COGS Information Gathering Handbook

January 27, 2015

Contents

Appendices

1. Introduction and Purpose

In furtherance of its mission to help ensure that vaccines and other necessary health-related products are available and affordable to those most in need in the developing world, the Bill & Melinda Gates Foundation (the "Foundation") makes grants to and other investments in manufacturers who produce such vaccines and other health-related products. In evaluating these investments, the Foundation needs to collect relevant production cost data from manufacturers in order to evaluate investment opportunities and establish fair and reasonable price targets. Recognizing that manufacturers may account for such costs in different ways, the Foundation would like to share with manufacturers and other relevant partners a standard methodology the Foundation uses to evaluate the production costs of a particular vaccine in a particular market (the "Vaccine").

This document provides the Foundation's methodology for data gathering, aggregating, and allocating cost components so it can understand the Vaccine's fully-loaded cost base. Using a robust and appropriate methodology to estimate costs lies at the core of a fair and sustainable system for providing critical vaccines to the developing world in a manner consistent with the following objectives:

- Vaccine access and affordability is improved in lower-income markets
- The manufacturer earns an appropriate return on investments (and does not earn a return that would be inappropriate in light of the Foundation's charitable mission and status)

The intent of collecting cost data pursuant to a standard methodology is to ensure that the Foundation uses for its own analysis only those costs that are tied directly to the development and production of a specific vaccine for particular countries or regions (referred to herein as "markets"), and other costs (i.e., those attributable to or already absorbed by the other markets – such as developing world countries) are appropriately allocated or excluded.

Any production cost data received from a manufacturer will be limited to the Foundation's internal use for its own assessments. To be clear, no information provided to the Foundation by one manufacturer will be shared with any other manufacturer. Also, please note that while we ask manufacturers to employ this methodology when providing cost-related information to the Foundation, we understand and appreciate that manufacturers will continue to use their own cost allocation methodology for other purposes.

1.1. Organization of this Document

The remainder of this document is organized into the following sections:

- **Section 2** explains why costs are allocated and describes several allocation methods

- **Section 3** discusses the steps to building and assessing the fully-loaded cost base, including how to frame the scope of the project, gathering the external assumptions and vaccine-specific production costs, and instructions on using the template tables included in Appendix A

- **Appendix A** is an Excel workbook containing 10 tables that the manufacturer can complete to provide the Foundation with information about its fully-loaded cost base

2. Allocating costs

There are generally two reasons for allocating costs:

- To isolate the costs of resources used in the manufacturing of the Vaccine, where the manufacturer is involved in the production of multiple products

- To isolate the costs of production specific to a particular geography, where the Vaccine is sold in multiple markets

The metric used to allocate costs is called an "allocation key" and is based on some observable characteristic of the production or sale of the Vaccine. For the purposes of this costing analysis, the choice of allocation key should balance accuracy, simplicity, and equity, with the greatest weight placed on accuracy.

- **Accuracy** – The allocation key should reliably reflect the cost drivers

    - For example, if the cost of fill/finish is primarily driven by the amount of time it takes to fill/finish a particular vaccine, and the time it takes to fill/finish two different vaccines is approximately equal on a per-dose basis, then allocation by volume would provide a reasonable estimate of the resources used by each vaccine

- **Simplicity** – The allocation key should be easily and inexpensively obtained

    - For example, production volume is often readily available, whereas actual time spent by employees on particular activities may be unavailable or require additional, and perhaps costly, analysis

- **Equity** – The allocation key should take into consideration the ability to bear the cost

    - For example, a higher margin product earning a larger return should bear a greater proportion of investment costs and indirect costs associated with production. In this way, products sold in higher-income countries may have a higher fully-loaded cost base than (nearly) identical products sold in lower-income countries

The primary allocation keys used are volume and revenue. However, there are many other common allocation keys (some of which are described below). Any observable characteristic could be used as an allocation key provided that it leads to a reasonably accurate apportionment of costs.

When allocating costs, the manufacturer should avoid using "rules of thumb" that are not based on the actual production of the Vaccine, and should always ensure that the allocation method employed would not lead to over-allocation of costs if applied to all of the

manufacturer's products (e.g., allocating 30% of overhead costs to each of its 10 vaccine products, which would lead to a total allocation of 300% of overhead costs).

