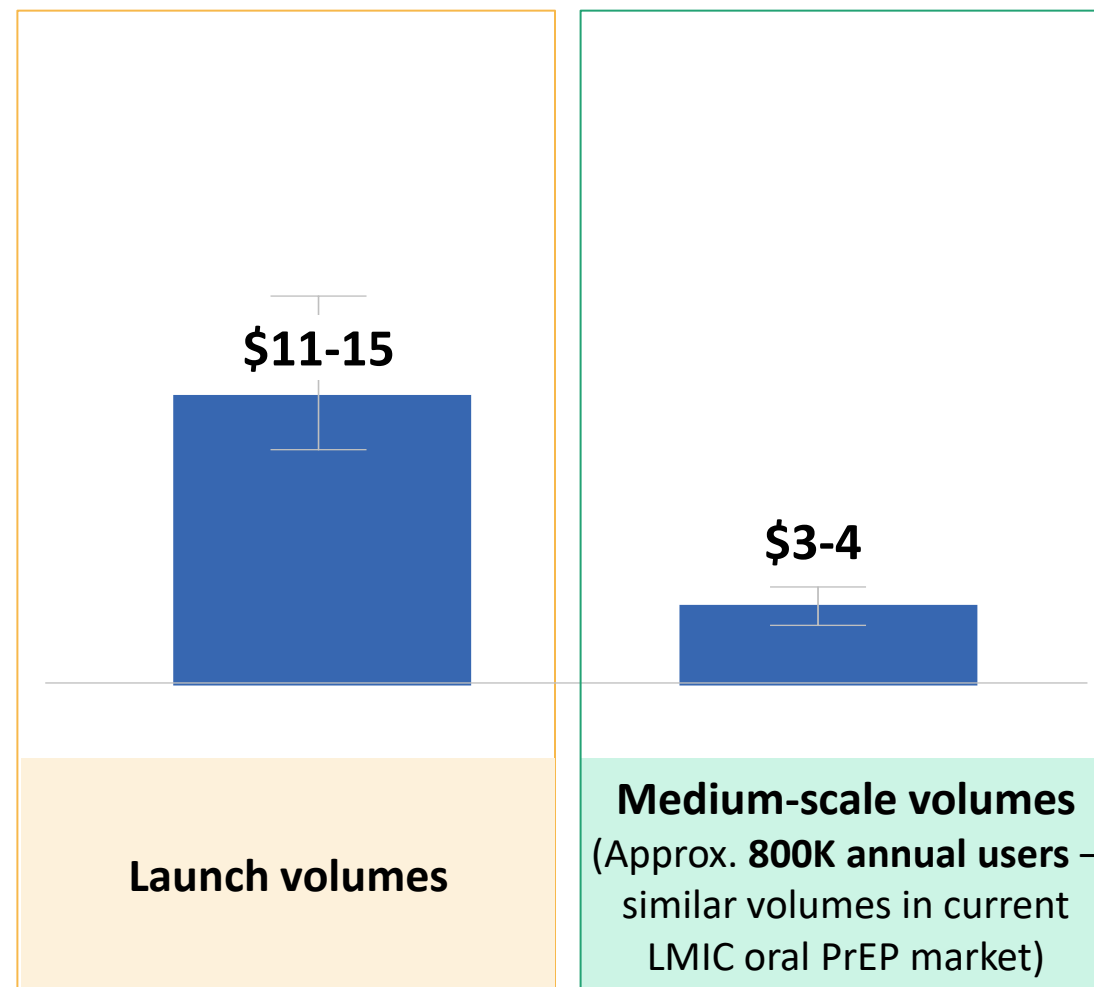
- Based on **cabotegravir and dolutegravir's similar structures**, the price per kilogram of API is expected to be similar.
- CAB API is prepared using conventional facilities** in a four-step synthesis, using chemistry like that used for DTG API

Figure 1. Cabotegravir and Dolutegravir Chemical Structures



- In 2016, 20kg of DTG API was imported from China to India at \$3,232/kg. Accounting for recent increases in the cost of API and raw materials from China since then, **CAB API is expected to conservatively cost \$3,600/kg, so each vial of CAB-LA (600mg) is estimated at \$2.16 (\$12.96 PPPY) at low volumes.**
- In 2019, 3MT of DTG API was imported from China to India at an average price of \$744/kg. **At \$1,000/kg, 600 mg of CAB will cost \$0.60 (\$3.60 PPPY) at medium-scale volumes.**

Estimated API Cost Components PPPY*



*Note: costs are estimates; uncertainty bands reflect the range of potential values



