MARCH 2024

CASE STUDY

value balancing alliance

VBA HEALTH CLUSTER

Social Impact of Innovative Medicine

ABOUT THE VALUE BALANCING ALLIANCE'S HEALTH CLUSTER

The Value Balancing Alliance e.V. (VBA) is a growing not-for-profit alliance with the common goal to change the way company performance is measured and valued. The alliance's objectives are to develop, test, and pilot a standardised impact accounting methodology.

The VBA's Health Cluster was established with the objective of driving industry-specific impact accounting guidelines tailored to the needs of the healthcare sector. It comprises several prominent international companies within the industry, including Bayer, CSS, Dräeger, Novartis, Roche, and Sana Kliniken. The alliance receives support from the four major professional services networks—Deloitte, EY, KPMG, and PwC—as well as from other research organizations such as WifOR.

The health cluster has utilized its expertise to establish a methodology focusing on the industry-specific product impacts of the health sector, complementing other industry-agnostic indicators. As of the end of 2023, several cluster members have initiated pilot projects to test and continue enhancing this methodology.

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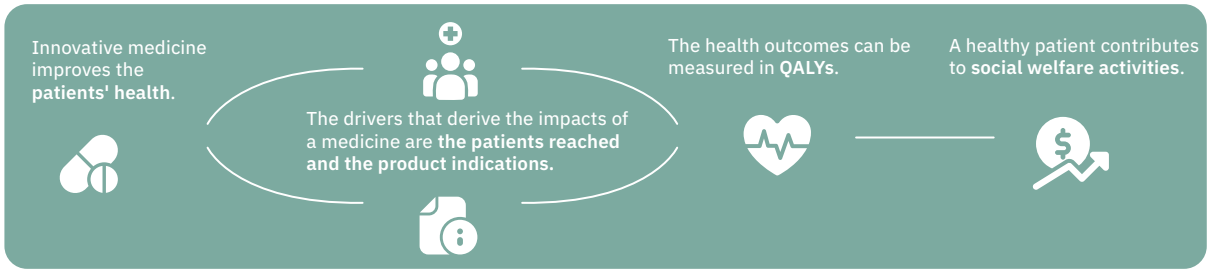


Innovative medicine

The purpose of this document is to outline the methodology to measure the product impact of innovative medicines based on a social perspective. It focuses on the health effects produced by pharmaceuticals for human use - i.e., substances which are used in or administered to human beings to restore, correct or modify physiological functions - with respect to the standard of care (SoC).

The impact drivers: PRs and PIs

To understand the consumer or patient-related impacts of the pharmaceutical industry, the impact drivers considered are the patients reached (PR) and product indications (PI).

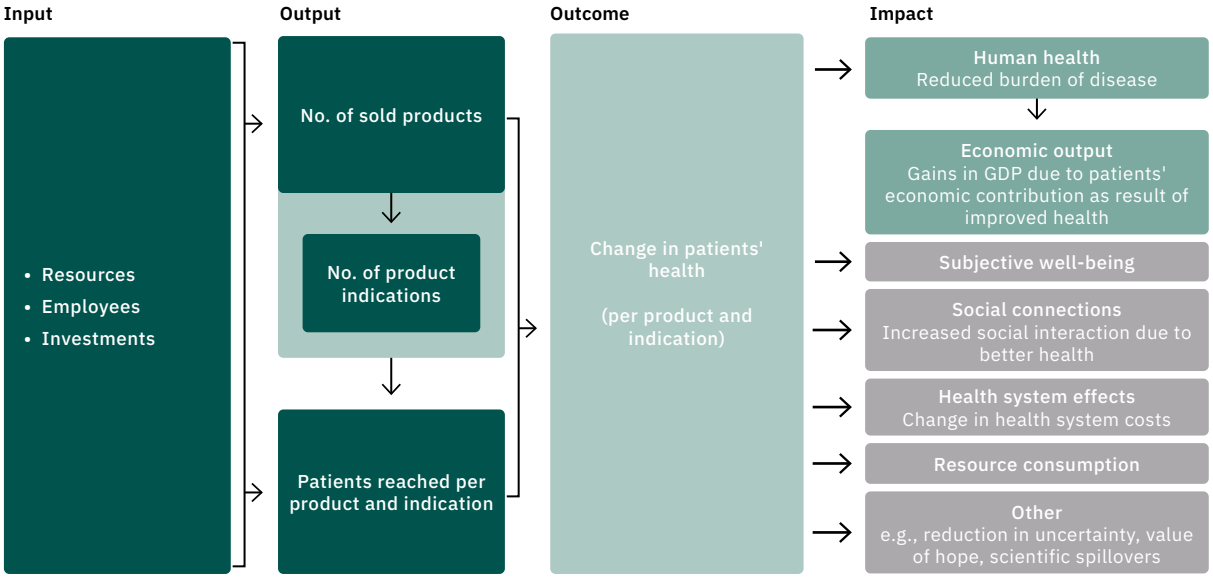
Change in patients' health: the QALYs

In line with many empirical studies, this methodology employs the concept of quality-adjusted life years (QALYs). Each year of perfect health is considered as 1 QALY, while lower values represent a decrease in health-related quality of life during that period. As for every medicine one or more specific approved indication exists. the QALYs must be defined for each indication separately.

Societal value of a QALY

To measure it, this document introduces a methodology for measuring and valuing the social impact of medicines, which focus on the social and economic perspective.