2.1. Volume Allocation

A **volume allocation key** allocates costs to different products and markets based on the relative volume sold. For example:

- 100 million doses of a vaccine are produced and sold in different countries
    - 90 million are sold in high-income countries
    - 10 million are sold in low-income countries
    - Based on a volume allocation, 10 percent of costs would be allocated to production for low-income countries
- A fill and finish facility with a 25 million dose capacity is shared between two vaccines
    - 5 million doses of Vaccine A are sold by the facility
    - 20 million doses of Vaccine B are sold by the facility
    - Based on a volume allocation, 20 percent of costs would be allocated to Vaccine A

The volume allocation key implicitly assumes that the cost to produce a single dose does not vary across products.

Note that volume sold may differ from volume produced. For example:

- A manufacturer may intentionally over-produce to stockpile inventory for future sale
- A manufacturer may experience wasted batches due to a manufacturing flaw

2.2. Revenue Allocation

A **revenue allocation key** allocates costs to different products and markets based on relative revenues.[1]

[1] A price allocation key, where costs are apportioned based on the relative selling price of joint products, is sometimes used as a shortcut to a revenue allocation. This should be avoided. In instances where the relative volume of outputs is stable with the level of inputs, allocation by price is identical to allocation by revenue. However, a price allocation may lead to a misleading fully-loaded cost base when the ratio of inputs to outputs varies.

For example:

- 20 million doses of a vaccine are produced and sold in different countries
    - 10 million are sold in high-income countries at $9 per dose
    - 10 million doses are sold in low-income countries at $1 per dose
    - Based on a revenue allocation, 10 percent of costs would be allocated to low-income countries
        - By comparison, if this were using a volume allocation, then 50 percent of costs would be allocated to low-income countries

2.3. Other Allocation Keys

Other allocation keys may be appropriate in apportioning costs to different products and markets in certain circumstances.

Here are some examples of other allocation keys that may be appropriate:

- **Time** – Use of a bulk production facility is split between two vaccines. Every year the facility produces Vaccine A for 13 weeks and Vaccine B for 26 weeks, with the remaining 13 weeks necessary for transitioning the facility between vaccines. Based on a time allocation, 33 percent of costs would be allocated to Vaccine A and 67 percent of costs to Vaccine B.

- **Square Footage** – If a building has production split between two suites, then it may be appropriate to allocate the indirect building costs based on the suites' square footage or the relative value of assets employed by each suite.

- **Headcount** – Costs of employee benefits may be most appropriately allocated based on the number of employees engaged in a particular activity.

3. Costing Overview

The Vaccine's fully-loaded cost base should be estimated based on actual historical costs adjusted to reflect the average production yields and volumes expected over the period being

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For example, bulk antigen (the input) can be used to produce vaccines for both high-income and low-income countries (the outputs) in whatever proportions a manufacturer chooses. If the costs of bulk antigen are allocated based on price, then the allocation of costs is independent of volume. This can lead to misleading results, such as the total cost of bulk antigen to produce a single dose for high-income countries is the same as the total cost to produce 1 million doses.

analyzed. If historical cost information for the Vaccine is not available, then projections based on the manufacturer's past experience with similar products may be informative to the costing analysis.

As explained in Section 2 above, because vaccines are often produced in shared facilities and delivered to multiple markets (some of which may be outside the scope of the costing analysis), allocation keys are used to apportion shared costs and expenses included in the Vaccine's fully-loaded cost base.

The following sections describe cost categories, including category definitions and guidelines on how to include costs. These specific cost categories are designed to be generic enough to cover all relevant costs. However, depending on the level of detail available and the Vaccine manufacturer's internal accounting, other cost categories may be included in addition to or instead of those below.

The Vaccine's manufacturer should compile the annual costs, inflation, and other details for each of these categories in the tables provided in Appendix A. To aid in the subsequent validation of the fully-loaded cost base, include references to source documents and backup materials used to estimate the included costs.

3.1. Cost Categories

3.1.1. Property, Plant, and Equipment (PP&E)

Definition

PP&E refers to the fixed assets held on the manufacturer's balance sheet at cost and is depreciated over time.

PP&E may include items such as:

- Land
- Buildings
- Machinery and equipment
- Furniture and fixtures
- Office equipment
- Infrastructure (e.g., roads)

Guidelines

PP&E costs excluding land (which has an indefinite useful life) should be capitalized. The fully-loaded cost base of the Vaccine will be affected by PP&E through depreciation and Repairs & Maintenance. For inclusion in the fully-loaded cost base, the appropriate depreciation schedule may differ from the accounting or tax treatment.

In Appendix A, details of existing PP&E should be entered into Table A-7, while capital investment into new PP&E should be entered into Table A-8 and appropriately allocated to the Vaccine.