Formulation: CAB-LA is more complex than many injectables on the market so formulation costs are estimated at \$2.00-3.50 per vial (4-7 times more than other injectables)

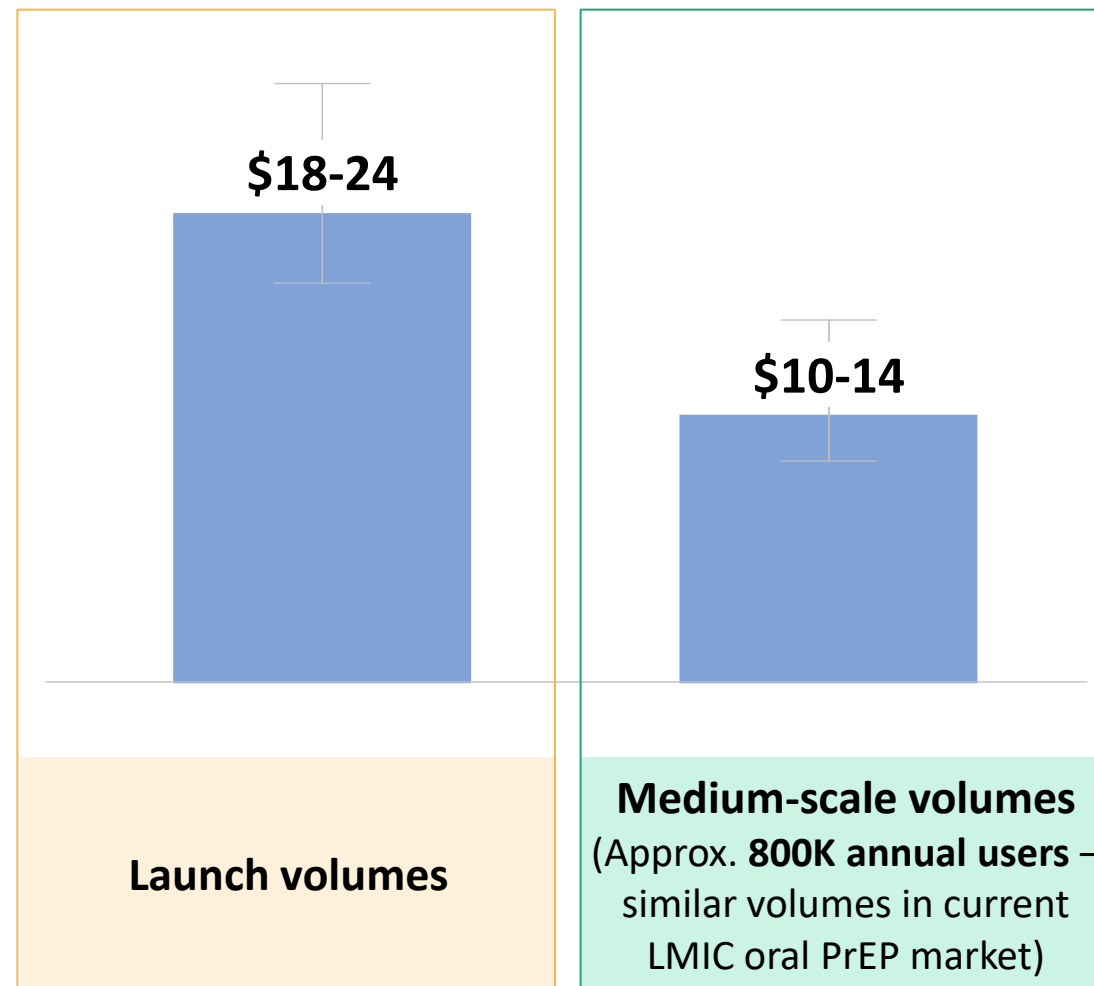
DATA & SOURCES:

- The main formulation process step is **wet-bead nano milling** which reduces particle size (Figure 2).
- While injectables made at large scale cost approximately \$0.50 per vial, as a more complex sterile product, CHAI estimates the formulation cost to be **\$3.50 per vial (\$21.00 PPPY) at launch.**
- Efficiencies with increased volumes and larger batch sizes are expected to bring these costs down to **\$2.00 per vial (\$12.00 PPPY) at medium-scale.**

Figure 2. Nanomill



Estimated Formulation Cost Components PPPY*



*Note: costs are estimates; uncertainty bands reflect the range of potential values