IMPACT PATHWAY



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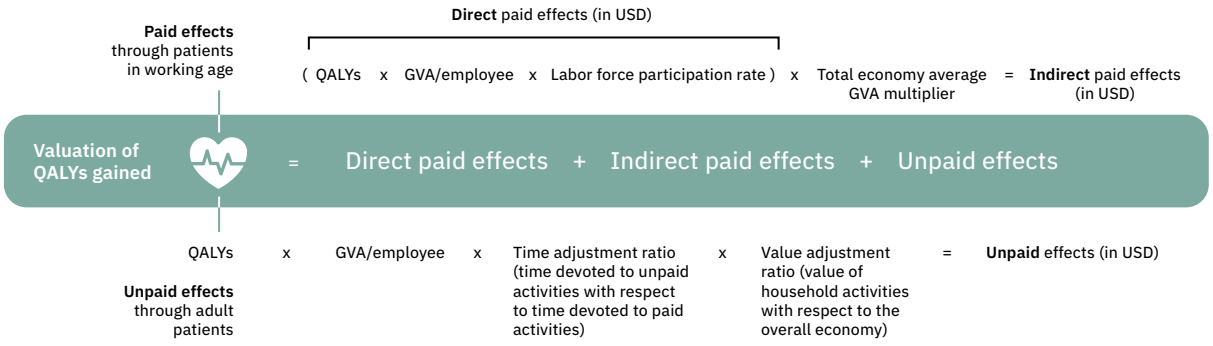

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1.

INTRODUCTION

1. INTRODUCTION

1.1 DOCUMENT PURPOSE

The purpose of this document is to outline a methodological approach to measuring the product impact of medicines. The impact methodology is designed for measuring and valuing the impact of medicines-based health interventions and pharmaceutical activities in monetary terms.

This document focuses on a **specific case study: the social impact of innovative medicines**. Improving the health of patients result in time gained for activities contributing to social welfare. With this perspective, the methodology measures the economic activity generated through paid and unpaid effects.

This draft methodology has been **developed for piloting by VBA's health cluster**. It has not received formal approval as part of the impact accounting methodology produced in partnership by the International Foundation for Valuing Impacts (IFVI) and VBA, and governed by an independent Valuation Technical & Practitioner Committee (VTPC). Piloting the methodology serves as a valuable effort to provide relevant information for decision-making to companies and to evaluate different valuation techniques, which will assist IFVI and the VBA in their methodology development process. It is worth noting that any methodology developed by the partnership and approved by the VTPC may differ from the information presented in this document.

This methodology is applicable for assessing and quantifying the influence of an entity's impact on society by evaluating the downstream effects of innovative medicines on the economic system and society. The resulting information may be used to inform the decisions of:

a) managers of the entity: measuring the triggering stakeholder effects of business decisions related to medicines on society and the economy in the downstream phases of the value chain;
b) existing or potential investors, lenders, and other creditors: informing investment decisions based on the social importance of an entity's downstream phases; and
c) affected stakeholders: public administrations, health institutions, and other affected stakeholders, understanding the social perspective of the health impacts produced by a specific entity in a region beyond purely clinical effects.

This methodology aims to align with other existing developments, such as the Value Balancing Alliance (VBA) downstream sector agnostic guidance, especially when considering a pragmatic approach for impact measurement and providing valuation methods based on publicly available resources. It also aligns with other frameworks mentioned in the guidance, such as the well-being perspective and life cycle assessment, particularly on the use phase.

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1.2 THE HEALTH CARE SECTOR AND THE SOCIAL IMPACT OF MEDICINES

The health care sector is essential for sustaining and improving human well-being.[1] The World Health Organization (WHO) defines health as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity".[2] and health is a fundamental human right.[3] Health care can be defined as a multifaceted system dedicated to promoting and preserving the well-being of individuals by providing products and services focused on preventing and treating illnesses and enhancing overall health.[4] Therefore, the importance of health care entities is crucial for the well-being of individuals, which, in turn, is critical for the flourishing of societies.

In recent years, there has been a particular focus on examining the impacts produced by organizations,[5] and health care entities have been no exception. Even though there is an emphasis on environmental and governance topics[6] – similar to other industries – the specific nature of health care products and services stresses the importance of the social dimension.[7] In addition, the long-standing history of research in the health care field has led to the design of methods and techniques to measure and integrate health outcomes resulting from various treatments in decision-making processes. Some of these have become mandatory requirements to demonstrate the effectiveness of specific treatments, enhancing entities' maturity in measuring health outcomes and social impacts, particularly in the pharmaceuticals industry.

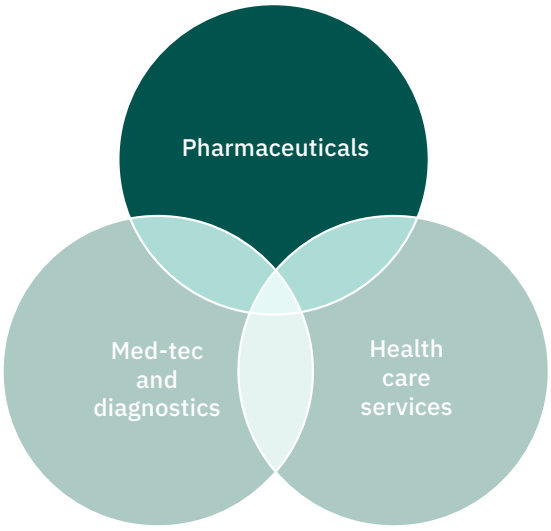

Figure 1: The health care sector[8]

1 Lenzen et al (2020): The environmental footprint of health care.

2 World Health Organization Constitution (1946).

3 United Nations (1947): Universal Declaration of Human Rights.

4 Institute of Medicine (2001) Committee on Quality of Health Care in America.

5 G7's Impact Task Force (2021): Time to Deliver.

6 Deloitte (2022): Global Health Care Outlook.

7 MSCI (2023): ESG Industry Materiality Map, Health Care, S&P (2023): Health Care Key Sustainability Factors, SASB (2023): Materiality, Health Care.

8 VBA (2022) a division proposal based on NACE, UN ISIC, Global Industry Classification Standard, WHO, S&P, MSCI and SASB.