Examples

- In order to supply the Vaccine to lower-income markets, the manufacturer will build a new, dedicated $10 million facility in 2015 that will begin operating on January 1, 2016, with a useful life of 20 years
    - For each year that this facility is in operation (i.e., 2016 to 2035), a depreciation expense of $500,000 will be incurred
- If an investment in PP&E is being paid for through a grant from a government or philanthropic organization, then the depreciation expense should be calculated based only on the investment portion paid for by the manufacturer
    - If the investment is completely covered by a grant, then the depreciation expense should be excluded from the fully-loaded cost base
    - If depreciation expense is being used as a proxy for expected Repairs & Maintenance costs, then the R&M should be adjusted to include the total investment cost (see **Section 3.1.4**)

3.1.2. Research and Development (R&D)

Definition

R&D refers to the costs incurred to discover, develop, and bring a product to market

R&D may include items such as:

- Discovery of the antigen
- Historical research costs
- Clinical trials

- Regulatory approval
- Market development and testing

Guidelines

For accounting purposes, R&D is typically expensed in the year it is incurred, rather than capitalized. However, to smooth out costs and ensure that all relevant investment costs are included, R&D directly related to the Vaccine should be capitalized and affect the fully-loaded cost base through depreciation. Historical R&D that is not directly related to the Vaccine should be excluded.

In Appendix A, R&D related to the Vaccine should be entered into Table A-8 and appropriately allocated to the Vaccine.

Examples

- The Vaccine requires the manufacturer to employ technology and processes it does not have previous experience with, and therefore it must incur R&D costs before production can begin
    - These costs are specifically related to the Vaccine and should be included in the cost base
    - If these costs relate to the Vaccine, as well as other vaccines currently in production, the costs should be allocated among vaccines using an appropriate allocation key

3.1.3. Depreciation

Definition

Depreciation is a notional cost that generally follows a schedule where a portion of value is assumed to be "used up" each year over the useful life of an asset. Depending on the type of asset, there may or may not be residual value to the asset at the end of its useful life.

Depreciation allows investment costs to be smoothed out over the term of the agreement and is more amenable to a "cost-plus" pricing approach.

Depreciation may be included for items such as:

- Property, Plant, and Equipment
- Research and Development that can be specifically ascribed to the Vaccine

Guidelines

For inclusion in fully-loaded cost base, the appropriate depreciation schedule may differ from an accounting or tax treatment.

The expected useful life and residual value should be evaluated for reasonableness.

In Appendix A, depreciation should be associated with a particular set of fixed assets and described in Table A-7.

Examples

- Tax regulations in the manufacturer's country require all equipment to be depreciated over a useful life of 8 years, but in the manufacturer's experience the equipment has a useful life of 15 years
    - Depreciation included in the fully-loaded cost base should be calculated based on a 15 year useful life

3.1.4. Repairs and Maintenance (R&M)

Definition

R&M refers to costs incurred to maintain capital assets in working order.

Fixed assets, such as Property, Plant, and Equipment, require periodic maintenance and occasional repairs when they break down to keep them in good working order.

Guidelines

Any expenditure that is intended to extend the useful life of the asset is actually a capital investment, and should not be included in R&M.

Where estimates of R&M are unavailable, depreciation may be useful as an indicator of expected R&M.

There may be a correlation between the choice of depreciation method and expected R&M. For example, a manufacturer may use double-declining depreciation where it expects few R&M expenses in early years, but greater R&M expenses as the asset ages. For simplicity R&M expenses should be assumed to be smooth over the life of assets.

In Appendix A, R&M should be entered as one or more items in Table A-5 and appropriately allocated to the Vaccine.

Examples

- Historically, R&M has been between $120,000 and $185,000 per annum, and annual depreciation is expected to be $140,000
    - Future R&M can reasonably be projected to be around $140,000 per annum

3.1.5. Consumables and Packaging Materials

Definition

Consumables and Packaging Materials refer to materials that are used up in the production of the Vaccine.

Consumables and Packaging Materials may include items such as:

- Bulk biological and chemical agents
- Vials
- Labels
- Boxes

Guidelines

The quantity of consumables and packaging materials necessary for a single unit of the Product should be based on actual production runs, wherever possible. The fully-loaded cost base includes actual (not theoretical or target) yields and accounts for expected normal loss rates (e.g., broken vials and overfill).

If large increases in production are being contemplated then "volume discounts" may be available from suppliers of consumables and packaging materials, which would lower costs on a per dose basis and should be included.