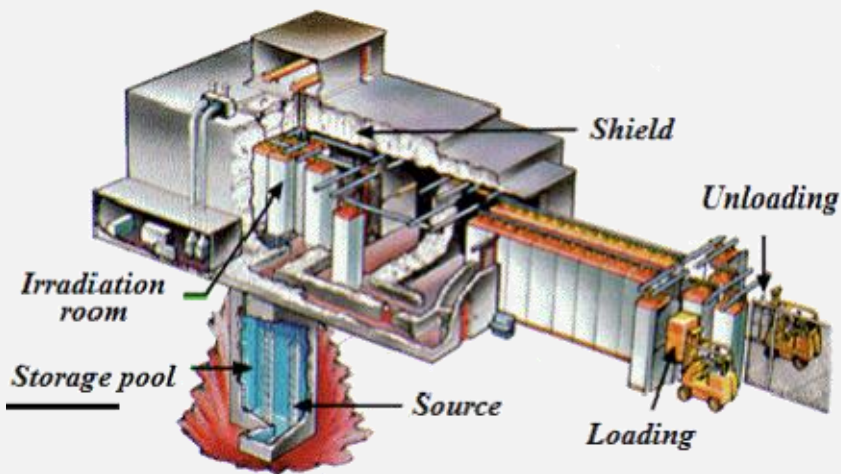


Sterilization: Gamma irradiation is used for sterilization of both CAB API and the finished dosage form

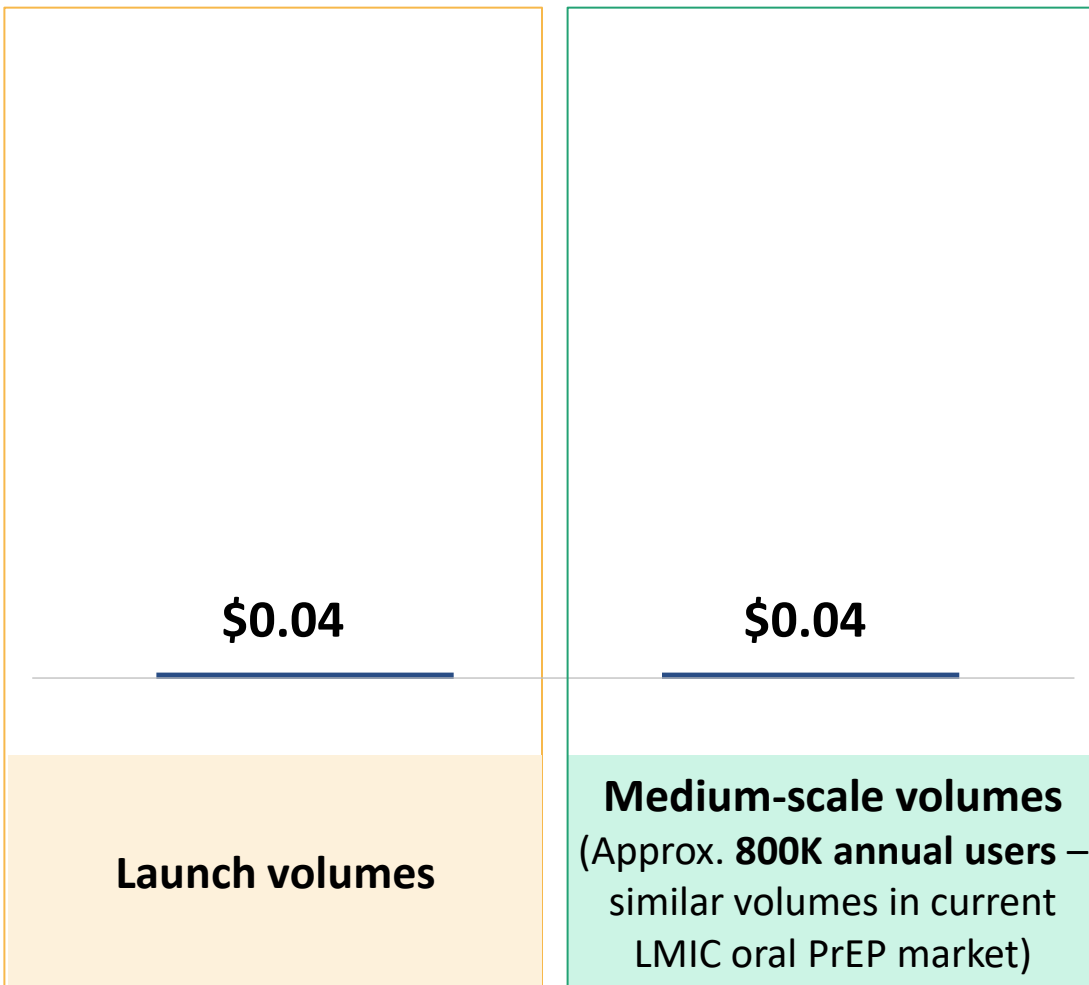
DATA & SOURCES:

- As a suspension, CAB-LA requires a more complex formulation process and must undergo **two sterilization steps** (both as a drug substance before formulation and after vial filling). This is done through gamma irradiation (Figure 3).
- Estimated cost of irradiation is \$0.70 per kg of weight loaded into the unit, which is equivalent to approximately **\$0.04 PPPY**.
- These costs are not expected to decrease at larger scales.