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In this sense, the field of health economics has attracted special attention when it comes to quantifying the health impacts of medicines, with the results widely utilized in cost-benefit analyses in both the public and private sectors.[9] Furthermore, certain pharmaceutical entities are extending the use of this expertise beyond regulatory requirements, aiming to measure their impacts.[10] [11] As a result, part of the initial sectorial focus of the impact accounting movement was also placed on the impact of medicines.[12] Using the existing research as the foundation for the pharmaceutical industry's product impact framework, this paper therefore centers on the social impact of innovative medicines.

To measure social impact, this document introduces a methodology grounded in **the initial approach as outlined by WifOR and Novartis** for measuring and valuing the social impact of medicines, which focuses on the **social and economic perspective**. The primary goal of the framework is to provide insights into the **value that medical R&D brings to societies** and to interested parties such as payors, investors, and other stakeholders. For this purpose, the methodology involves a quantification of patients' health outcomes resulting from innovative medicines in comparison to the standard of care (SoC) scenario and then applies a valuation factor based on the time gained for activities contributing to social welfare as a result of improved health outcomes. In this sense, activities contributing to social welfare encompass both paid and unpaid work, reflecting contributions to societal well-being beyond economic measures like GDP. This includes not only the direct GVA effects generated by healthier patients, but also household chores, caregiving responsibilities, and voluntary activities often overlooked in conventional assessments. Additionally, our approach acknowledges the indirect effects of productivity changes within the economy, recognizing the interconnectedness of various sectors and the ripple effects of healthier societies. As a result, the findings extend beyond pure clinical benefits, measuring the incremental effects produced by medicines on the economy and society.

9 A definition of public and private sector can be found in World Health Organization (2002).

10 WifOR Institute (2021): Social Impact of innovative medicines – a systematic approach to capture the societal and macroeconomic dimension of medicines. A Meta-Study for Novartis.

11 Roche (2017): Natural Capital Protocol Pilot Study.

12 See for example Harvard Business School's Impact Weighted Accounts (2021): Accounting for product impact in the pharmaceutical industry.

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2.

TOPIC BACKGROUND

2. TOPIC BACKGROUND

2.1 DEFINITION OF KEY CONCEPTS AND IMPACT DRIVERS

Downstream activities cover all activities and business relationships mainly linked to distribution and transportation, product use by consumers and end-users, and product end-of-life. As each industry has a distinct effect on consumers as well as other stakeholders, addressing downstream impacts in a general and industry-agnostic manner is challenging. This industry-specific methodology aims to explore the further impacts related to the **use phase** of innovative medicines.

In the context of medicines, the main **impacts** – which can be defined as changes in one or more dimension of people's well-being directly or through a change in the condition of the natural environment – are produced directly through **changes on human health**[13] and indirectly through fostering of thriving societies as healthy individuals enjoy extra time for activities **contributing to social welfare**.

To understand the patient-related impacts of the pharmaceutical industry, the **impact drivers** of medicine need to be defined. Impact drivers can be described as the sequence of an entity's inputs and outputs that may have positive and/or negative effects on people's well-being. When measuring the impacts of medicines, there are two main drivers to consider: patients reached and product indications (see Figure 2).

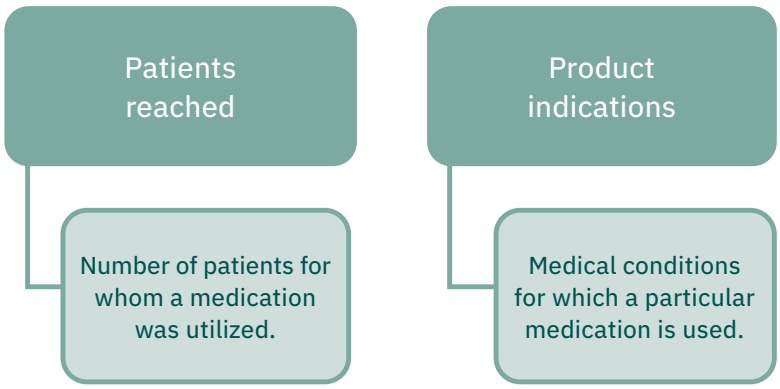

Figure 2: Impact drivers to address the social impact of medicines

To measure the impact of medicine, as a first step, the number of patients for whom a medication was utilized needs to be defined—also termed **patients reached (PR)**. PR numbers could be presented in a detailed way (e.g., per product, country, and year) or in a more aggregated manner (e.g., a cluster of products, countries, and years).

The pharmaceutical products may have different uses and applications. As defined by the European Medicines Agency (EMA) an **indication** is a medical condition that a medicine is used for. This can include the treatment, prevention, and diagnosis of a disease.[14]

13 See key dimensions of the OECD well-being framework; OECD (2020). Well-being framework, How's Life?

14 European Medicines Agency: Indication.

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Generally, the value of medicines is derived from the **health outcomes** that they can create for patients.[15] In line with empirical studies, this methodology utilizes the concept of quality-adjusted life years (**QALYs**) to measure the health outcome of medicines. A QALY is a measure frequently used in health economics to assess the quality and quantity of life a person gains as a result of a medical intervention or treatment. It combines both the length of life (quantity) and the quality of life (utility) into a single metric.[16] Each year of perfect health is considered 1 QALY, while lower values represent a decrease in health-related quality of life during that period. QALYs provide a net standardized and quantitative way to compare the impact of different health care interventions, policies, or treatments on patients' well-being. Because for every medicine one or more specific approved indication exists, the QALYs must be defined for each indication separately.[17]

Clinical studies often use QALYs to quantify what additional benefits a medication can deliver compared to the SoC for patients in various age groups. The term SoC defines established pharmaceutical treatments – or, in some cases, other therapeutic interventions – against which new products are compared in clinical and pharmacoeconomic trials. If no active comparison is available, the comparator may be a placebo or a no-treatment setting, subject to ethical considerations, particularly in situations where withholding standard treatment could significantly impact patient health.[18] The SoC can vary over time and by geographical region, as it is influenced by current medical practices and guidelines, which are subject to change.