Be careful when accounting for variable costs that are used in different multiples than 1 dose, e.g., if a box contains 6 doses, then the per dose cost of the box is the unit cost of the box divided by 6.

Bulk antigen obtained from a third party (as with all products obtained from third parties) should be included at cost to the manufacturer, without any additional markup.

In Appendix A, consumables and packaging materials should be broken down and input into Table A-4 with as much detail as possible.

Examples

- Due to overfill, breakage, and other types of wastage, raw materials for a theoretical yield of 112 million doses are required to actually produce 100 million doses
    - Raw material costs per dose should be calculated based on the cost of materials necessary for 112 million doses, divided by the actual yield of 100 million doses

3.1.6. Overhead

Definition

Overhead refers to indirect costs which are necessary for the business to function, but which cannot be directly allocated to any particular product.

Overhead may include items such as:

- Management salaries, wages, and benefits (i.e., indirect labor costs)
- IT systems
- Insurance
- Staff training
- Security
- Other head office or back office expenses

Guidelines

Overhead costs should be evaluated individually and allocated among products using an appropriate allocation key.

Care should be taken to ensure that allocations are appropriate for the Vaccine such that there is not over-allocation of total costs.

All goods and services obtained from third parties should be included at cost to the manufacturer (including any costs of managing those third parties), without any additional markup.

In Appendix A, overhead should be input into Table A-5 and appropriately allocated to the Vaccine.

Examples

- For internal budgeting and planning purposes and as a rule of thumb, a manufacturer includes 30 percent of overhead in the cost base to evaluate the sustainability of producing a new vaccine
    - In fact, with the addition of the new vaccine the manufacturer will have 10 different vaccines with overhead costs allocated evenly between each
    - The fully-loaded cost base should include only 10 percent of total overhead, otherwise the costs will be over-allocated among products

3.1.7. Labor

Definition

Labor refers to employee wages, benefits, and staff training costs.

Labor may include items such as:

- Direct labor costs specifically associated with the manufacturing of the Vaccine
- Indirect labor costs for manufacturer executives, supervisory staff, and administrative employees

Guidelines

Direct labor costs may be semi-variable in that small changes in production volume may not significantly affect costs, while larger changes and/or process improvements may increase or decrease costs considerably. Where projections of future costs incorporate large changes in production or processes, the reasonableness of direct labor costs should be considered.

Labor costs are particularly subject to changes in efficiency when the Vaccine is novel to the manufacturer. It may be the case that the labor required in the early stages of vaccine development (before the manufacturer has much experience with the Vaccine) may be greater than the amount of labor required later. Manufacturers frequently exhibit “learning-by-doing” whereby productivity increases and headcount decreases as experience is gained producing the Vaccine. Because of this, projected labor costs that are based on initial, small production runs should include some consideration for future efficiency increases.

Be cautious about possible double counting between indirect labor costs (management) and Overhead costs.

In Appendix A, labor should be input into Table A-5 and appropriately allocated to the Vaccine.

Examples

- In the first year of production the manufacturer expects to have 20 full-time employees engaged in the Vaccine production, but, based on the manufacturer's experience with other vaccines, by the fifth year of production it expects to need only 10 full-time employees
    - The manufacturer's labor costs should decline to reflect the reduction in labor necessary as experience is gained in the Vaccine's production

3.1.8. Licensing Income / Expense

Definition

Licensing Income / Expense refers to recurring costs and lump-sum payments made to the intellectual property (IP) owner for the right to use a technology or process.

Licensing Income / Expense may include items such as:

- Royalty rate as a percentage of revenues
- Milestone payments
- Sublicensing income

Guidelines

In developing the Vaccine, manufacturers may create IP that can be licensed to other manufacturers (subject, of course, to any global access commitments the manufacturer has made to the Foundation)[2]. When the costs to develop such IP are included in the fully-loaded cost base of the Vaccine, any income received from licensing that IP must also be included in the assessment.

Expenses incurred licensing IP from third-parties must be allocated across all relevant products and markets included in the fully-loaded cost base of the Vaccine in the same way as with other expenses.

In Appendix A, Licensing income and expenses should be input into Table A-7 and appropriately allocated to the Vaccine.

[2] As a general matter, "global access" requires that (a) the knowledge and information gained from a Foundation-funded project be promptly and broadly disseminated and (b) products, services, processes, technologies, materials, software, data or other innovations resulting from this project be made available and accessible at an affordable price to people most in need within developing countries.