Figure 3. Gamma Irradiation



Estimated Sterilization Cost Components PPPY*



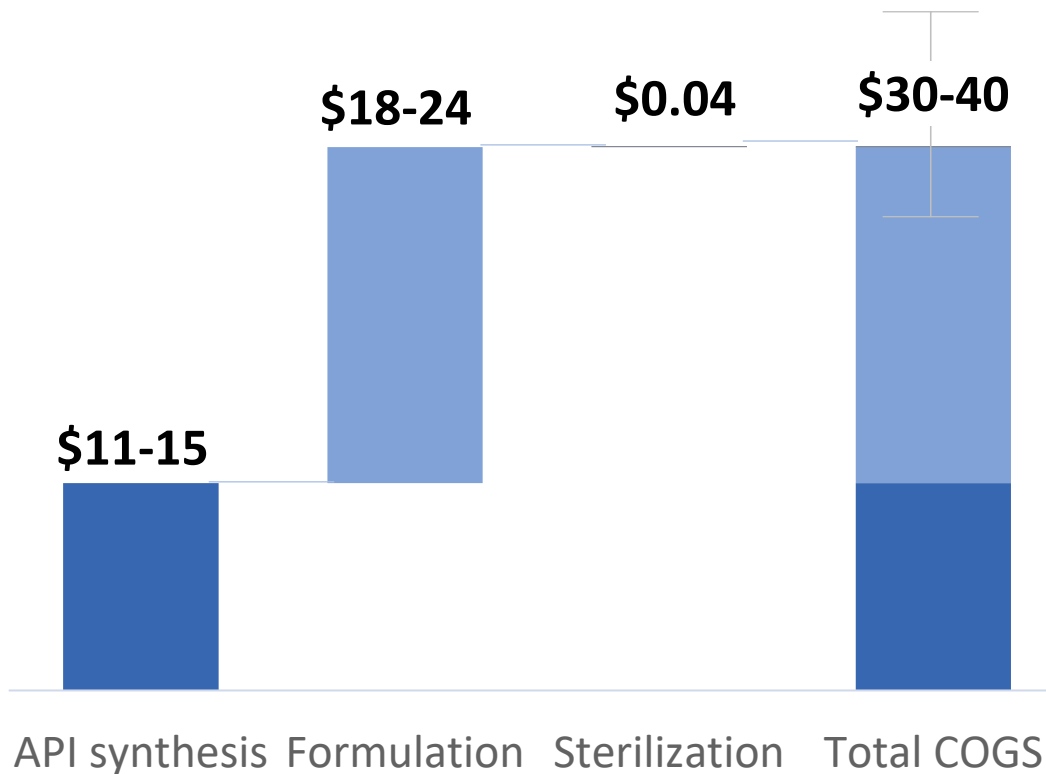
*Note: costs are estimates; uncertainty bands not shown due to small scale



Total COGS for Generic CAB-LA: Putting these steps together leads to total estimated production costs for generic CAB-LA of \$16-34 PPPY

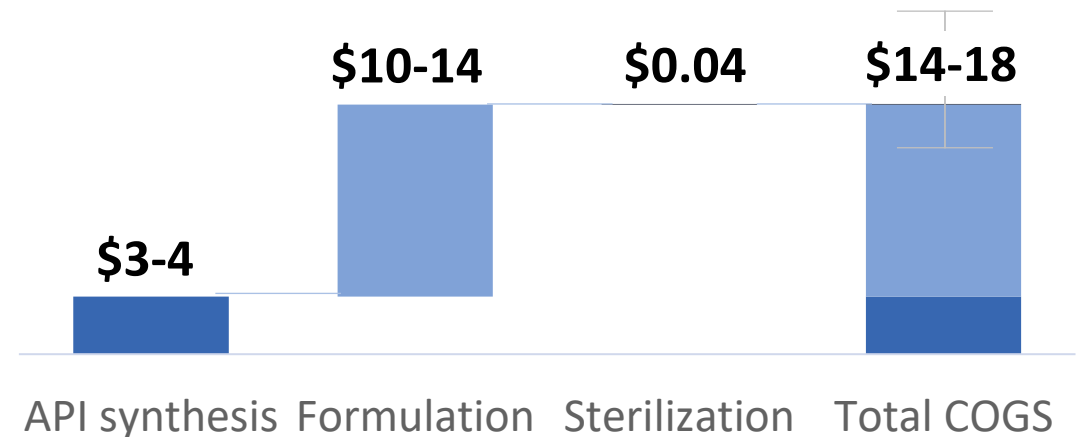
Total Generic CAB-LA COGS (PPPY)*

Generic CAB-LA COGS: Launch Volumes



Launch volumes

Generic CAB-LA COGS: Medium-Scale Volumes



Approximately **800K users** (similar volumes seen in current LMIC oral PrEP market)