This approach significantly streamlines the process of impact **attribution**. By focusing on comparison with the SoC, it directly links health outcomes to the specific pharmaceutical intervention, thus bypassing the complexities involved in disentangling contributions of various actors within the patient journey. Employing SoC as an important and widely accepted reference scenario for determining product impact on patients in the pharmaceutical industry also serves as an effective approach to attribution of product impacts. Pharmaceutical entities are integral parts of a broader value chain. Therefore, impacts on patients' health may need attribution to different actors along this journey. Comparing the health outcomes produced by the medicine under study with those of the SoC allows for the isolation of the product's impact from the influence of other actors in the value chain.

As a result, SoC comparison provides a clear and precise analysis of the medicine's impact, which is crucial for stakeholders who depend on robust and unambiguous data.

Furthermore, the SoC also serves as a clear **benchmark for innovation** in treatment development. This sets the basis that medical R&D strives to surpass to ensure better health care for patients worldwide.

15 WifOR Institute (2021): Social Impact of innovative medicines – a systematic approach to capture the societal and macroeconomic dimension of medicines. A Meta-Study for Novartis; ISPOR (2021): Defining Elements of Value in Health Care.

16 Whitehead et al. (2010): Health outcomes in economic evaluation: the QALY and utilities.

17 WHO (2020): WHO methods and data sources for global burden of disease estimates 2000-2019; Caro, J. J., et al. (2019): Determining value in health technology assessment: stay the course or tack away?

18 Moffett et al (2011): The Standard of Care: Legal History and Definitions.

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2.2 SCOPE OF THE PRESENTED METHODOLOGY

The methodology is designed to assess the impact of innovative medicines on patients' well-being, with a primary focus on their health and valued from a social perspective via the socioeconomic effects of medical care.

This guidance focuses on in-market **pharmaceuticals** for human use, i.e., substances used in or administered to human beings to restore, correct, or modify physiological functions. Pharmaceuticals for human use are further specified by the Anatomical Therapeutic Chemical (ATC) classification scheme based on their therapeutic function. To maintain clarity and uniformity in communication, we consistently use the terms 'medicines' throughout this document. Products with the sole purpose of medical diagnosis (e.g., X-ray contrast agents), medical devices, food supplements, personal care products, bulk chemicals, or veterinary medicines are not initially covered by this guidance. However, some rules may also be applicable for such similar product groups.[19]

With the aim of capturing the main social **downstream impact** of pharmaceutical products, the methodology encompasses the **main health outcomes** resulting from the utilization thereof. This includes assessing the impact of medicines on patients' health with QALYs as a measure of well-being. Thus, in this methodology, the QALY metric serves as a measure of the relative changes in the health of patients due to the effects of innovative medicines, isolating other factors by taking the SoC as a reference scenario.[20] [21] This is particularly significant because it allows the focus to be on the **innovative effects** and the value added by R&D activities in the pharmaceutical industry. By not considering the effects already fulfilled by the SoC, the methodology directs attention towards the unique contributions of innovative products, thereby highlighting the advancements made through R&D.

There are additional downstream impacts that are not captured by this methodology. These include, among others, equitable **access to medicines,**[22] [23] marketing and **sales practices,**[24] [25] and potential **environmental consequences** resulting from increased resource usage due to longer human lifespans. Although some of these topics may be touched upon in the current methodology – e.g., some of the patients reached are certain population groups for which access to pharmaceuticals is guaranteed – they constitute a field for future research.

19 Definition retrieved from Siegert et al. (2019): Product Category Rules (PCR) for pharmaceutical products and processes.

20 In some cases, alternative metrics such as the disability-adjusted life years (DALYs), Life Years Saved (LYS) or Life Years Gained (LYG) can also be used to calculate the medicines' health benefits on patients.

21 Some researchers have outlined other health impacts that could be measured beyond QALYs. See WifOr Institute (2021): Social Impact of innovative medicines – a systematic approach to capture the societal and macroeconomic dimension of medicines. A Meta-Study for Novartis and ISPOR (2017): Defining Elements of Value in Health Care—A Health Economics Approach: An ISPOR Special Task Force Report.

22 IWA (2021): Accounting for the product impact of medicines; SASB (2023): Industry material topics, MSCI (2023): Materiality Map; S&P (2023): CSA Weights.

23 Barros (2010): Pharmaceutical policies in European countries; Berndt et al (2010): Pricing and reimbursement in US pharmaceutical markets.

24 IWA (2021): Accounting for the product impact of medicines, SASB (2023): Industry material topics; S&P (2023): CSA Weights.

25 Chandra et al (2014): The impact of patient cost-sharing on low income populations: Evidence from Massachusetts.

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Special cases like **adverse effects** or **product recalls**[26] can be considered included within the scope of this methodology. When computing health outcomes in QALYs, in most cases, a net impact perspective is taken, including potential adverse effects or issues related to product quality management.

Moreover, there are other important impacts of medicines **beyond pure health outcomes** that could be considered, such as the social value of reducing uncertainty, the loss of fear of contagion, the value of hope, or scientific spillovers,[27] but these have been left out in this first approach in order to focus a robust valuation of the impact of medicines on health.

26 IWA (2021): Accounting for the product impact of medicines, SASB (2023): Industry material topics, MSCI (2023): Materiality Map; S&P (2023): CSA Weights.

27 ISPOR (2017): Defining Elements of Value in Health Care—A Health Economics Approach: An ISPOR Special Task Force Report.

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3.