Examples

- Sometimes royalties are designed as a "step-down" royalty rate, where the royalty rate goes down as the volume produced goes up
    - Any additional benefit from a lower royalty rate should be fully allocated to the Vaccine in lower-income markets

3.1.9. Cost to Commercialize

Definition

Cost to Commercialize refers to expenses incurred to market, sell, and distribute a product.

Cost to Commercialize may include items such as:

- Advertising
- Marketing materials
- Sales force
- Distribution (?)

Guidelines

Only costs to commercialize that are directly attributable to the Vaccine in the market of interest should be included. As these costs can also be interpreted as overhead, ensure that this cost category is only included once.

In Appendix A, costs to commercialize should be input into Table A-5 and appropriately allocated to the Vaccine.

Examples

- The manufacturer is intending to supply the Vaccine through GAVI to several countries, including India. Additionally, the manufacturer intends to market the Vaccine in India outside of the agreement with GAVI
    - Any costs to commercialize that are not related to the specific agreement in question should be excluded from the Vaccine's cost base

3.2. Calculate the Fully-Loaded Cost Base Using the Template Tables

Appendix A contains template tables for information gathering and is provided as an attached Excel file.

The tables in Appendix A are intended to provide a starting point to the information required to analyse the Vaccine's fully-loaded cost base and its cost per dose for Foundation purposes.

In any costing analysis, the level of detail and information available will differ. Adjustments and adaptations to the tables in Appendix A should be made where necessary. Once the basic information is gathered and categorized, parties will be better able to carry out more complex analyses to evaluate particular cost sensitivities and contingencies.

If a party finds that the circumstances of the costing exercise are such that the template tables are not appropriate, it may still be helpful to refer to the template tables to inform the data gathering process. In all cases, the manufacturer should detail the sources of all data inputs used in building up the main cost elements.

Instructions for filling in the template tables in Appendix A are provided below. When completing the tables, use care to only enter information into the green shaded cells. All income and expenses should be entered into the tables in the currency in which they are paid or received.

3.2.1. General Information (Table A-1)

This table should be completed first as it contains some general information about the Vaccine that is referenced by the other tables.

Vaccine Name	Enter the name of the Vaccine.
Market Labels	Enter a label for each market that the Vaccine has been or is expected to be sold in. Only markets where the price varies significantly need be differentiated. Otherwise, markets can be grouped and all costs can be entered on a volume-weighted average basis. For example, market labels may include "GAVI," "UNICEF," "Europe," or "Other"
Start Year	Enter the first year of projected costs (usually the current year). Subsequent tables will use this value to include cells for 10 years of historical and 10 years of projected cost information.
Effective Tax Rate	Enter the effective tax rate of the manufacturer (i.e., total taxes paid divided by taxable income).
Discount Rate	Enter the manufacturer's weighted average cost of capital or discount rate used for project planning purposes.

Reporting Currency and Conversion Rate per USD	Enter the main currency that the manufacturer's costs are denominated in, as well as the assumed exchange rate to USD. If costs are denominated in multiple currencies, add additional rows so that all exchange rates are provided.

3.2.2. Allocation Keys (Table A-2)

For each row of the table, enter a label for the allocation key and the percentage allocation to each of the three markets in ***columns C through E***. Each allocation key should assign 100 percent of the costs, and the "Notes" field in ***column H*** should describe how the allocation key was determined.

Any supplemental materials used to calculate the allocation keys should be referred to in the Notes field and attached in the submission.

All allocation keys used in subsequent tables should be included in Table A-2.

Insert additional rows as needed.

3.2.3. Vaccine Price, Volume, and Revenue (Table A-3)

This table includes columns for inputting 10 years of historical data and 10 years of projections. Enter as much information as available and insert additional columns if the projection period extends beyond 10 years.

Historical and projected sales volume by market by year should be entered into the green cells in ***rows 8 to 10***.

Historical sales revenue should be entered into the green cells in ***rows 17 to 19***.

3.2.4. Variable Costs (Table A-4)

For each variable cost, enter the average cost per dose in the currency in which it is incurred in ***columns C and D***. Costs to input into this table include items such as raw materials and packaging materials.

If costs are expected to change over time, or particular costs apply only in certain years, enter the "Start Year" and "End Year" in ***columns E and F*** to indicate which costs apply when.

In ***column G*** include the expected inflation rate for each cost during the projection period.

Insert additional rows as needed.