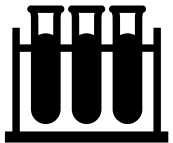
*Note: costs are estimates; uncertainty bands reflect the range of potential values



Total COGS for Generic CAB-LA: Key Takeaways



Total estimated **COGS for generic CAB-LA range between \$30-40 PPPY at launch and \$14-18 PPPY at medium-scale volumes***. As a point of reference, the price for the current standard of care for biomedical HIV prevention (generic TDF/FTC) is currently [listed](#) at \$48 PPPY according to the USAID Global Health Supply Chain Program e-Catalog.



At both launch and medium-scale volumes*, **formulation is the main cost driver** for manufacturing generic CAB-LA. However, as a long-acting product, the quantities of API required (and consequently API costs) are relatively low compared to daily oral products, offsetting the higher formulation costs.



There are significant opportunities to reduce formulation costs with increased volumes, reaching similar levels to other injectable products. However, **formulation costs for CAB-LA are assumed to be higher than for other injectable products** in both scenarios due to increased manufacturing complexity.



API and synthesis costs make up a higher proportion of the total COGS in the launch volume scenario. This cost category offers the **greatest opportunity for reduction at medium-scale volumes***.

*In this case, medium-scale is defined as when the market reaches 800,000 annual users.

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Expense

Description



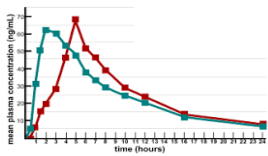
1



Nano mill

Based on industry consultations, the type of nano mill required will cost approximately **\$2M per supplier**. Ordering a nano mill comes with an approximately 6–12-month lead time.

2



Bioequivalence (BE) studies

A typical BE study costs approximately \$200K. To account for the more complex design and longer duration needed for CAB-LA, CHAI estimates **\$1M for BE studies**.

3



Product development

Typical product development costs approximately \$1M. Due to the complexity of developing CAB-LA, CHAI estimates **\$5M for product development costs**.





Total CapEx and development costs are estimated at \$8-10 M. This represents a key area for donor support and a high-impact investment opportunity to accelerate generic development.

If CapEx and development costs must be covered by generic manufacturers alone, we can expect significant price increases

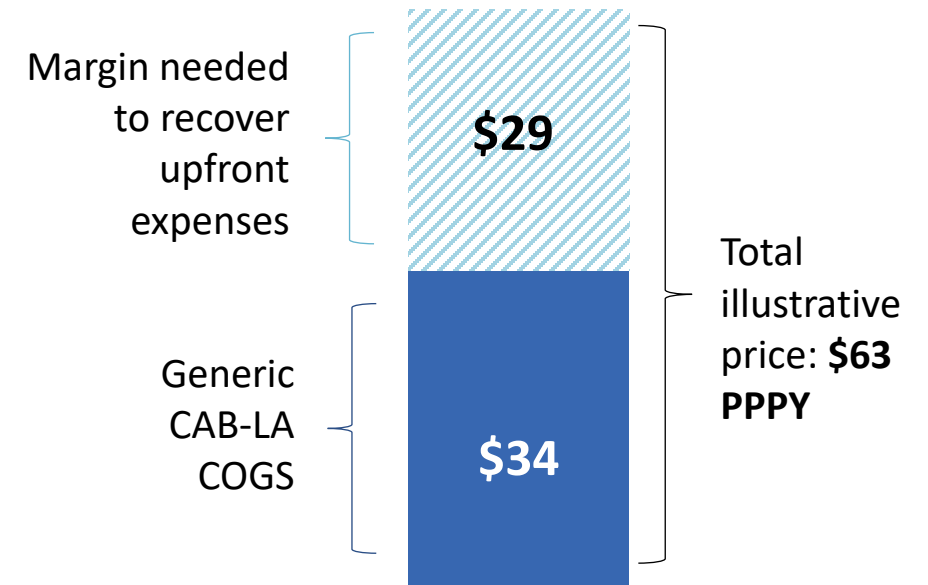
Illustrative Calculation of Margin Needed for Companies to Recover Start-Up Expenses:

 **\$10 M in Start-Up Expenses** →  **Company aims to recover start-up expenses in 1 year**

 **350,000 annual users** × **6 vials per user per year** = **2.1 M vials** 

$$\frac{\$10 \text{ M in Start-Up Expenses}}{2.1 \text{ M vials}} = \text{Margin of: } \mathbf{\$4.76} \text{ per vial needed to recover start-up expenses}$$
$$= \text{Margin of: } \mathbf{\$28.57} \text{ per person per year (PPPY) needed to recover start-up expenses}$$

Illustrative: Impact of Recovering Upfront Expenses on Price (PPPY)



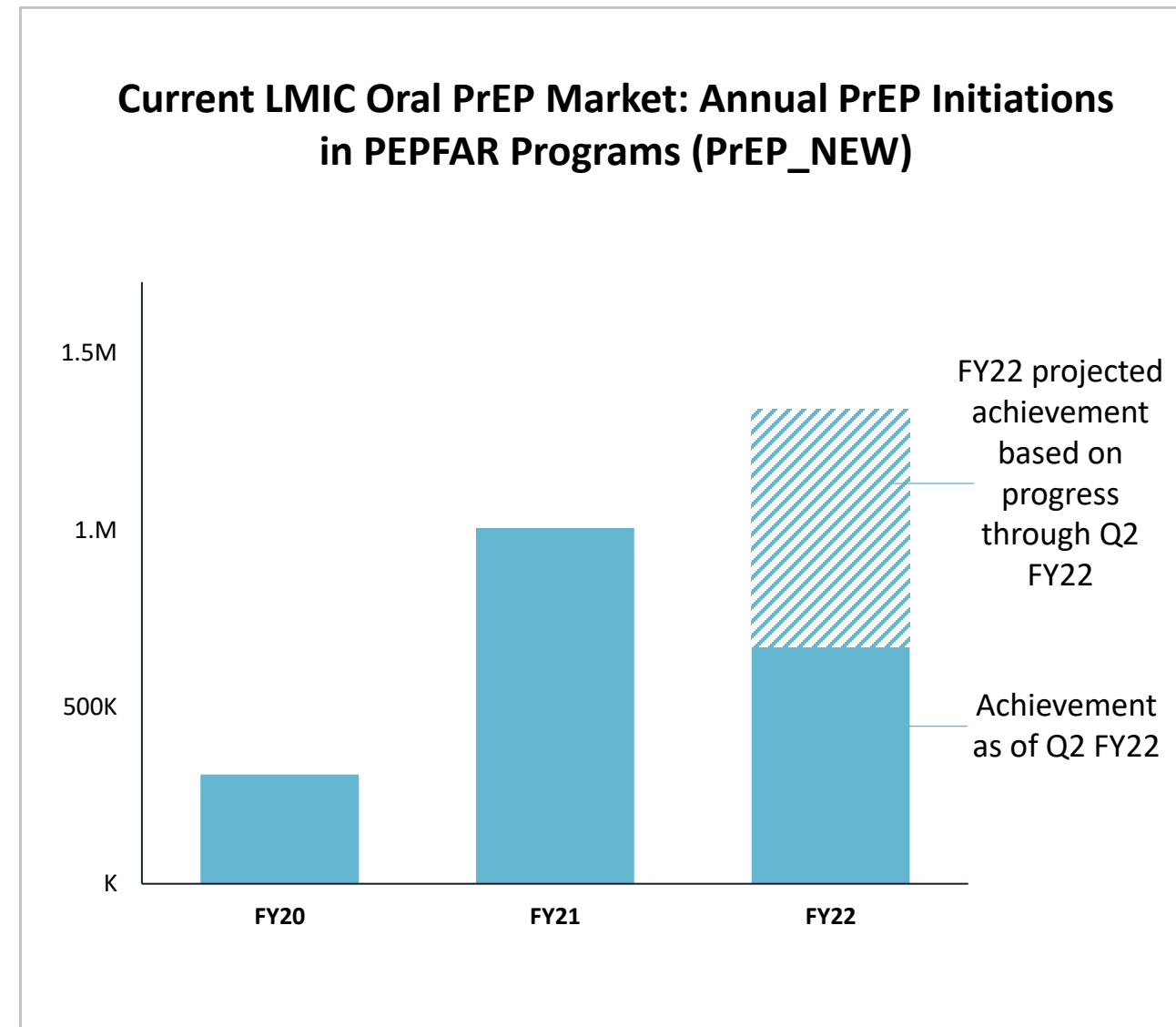
This illustrative analysis demonstrates how a lack of donor support for upfront costs could impact price. However, **ensuring affordable pricing is not the only function of incentives for generic development. A lack of donor support would have critical consequences for whether development progresses at all.**