IMPACT PATHWAY

3. IMPACT PATHWAY

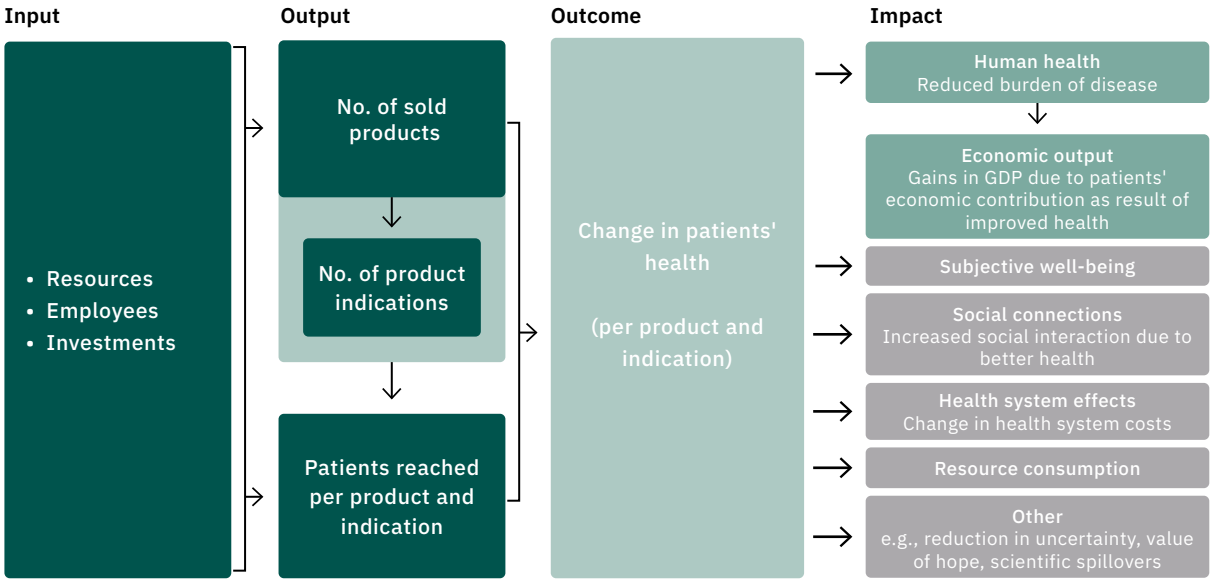

Figure 3: Simplified impact pathway for impact of medicine

The presented methodology concentrates on the social impacts related to the product effectiveness of medicine and its effects on patients' health.

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4.

IMPACT DRIVERS AND OUTCOME MEASUREMENT

4. IMPACT DRIVERS AND OUTCOME MEASUREMENT

The social impact of medicines is calculated based on three main elements: the number of consumers who benefit from these medicines (i.e., the patients reached or *PR*); the different uses or indications of each product (signalled as *i* in the equation below), and the quality-of-life improvement expected for each indication (represented by *QALYs)*.

$$\text{QALYs gained} = \sum_{i=1}^{n} \text{QALYs}_i * \text{PR}_i$$

Simplified health outcomes measurement formula[28]

Hence, the health outcomes produced by medicines can be derived from a defined set of input parameters, which will be explained in more detail in the following sections.

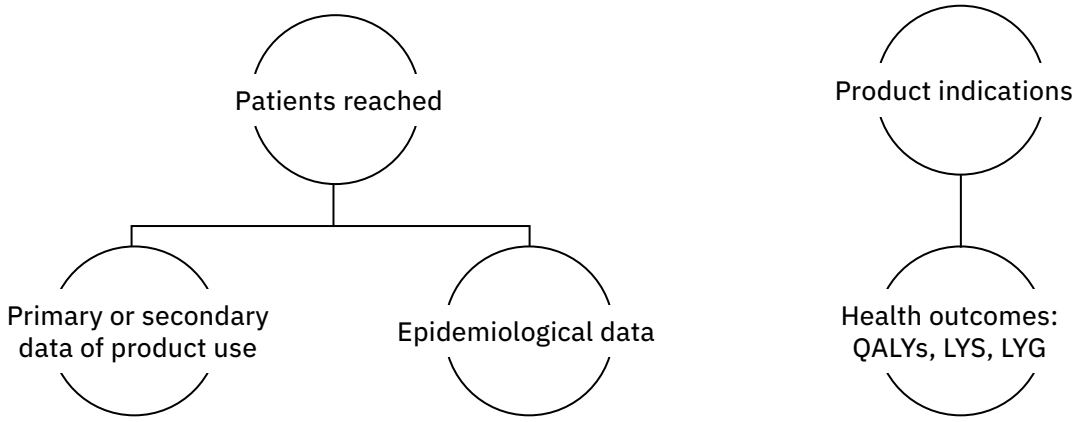

Figure 4: Information inputs for health outcome measurement

4.1 NUMBER OF PATIENTS REACHED (PR)

The number of patients reached is quantified per entity, per product or family of products, and per country in scope for a given year. It is important to note that there is not an established standard to calculate this figure.

When estimating patients reached, a common approach is considering volumes sold and factors such as dosage, treatment duration, and adherence to treatment for chronic treatments over a one-year time horizon. If one person requires multiple products, these may be accounted for separately in the entity's calculations.

28 The QALYs gained could be further subject to additional statistical adjustments. For instance, if annual discounting is performed, the annual undiscounted QALYs should be calculated (see section 5.3 "Calculating and adjusting QALYs gained").

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PRIMARY OR SECONDARY PRODUCT USE DATA

If available, primary data on patients reached should be used. Alternatively, the respective entity could provide forecasted PR figures based on indirect sources or estimations from market data.

EPIDEMIOLOGICAL DATA

For medicines with more than one indication, the patients reached data need to be distributed across the various existing indications. This is based on the reported prevalence data for each indication, i.e., each disease entity. This is termed 'Global Prevalence'.

Example

- → A product X has 4 SPC labels with 4 different cancer types.
- → Each indication (cancer type) has a prevalence.
- → Cancer A 0.2; Cancer B 0.4; Cancer C 0.009; Cancer D 0.02
- → The share for every indication is calculated by dividing the indication prevalence by the sum of all prevalence:
- → Cancer A share= 0.2/(0.2+0.4+0.009+0.02)= 0.32
- → Then 32% of the patients reached for product X will be assigned to the indication "Cancer A".

