PQMD
Partnership for Quality Medical Donations

InterAction
A UNITED VOICE FOR GLOBAL CHANGE
The largest alliance of U.S.-based international nongovernmental organizations focused on the world's poor and most vulnerable people.

Adopted December 2018

Introduction

With support from its members, InterAction and other interested parties, PQMD has developed a recommended methodology and a list of valuation sources to assist nonprofit organizations in determining the financial valuation of donated pharmaceutical products received in pursuit of their missions. The methodology is intended to help organizations to select an approach to recording GIK donations in their financial statements that is fair, appropriate and aligned to IRS requirements, FASB guidance, and GAAP principles. Additionally, the methodology serves as the basis for InterAction's NGO Standards related to valuation of donated goods.

Purpose

The purpose of the methodology is to guide decision-making by an individual organization. Ultimately, each organization is responsible to determine the valuation it records based on its own professional judgement and in consultation with its auditors. To ensure a consistent approach, however, the methodology is based on AICPA guidance related to gifts-in-kind valuation, which can be found here: AICPA Website. The methodology is illustrated by the included Decision Tree. In addition to the methodology, PQMD has assembled a Pharmaceutical Pricing Inputs Catalog that can be used to determine the value of specific products.

Decision Tree

The Decision Tree guides users through questions that help determine whether a procured product can be considered a donation and, if so, whether its valuation should be based on a U.S. market price, or an international price. The key questions are:

- *Is there a fee associated with GIK procurement?* And, if so, *is the fee paid substantially less than the rate commonly available to any individual or organization?* This question will lead to a decision as to whether a product has been procured through donation, and therefore recordable as donation revenue, or through purchase, which is not recordable as a donation.

- *Is the pharma GIK legally permissible for sale in the U.S.?* And, *is the U.S. the principal market as compared to any individual international market?* These two questions support decisions about whether donated products should be valued based on a U.S. market price, or an international price. Note that international price in this context is meant to refer to pricing available on the international market, as opposed to within any specific country.

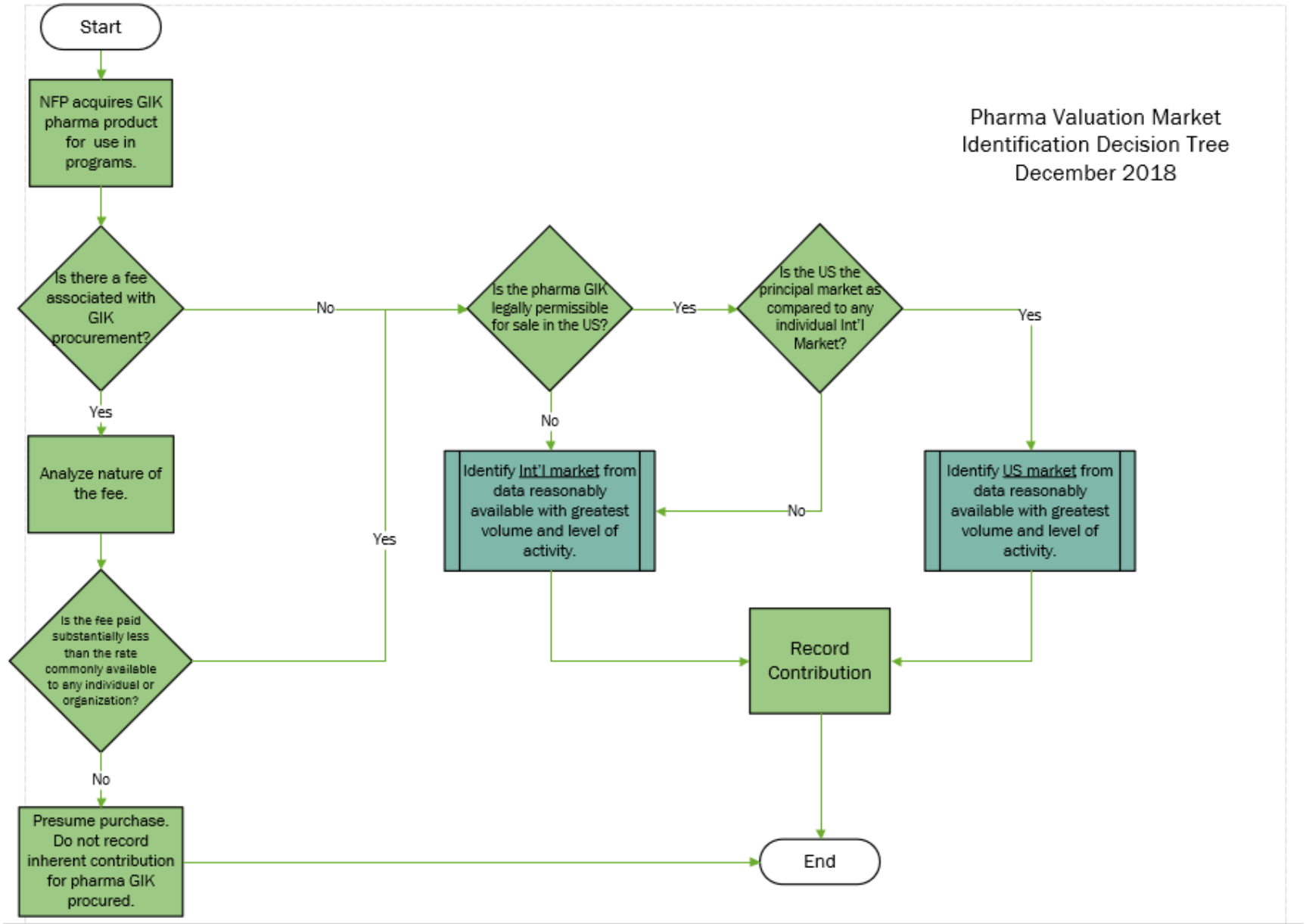
Based on a decision to use U.S. or international pricing, the Decision Tree then guides a user to utilize available pricing sources that are generally easy to use and include data based on a significant level of volume and activity.