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Generic manufacture has the potential to significantly increase affordability of CAB-LA and drive access; generic development support represents a high impact investment opportunity

Key Takeaways & Next Steps

- Using publicly available data, CHAI's COGS analysis demonstrates that generic manufacture has the potential to significantly increase affordability of CAB-LA.
- At volumes similar to the current oral PrEP market (see FY21 and FY22 right), efficiencies can drive further cost reductions.
- However, donor support to cover upfront expenses is critical to drive accelerated generic development. To minimize the time between licensing, generic registration, and impact at scale, a global concerted effort is needed.



Summary of COGS and Capital Expenditure Estimates

Generic CAB-LA COGS

CHAI analysis demonstrates that generic manufacture provides the opportunity to increase the affordability of CAB-LA, with **COGS estimated at \$30-40 PPPY at launch and \$14-16 PPPY at medium-scale:**

	Cost (PPPY)	
	Launch Volumes	Medium-Scale (Approx. 800K users)
API	\$11-15	\$3-4
Formulation	\$18-24	\$10-14
Sterilization	\$0.04	\$0.04
Total COGS	\$30-40	\$14-18

Capital Expenditure and Development Costs

Capital expenditure and development is estimated at \$8-10M. These costs are not included in COGS estimates and will increase prices if not covered by donor support:

Expense	Estimated Cost
Nano mill	\$2M
Bioequivalence studies	\$1M
Product development	\$5M
Total	\$8-10M

APPENDIX: COGS FAQ BRIEF

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 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.

KEY TERMS



Active Pharmaceutical Ingredients (APIs): Active pharmaceutical ingredients 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. This includes elements like raw materials for the APIs, costs associated with making APIs into the administration form (e.g., liquid for injection) and packaging.



Price: Price refers to the amount paid to purchase or procure 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.

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What is the difference between an originator and a generic drug and why are their costs different? (1/2)

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 products 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.

What is the difference between an originator and a generic drug and why are their costs different? (2/2)

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.

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.

[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](#))

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.

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.

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. Importantly, originators almost always cover these upfront expenses themselves, which is another reason for their higher drug 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.

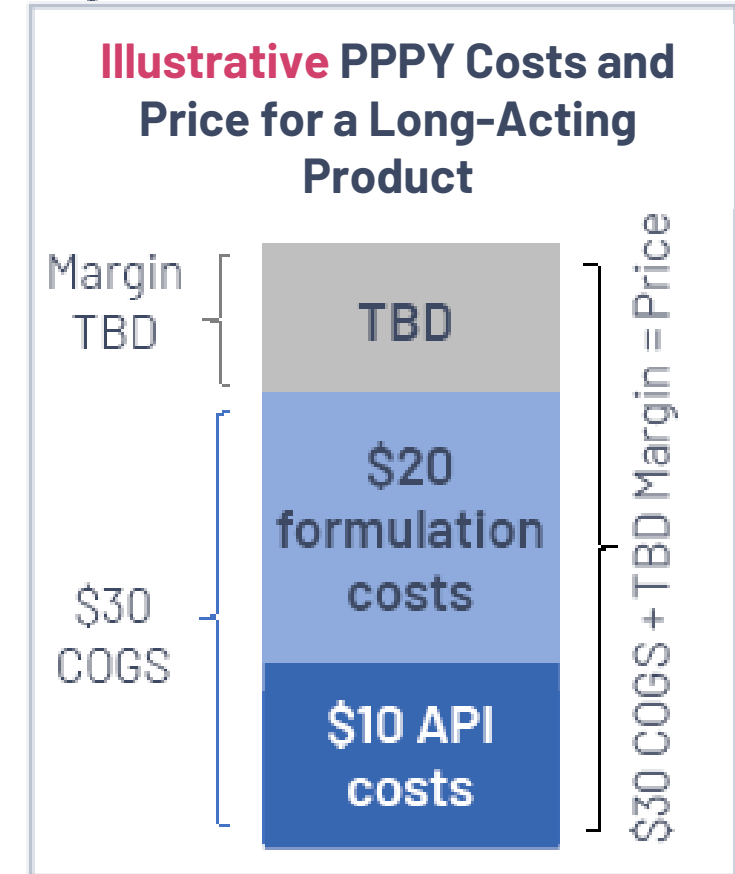
Pricing also depends on volumes – if low volumes are expected, a company will usually set a higher price to ensure they recover costs over the first few years after launch. If a company expects competitors to reach the market, they may try to recover costs over a shorter period of time, leading to further 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:

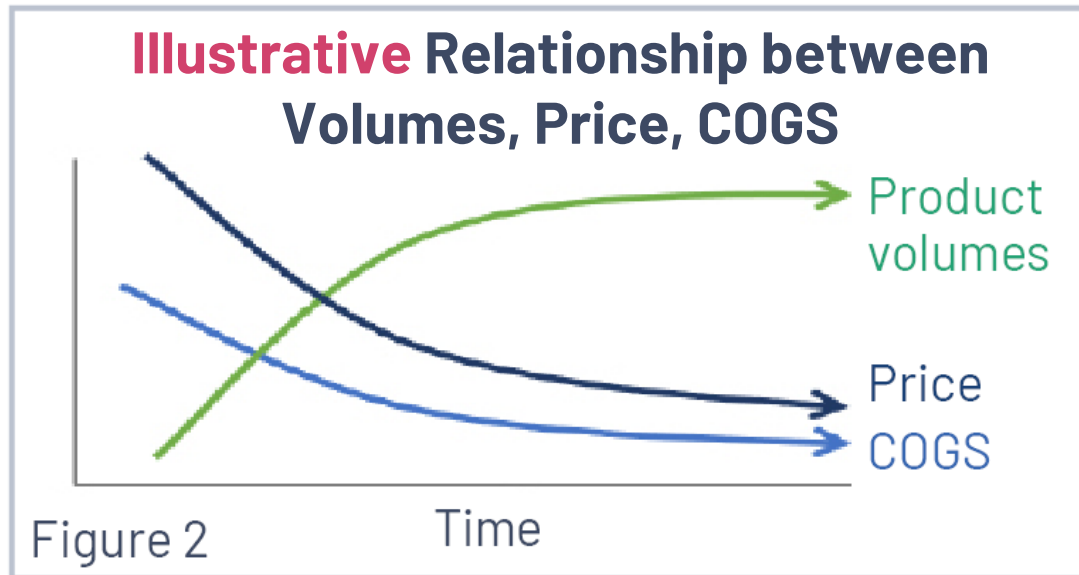
$$350,000 \text{ annual users} \times 6 \text{ vials per user per year} = 2.1 \text{ M vials} \rightarrow \frac{\$10 \text{ M start-up expenses}}{2.1 \text{ M vials}} = \$4.76 \text{ per vial or } \$28.57 \text{ PPPY margin needed to recover start-up expenses}$$

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.

Figure 1



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.

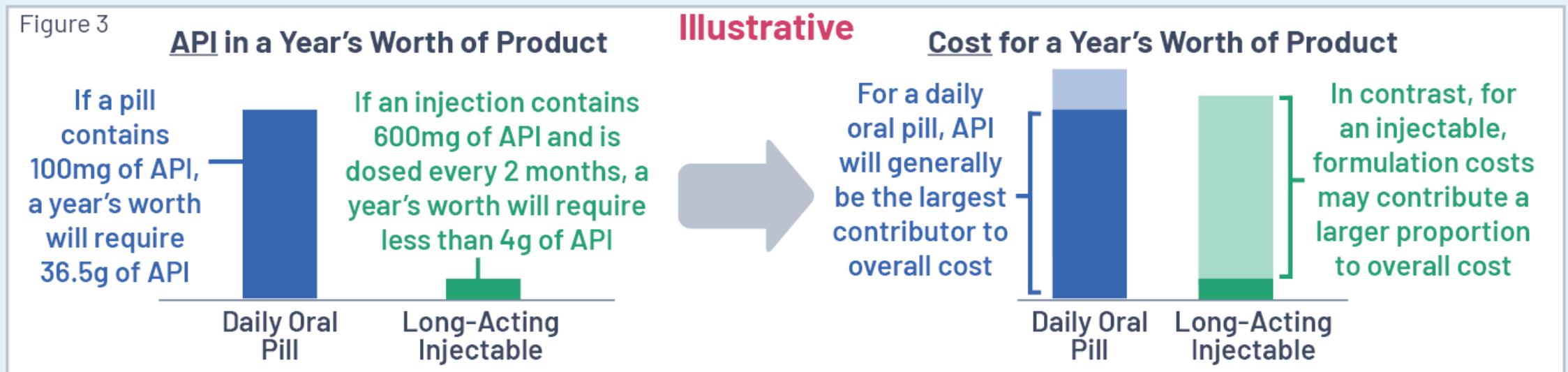
Application of COGS Analyses to Long-Acting Injectable Cabotegravir (CAB-LA)

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

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.



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,³ 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:



Making APIs

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.



Making the product formulation

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.



Sterilizing the product

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.