In addition, distribution of each disease entity across the age-groups used in the model is needed to allocate patients reached to these age groups. This age-specific prevalence is termed 'proportional prevalence'.

Prevalence data can be extracted from the Global Burden of Disease (GBD) study. If the disease pertaining to an indication is not available in the GBD database, prevalence data should be extracted from the literature.

4.2 PRODUCT INDICATIONS

The approved indications of each product, as they are described in the Summary of Product Characteristics (SPC) under "Therapeutic Indications", should serve as the basis for determining the QALYs. The reasoning for this is that each product sale is generated by a prescription, which is based on approved product indications. Literature research on clinical studies that assess the QALYs can be helpful when assessing the health outcomes of each product and indication. If empirical studies on QALYs are not available, results on Life Years Saved (LYS) or Life Years Gained (LYG) can be used alternatively as proxies.

The challenge with this approach is the occasional diversity in approved indications from one country or one continent to another. On the occasions where such diversity exists, **the EU (or the UK) SPC is preferred** and, if not available, the Product Information approved by the United States Food and Drug Administration (**FDA**). On certain occasions, a national SPC could be used instead.

The SPCs can be retrieved directly from the websites of the health authorities (e.g., EMA or FDA). Cross-checking of the approved indications between EU and USA SPC is recommended as a control to verify that there are no important discrepancies between the approved indications in the two markets.

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HEALTH OUTCOMES: QALYs

When analyzing the role of each product's effect on improving health, product indications can serve as a robust science-based tool. Thus, the SPC should guide the literature research on the QALYs associated with each product as well as other aspects such as the choice of the SoC selected as reference scenario.

Careful consideration should be given to all parts of the SPC, particularly where the posology and eligible for treatment populations are described, so that the choice of selected literature for QALYs is aligned with these specific attributes.

The literature search should be based on **peer-reviewed journals**. If no peer-reviewed publications can be found, the search is extended to **grey literature or further evidence.**[29] QALYs are selected, as they allow demonstration of health outcomes across diverse diseases. The incremental undiscounted QALY gains, compared to the SoC or another suitable comparator, should be calculated for the average patient for one year.

A major challenge is the fact that the publications reporting QALYs are in most cases originated in mid or high-income countries and thus the SoC and the therapeutic approach are not necessarily the same as in the low-income countries. Accordingly, it is advisable to opt for the **most broadly used therapeutic approach,** so that the most widely used SoC is considered. Comprehensive literature searches could be conducted via:

- → MEDLINE (accessed through PubMed)
- → ISPOR[30]
- → Other search engines (e.g., Google Scholar)

The objective is to identify published economic evaluations quantifying QALYs as the utility/effectiveness measure for every indication and medicine included in the study.

CRITERIA FOR SELECTION OF PUBLICATIONS

When multiple suitable publications are available for one medicine and indication, the selection of the best match should be based on the criteria listed below. The more criteria are fulfilled and prioritized in an ordinal fashion, the more the literature will offer an overall closer match to the country and disease indication of interest when comparing competing sources:

- → Overall quality of the study (determined by different factors, e.g., model used, inclusion/exclusion criteria, duration, the way the methodology and the results are detailed, institution, etc.)
- → Country of origin (e.g., experience in health technology assessments, etc.).
- → Population of the study
- → Strength and pharmaceutical form of the study medicine
- → Comparator
- → Year of the study

29 Grey literature typically encompasses non-peer-reviewed publications, often issued by organizations—whether for-profit or not-for-profit—that possess specialized knowledge and expertise on a particular subject. Examples include publications from scientific societies, patient associations, and entities such as the World Health Organization (WHO).

30 Accesible via ISPOR's search site.

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ASSUMPTIONS/STRATEGIES FOR MISSING QALY INPUTS

Several assumptions may be applied to handle missing inputs. Whenever literature reporting QALYs are not available, **LYS/LYG** can be used as an alternative metric for health gains. When QALYs and LYS/LYG are not found for a specific indication or medicine, the **Anatomical Therapeutic Chemical (ATC)**[31] classification system can be used to derive QALYs/LYS/LYG for proxy active molecules that are nearest in classification to the medicine in question. Almost always, the proxy molecule derives from the ATC4 group, meaning that it has the same route of administration and a similar mode of action. Attention should be drawn to ensure that the proxy molecule, even if it belongs to the same ATC group, does not substantially differ in terms of chemical and pharmacological properties (e.g., structure, efficacy, or safety).

For medicines for which QALY data are not available, one of the two approaches below is recommended:

- → If a proxy active molecule is indicated for the same disease or condition, then it should be used.
- → Otherwise, the minimum calculated QALY value from the entire portfolio in scope is applied as a conservative proxy.

"FULL-IMPACT" INCREMENTAL QALY

If comparisons are made against another medicine from the same family of molecules or the same generation of treatment medicines or indications because no publications are available for a medicine estimating QALYs compared to a SoC or another suitable comparator such as best supportive care (BSC), a previous-generation treatment that can be assimilated to SoC, surgery, placebo or no-treatment, then the "full-impact" QALY is calculated by combining the outcomes of the following two-step QALY search process:

- → **Step 1:** QALY data of the medicine of interest against a comparator different from SoC or placebo
- → **Step 2:** QALY data of the comparator from study in step 1 against the SoC or placebo

4.3 CALCULATING AND ADJUSTING QALYS GAINED

ANNUAL QALYS GAINED

After extracting medicine and indication-specific QALY information from the literature, the incremental undiscounted QALY gains of innovative medicines compared to the SoC should then be calculated for the average patient for one year. For medicines with multiple indications, the epidemiological weight based on the Global Prevalence estimates should be used to distribute the patients across different indications.