3.2.5. Fixed Costs (Table A-5)

For each fixed cost, enter the total annual cost (before allocation) in the currency in which it is incurred in ***columns C and D***. Costs to input into this table include items such as direct and indirect labor, power and fuel, repair and maintenance, and overhead.

Licensing expenses and fixed asset depreciation should not be included as they are dealt with separately in Table A-6 and Table A-7, respectively.

If costs are expected to change over time, or particular costs apply only in certain years, enter the "Start Year" and "End Year" in ***columns E and F*** to indicate which costs apply when.

In ***column G*** include the expected inflation rate for each cost during the projection period.

In ***column H*** indicate whether the cost is vaccine-specific or shared. If the cost is shared, specify the allocation key used in ***column I*** and calculate the allocated cost in ***column J***. If the cost is vaccine-specific (i.e., not allocated), place in ***column J*** the same value as ***column C***.

Insert additional rows as needed.

3.2.6. Licensing Expense and Income (Table A-6)

In Table A-6 enter the details about all licensing expenses related to the Vaccine's production, as well as licensing income received as a result of IP owned by the manufacturer that is related to the Vaccine's production.

In ***columns C and D*** provide the licensor or licensee name and the period of the current license. If there are renewal terms or conditions relevant to this costing analysis, describe those in ***column E***.

In ***column F*** identify whether the item is an expense or income, and in ***columns G and H*** enter the amount and the currency it in which it is incurred or received.

In ***columns I and J*** specify whether the income or expense is one-time or ongoing and whether it is specific to the Vaccine or shared among other products.

If the license is utilized by multiple products, specify the allocation key used in ***column K*** and calculate the allocated cost in ***column L***. If the cost is vaccine-specific (i.e., not allocated), place in ***column L*** the same value as ***column G***.

Insert additional rows as needed.

3.2.7. Existing Fixed Assets and Depreciation (Table A-7)

In Table A-7, enter the details about total value of fixed assets at each facility (including all buildings and equipment) involved in the production of the Vaccine (i.e., each facility for which depreciation is to be allocated to the Vaccine).

If building plans or aerial maps/photographs of the facilities are available, then include these as attachments to the submission.

In ***column C*** describe the functions and/or operations that take place at each facility, and in ***columns D and E*** include the facility's approximate square footage and capacity. Specify what other products utilize each facility in ***column F***.

In ***columns G and H*** input the book value of the facility's fixed assets in the currency in which it was purchased. State the depreciation methodology used in ***column I*** and the accumulated depreciation to date in ***column J***.

In ***columns K and L*** enter the average useful life of the fixed assets in each facility and the assumed residual value of the asset at the end of its useful life.

In ***column M*** enter the total annual depreciation before allocation to the Vaccine. If the facility is utilized by multiple products, specify the allocation key used for depreciation in ***column N*** and calculate the allocated cost in ***column O***. If the cost is vaccine-specific (i.e., not allocated), place in ***column O*** the same value as ***column M***.

Insert additional rows as needed.

3.2.8. Capital Investments (Table A-8)

Enter into this table all future anticipated capital investments related to the Vaccine during the projection period.

In ***column C*** input the expected useful life of the capital investment. This information will be used to calculate the additional depreciation expenses as a result of the investment.

In ***columns D and E*** specify whether the investment is specific to the Vaccine or shared among other products, and, if shared, how its costs are allocated to the Vaccine.

In ***column F*** enter the costs' currency, and in ***columns G through Z*** enter the capital investments in the year in which they are expected to be (or actually were) incurred.

Insert additional rows as needed.

3.2.9. Grants, Loans, and Outstanding Debt Related to the Vaccine (Table A-9)

In ***column C*** specify the when the grant was received or when the loan/debt was issued and when the principal is due.

In ***columns D and E*** enter the original amount received and the interest rate, if applicable. Describe any other relevant terms of the grant, debt, or loan in ***column F***. For example, the loan may be convertible to equity under certain conditions, or the grant may be paid only after reaching certain milestones.

In ***columns G and H*** specify whether the amount is specific to the Vaccine or shared among other products, and, if shared, on what basis are its costs allocated. Enter the amount allocated to the vaccine into ***column I***, and, in ***column J***, describe which expenditures the grant, loan, or debt is specifically related to.

Insert additional rows as needed.

3.2.10. Related Product Sales (Table A-10)

In Table A-10 enter the historical and projected sales volume and revenue for products related to the Vaccine. A product is considered to be related to the vaccine if it shares facilities with the Vaccine, or if costs are otherwise allocated between the two products.

This information is needed for the calculation of the volume and revenue allocation keys.