Pharmaceutical Pricing Inputs Catalog

Included along with the methodology is a list of potential international and U.S. pricing sources which is intended to provide organizations with insight into what the sources represent. Organizations should consider how to use these sources when valuing donated pharmaceutical products. PQMD and InterAction are not recommending the use of any specific source, but rather seeking to inform organizations about key source considerations so that organizations may exercise informed professional judgement in determining how to value its GIK. This source list is not intended to include all potential sources.

Transparency

In addition to utilizing these Decision Tree and Sources for Valuation resources, it is essential that each organization documents in writing, and makes available to the public, the rationale for its policy and practice related to pharmaceutical valuation. It is recommended this written rationale be included in annual financial statements and be published on appropriate pages of an organization's website.



*Legally permissible in this flow chart refers to those restrictions that affect the asset and not those affecting the entity. Legal restrictions that only affect the NFP do not affect the underlying value of the asset's fair value.

Pharmaceutical Pricing Inputs Catalog – December 2018

The Pharmaceutical Pricing Inputs Catalog should be used alongside the flowchart and narrative guidance to assist organizations in selecting one or more appropriate pricing sources for donated pharmaceuticals.

To use this Pharmaceutical Pricing Inputs Catalog, first, review the flowchart provided in the guidance. Determine where the product is legally permissible for sale (US or International). Then carefully review the possible sources noted as appropriate for international or US valuations. Because some sources do not include all market adjustments, your organization may determine that additional adjustments to source values are necessary to appropriately value the donated products under the GAAP definition of Fair Value, "the price that would be received to sell an asset…in an orderly transaction between market participants at the measurement date".

This catalog represents the sources most commonly used for donated valuations at the time of publication. It is not an exhaustive list of all pharmaceutical pricing sources.

Source	General Description	US/Int'l	Cost	Considerations for using this data source
Distributor / Manufacturer Price	Value provided by donating pharmaceutical company or value paid for purchased generic pharmaceuticals from distributor or manufacturer.	Int'l	Transaction based	When value provided by the donating company, ensure the value represents your organization's valuation methodology. If executing a purchase of pharmaceutical product for use in programs, determine if the fee paid represents a "handling fee". If so, the NGO should evaluate if the handling fee is representative of active marketplace transactions. If it is, then the "handling fee" is the product value. If not, then the market price, less the acquisition fee is the representative value assessed for the product. The market price would be determined using one of the valuation sources below.
International Medical Products Price Guide (IMPPG)	Formerly called International Drug Pricing Indicator Guide. The purpose of the guide is to provide a range of prices from international suppliers and buyers of medical products.	Int'l	Public, Free	The IMPPG can be found at: http://mshpriceguide.org. It is published by the Management Sciences for Health (MSH) Purpose of the guide is to make price information more widely available to improve procurement of quality-assured medicines for the lowest possible prices. It represents prices paid by both buyers and suppliers, within the publication timeframe Organizations can use this to establish market price in international markets, and could be used when the product from the specific manufacturer is not permissible for sale in the US market.

Company which aggregates pharmaceutical procurement data – can be international or US only.	Provide aggregated market pricing for specific drugs based on specific attributes.	Int'l	Fee based	These companies document a variety of specific attributes from actual market transactions, typically aggregating them annually. Attributes can include things such as country, manufacturer, month, wholesale/retail/manufacturer, etc. Data reflects only those transactions from participating manufacturing, wholesale, or retail entities (clinics, pharmacies, hospitals, etc.). Examples of companies are below. All are fee-based services http://www.imshealth.com/ - this is a subsidiary of IQVIA. It gathers data on both FDA and non-FDA approved manufacturers/products world-wide. It would likely be used to establish values for products where the US is NOT the principle market because the drug from the specific manufacturer is not permissible for sale in the US market www.analysource.com – this is a division of DMD America. It gathers information on FDA approved drugs, and would likely be to establish values where US is the principle market because the drug from the specific manufacturer is permissible for sale in the US market www.fdbhealth – this is the managing company for First Databank. This source draws on their partnership with DMD America, and uses their Analysource tool in pricing analysis. Using this source is the same as using Analysource