31 A definition of the ATC classification can be found in the World Health Organization.

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Subsequently, the QALY estimates for every medicine and indication are multiplied by the number of PR to the corresponding medicine and indication in the country and reporting year of the analysis, with the result that:

1. PR are distributed among the indications of the medicine depending on the prevalence of the indications.
2. The annual QALY is calculated for each medicine-indication combination and each PR is assigned the corresponding annual QALY gain (per patient).

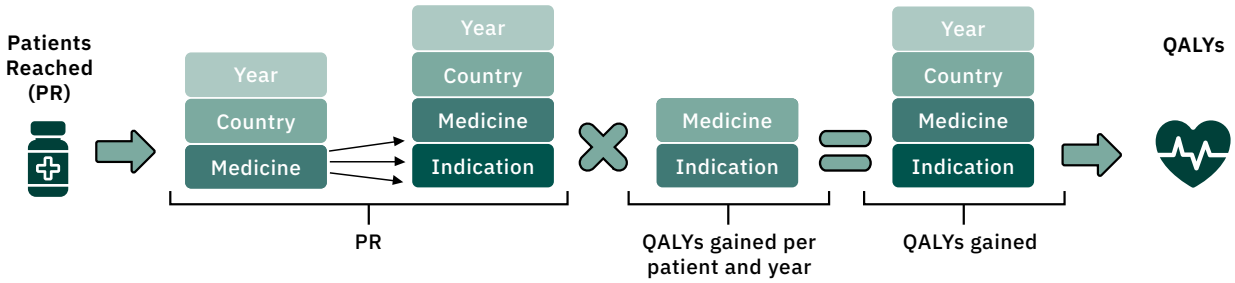

Figure 5: From patients reached and product indications to QALYs

To calculate the annual QALYs gained from the total QALYs gained over a given time horizon – which are usually discounted – the discounted total QALY needs to be undiscounted, which is done using the following approximation:

$$udQALY_{m,i} = dQALY_{m,i} \times (1 + r)^{TH/2}$$

undiscounted total QALYs gained per medicine and indication: $udQALY_{m,i}$

discounted total QALYs gained per medicine and indication: $dQALY_{m,i}$

discounting rate: r

time horizon: TH

The annual undiscounted QALYs gained $aQALY_{ud}$ are then calculated by dividing the undiscounted total QALYs gained by the time horizon:

$$a\_udQALY_{m,i} = \frac{udQALY_{m,i}}{TH}$$

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QALYS GAINED BY INDICATION AND AGE GROUP

The formula to calculate the patients per indication and age share from the total patients reached by the entity for a specific product and country is the following:

$$PR_{c,m,i,a} = PR_{c,m} \cdot iw_{m,i} \cdot pp_{i,a}$$

Patients reached per country and medicine (given by customer): $PR_{c,m}$
Patients reached per country, medicine, indication and age group: $PR_{c,m,i,a}$
Proportional prevalence per age group for indication i: $pp_{i,a}$

The indication weight reflects the proportion of an indication over the overall indications of a product. To obtain it, the global prevalence of each indication can be used to calculate the share accordingly:

$$iw_{m,i} = \frac{p_{m,i}}{\sum_{i=1}^{k} p_{m,i}}$$

Indication weight of indication i from a product: iw_i
Global prevalence of indication i from a product: $p_{m,i}$

From the patients reached per country, medicine, indication, and age group, the total number of QALYs gained per country, medicine, indication, and age-group can be calculated by convolution with the undiscounted QALY per patient per year (annual QALYs gained):

$$QALY_{c,m,i,a} = PR_{c,m,i,a} \cdot a\_udQALY_{m,i}$$

Example: The health benefit calculation of product *m*

Indication *i*	**Patients Reached (PR_c)**	**Indication weight (iw_i)**	**QALY (undiscounted) per patient year (a_udQALY_i)**	**Proportional prevalence ($pp_{i,age}$)**		
				<20	**20-59**	**≥60**
Post-MI	10,000	40%	0.05	0%	40%	60%
Essential Hypertension		30%	0.002	0%	70%	30%
Chronic heart failure		30%	0.001	0%	20%	80%

Example QALY calculation for product *m* and indication “Post-MI”:

<20: 10,000 · 0.4 · 0.05 · 0 = **0** QALYs gained
20-59: 10,000 · 0.4 · 0.05 · 0.4 = **80** QALYs gained
≥60: 10,000 · 0.4 · 0.05 · 0.6 = **120** QALYs gained

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5.

IMPACT AND VALUATION

5. IMPACT AND VALUATION

5.1 SOCIOECONOMIC VALUATION BASED ON PRODUCTIVITY APPROACH

This methodology is based on the valuation of the socioeconomic effects that come along with a more healthy and productive population due to the use of pharmaceutical products in a specific region.

The estimation model of the socioeconomic impacts directly builds on the results from the quantification of health outcomes by measuring the value-added effects created through gained productive time due to medicine treatment. When valuing health outcomes with a productivity approach, the primary assumption is that gaining QALYs leads to an increase in productive time as a patient's life expectancy and quality of life increases, thus generating direct and indirect effects on economic output.

Therefore, once the health benefits, i.e., the QALYs gained compared to standard of care and stratified by countries, medication, indication, and years are quantified, the QALYs can be monetized in terms of potential welfare effects as measured by the Gross Value Added (GVA).