Federal Upper Limit (FUL)	Affordable Care Act Federal Upper Limits (FUL) based on the weighted average of the most recently reported monthly average manufacturer price (AMP) for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis	US	Public, Free	Also called Medicaid FUL, it is the upper price limit by which the Federal Government will reimburse for Medicaid pharma products. This is no less than 175% of the average manufacturer price (AMP). The information is based on actual sales information and is updated monthly. It can be located at this link: https://data.medicaid.gov/Drug-Pricing-and-Payment/Federal-Upper-Limits-2018-02/cmk7-uy43/data This source could be used for products from a manufacturer permissible for sale in the US.
National Average Drug Acquisition Cost (NADAC)	Calculated value intended primarily for use by state Medicaid.	US	Public, Free	Originally developed in 2010 as an alternative to AWP. The NADAC survey process focuses on retail community pharmacy drug ingredient costs. The survey collects acquisition costs for covered outpatient drugs purchased by retail community pharmacies, which include invoice purchase prices from independent and chain retail community pharmacies https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html This source could be used where products from the specific manufacturer are legally permissible for sale in the US.
State Maximum Allowable Cost (MAC)	The maximum amount a given state will reimburse for Medicaid pharma products.	US	Public, Free	Based on actual sales information and updated monthly. An example is the Ohio MAC at the link below. https://druglookup.ohgov.changehealthcare.com/DrugSearch This source could be used where products from the specific manufacturer are legally permissible for sale in the US.

Wholesale Acquisition Cost (WAC)	The wholesale acquisition cost (WAC) is an estimate of the manufacturer's list price for a drug to wholesalers or direct purchasers, but does not include prompt pay or other discounts, rebates or reductions in price. [1]	US	Fee Based	WAC is most commonly used as a benchmark in pharmacy purchases of drugs. It can be accessed through sources like Redbook, Medi-Span and First Databank. They can be linked at: https://www.fdbhealth.com/ www.micromedexsolutions.com/micromedex2/4.31.0/webhelp/RED_Book http://www.wolterskluwercdi.com/drug-data/medi-span-electronic-drug-file/ This source could be used where products from the specific manufacturer are legally permissible for sale in the US. WAC is not based on actual sales transactions, and organizations should consider whether an adjustment is advisable if using WAC as a basis for valuation. [2]

[1] Definition of WAC: https://www.ssa.gov/OP_Home/ssact/title18/1847A.htm for source of this legal definition.

[2] This language based on 2005 DHHS OIG's investigation into the price differences between AMP and WAC/AWP (see pg 3). https://oig.hhs.gov/oei/reports/oei-05-05-00240.pdf. This is also referenced by one of the publishers of WAC: https://www.wolterskluwercdi.com/blog/ful-story-what-you-need-know-about-new-aca-ful-pricing/

Average Wholesale Price (AWP)	An estimate of the list price retail pharmacies pay for drugs from their wholesale distributor. This price is calculated and published by 3rd party companies. It does not reflect actual prices paid for drug products, nor any discounts, rebates, or other price reductions. [3]	US	Fee based	AWP is most commonly used as a benchmark in pharmacy purchases of drugs and often reflects a 20% markup compared to WAC. [4] It can be accessed through sources like Redbook, Medi-Span and First Databank. They can be linked at: https://www.fdbhealth.com/ www.micromedexsolutions.com/micromedex2/4.31.0/webhelp/RED_Book http://www.wolterskluwercdi.com/drug-data/medi-span-electronic-drug-file/ This source could be used where products from the specific manufacturer are legally permissible for sale in the US. AWP is not based on actual sales transactions, and organizations should consider whether an adjustment is necessary if using AWP as a basis for valuation. [5]
Average Manufacturer Price (AMP)	The average price paid to the manufacturer for the drug in the United States by wholesalers for drug distribution to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.	US	Public, Free	The AMP is statutorily defined and its calculation is based on actual sales transactions. It is not inclusive of any rebates or discounts, and is based on actual sales data and updated monthly. This source provides the baseline to determine the Medicaid FUL. It typically represents a price that is substantially lower than both the average wholesale price and the wholesale acquisition cost. This source would likely not be used as is, but is a contributor to the Federal Upper Limit.

[3] AWP is not based on actual market transactions: https://www.wolterskluwercdi.com/sites/default/files/documents/WKH_AWP_Policy.pdf

[4] Per Red Book publisher: https://www.micromedexsolutions.com/micromedex2/4.31.0/WebHelp/RED_BOOK/AWP_Policy/AWP_Policy.htm

[5] This language based on 2005 DHHS OIG's investigation into the price differences between AMP and WAC/AWP (see pg 3). Additional information can be found at this AWP publisher's site: https://www.wolterskluwercdi.com/blog/ful-story-what-you-need-know-about-new-aca-ful-pricing/