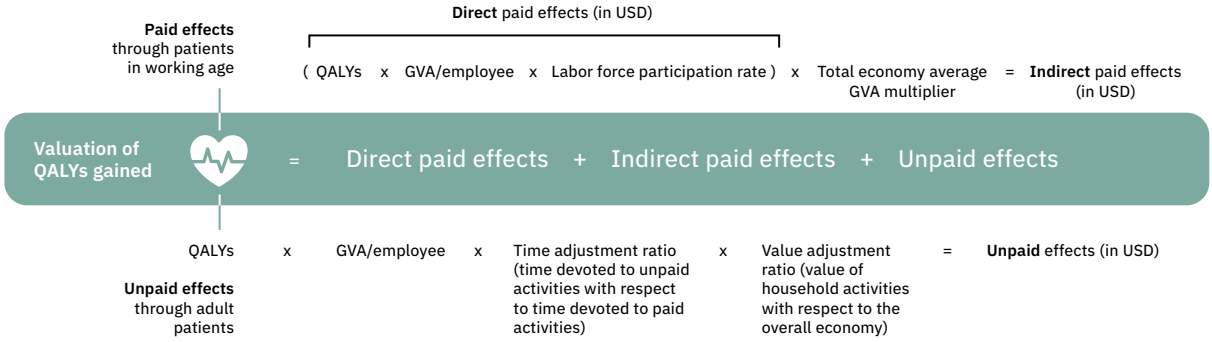

Figure 6: The social impact of medicines valuation technique

In this valuation approach, three different productivity effects are estimated:

1. **Direct paid effects:** A healthier and longer-lived population is able to participate on the labour market for a longer time, thus contributing to economic welfare.
2. **Indirect paid effects:** An increase in production triggers further production of intermediate goods and services in other industry sectors, creating the so-called *indirect* GVA effects. Indirect effects are effects arising due to the input an industry demands from other economic agents. Order placements result in an increase of economic activity at commissioned agents and their suppliers. This stimulus increases GVA and other key economic figures along the supply chain.
3. **Unpaid effects:** Beside participating in the labor market, a healthier and longer-lived population is also able to spend their time on unpaid activities like housework, volunteering, or caring. While these activities are not measured by the national accounting system, they contribute considerably to social welfare beyond GDP. We approximate these welfare effects in monetary terms by applying GVA estimates from comparable market activities.

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SOCIOECONOMIC INPUT PARAMETERS FOR IMPACT VALUATION

To calculate the change in economic output due to the health outcomes produced by the use of an entity's products, the following country-specific socioeconomic input parameters should be considered:

- → GVA per economic active person
- → Labor force participation rate
- → Indirect GVA multiplier (economy average)
- → Time adjustment ratio (unpaid/paid)
- → GVA adjustment ratio (unpaid/paid)

The following sections, describe the calculation of these parameters as well as the recommended data sources. When multiple data sources are available, a prioritization is indicated. For instance, the labor force data can be retrieved from the World Bank Development Indicators database, which is considered **priority 1**. Where data is missing, the national statistical office (NSO) database could be used and is considered **priority 2**. In some cases, when no inputs are available for a specific country, proxy countries for which data is available can be used.

GVA PER ECONOMIC ACTIVE PERSON

Direct paid GVA effects are monetized using the labor productivity of the working population in the society, which can be expressed as the **GVA contribution of the average worker** measured by GVA per employee in USD. Therefore, the total GVA (at basic prices; measured in USD) $GVA_{c,t}$, is divided by the size of the labor force ($L_{c,t}$) in the respective country $_c$ and year $_t$:

$$GVA\ per\ economic\ active\ person_{c,t} = \frac{GVA_{c,t}}{L_{c,t}}$$

The GVA and labor force information can be extracted from the following sources (in descending priority):

- → World Bank Development Indicators[32] in the year of the analysis
- → World Bank Development Indicators in the most recent year available
- → UN National Accounts[33]
- → National statistical office

32 The World Bank. World Development Indicators; https://databank.worldbank.org/source/world-development-indicators.

33 United Nations (UN), Statistics Division. National Accounts Main Aggregates Database.

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LABOR FORCE PARTICIPATION RATE

The labor force participation rate is the proportion of the population aged 15 and older who are actively **engaged in the workforce**.[34] In other words, all people who supply labor for the production of goods and services during a specified period.

This input can be directly extracted from the listed sources (in descending priority) and, therefore, does not need to be calculated:

- → World Bank Development Indicators
- → National statistical office

TOTAL ECONOMY AVERAGE GVA MULTIPLIER: INDIRECT

The indirect total economy-wide average multiplier is used to identify indirect GVA effects from paid work and is calculated by taking the **indirect GVA effects in the economy** and dividing them by the direct GVA effects in the economy:

$$Total\ Economy\ Average\ multiplier\ indirect\ _c = \frac{\sum_{j=1}^{n}\left(GVA_{c,j} * indirect\ multiplier_{c,j}\right)}{\sum_{j=1}^{n} GVA_{c,j}}$$

Where:

$indirect\ multiplier_{c,j}$ is the indirect multiplier[35] in sector *j* and in the corresponding country.

The following sources can be consulted to obtain the inputs to calculate the indirect total economy wide average multiplier (in descending priority):

- → WIOD[36] country c
- → EORA[37] country c
- → WIOD proxy country
- → EORA proxy country

34 While the ideal age group for the analysis is 20-60 years, data for 15-64 years from the World Bank serves as the best available approximation, under the assumption that the inclusion of a slightly broader age group does not significantly distort the parameter for our purposes.

35 The sector specific indirect multiplier is calculated via an input output model. The indirect multiplier quantifies the additional economic activity resulting from initial changes in spending or production within a specific sector, illustrating the interconnected impact across various sectors in the economy.

36 Timmer MP, Dietzenbacher E, Los B, Stehrer R, de Vries GJ. An Illustrated User Guide to the World Input-Output Database: The Case of Global Automotive Production: User Guide to World Input-Output Database. Rev Int Econ. 2015;23(3):575-605. doi:10.1111/roie.12178.

37 Lenzen M, Kanemoto K, Moran D, Geschke A. Mapping the Structure of the World Economy. Environ Sci Technol. 2012;46(15):8374-8381. doi:10.1021/es300171x.

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TIME ADJUSTMENT RATIO (PAID/UNPAID)

No statistics exist on the value contribution of one year of unpaid work. Therefore, the paid work productivity is adjusted by the time spent on unpaid work activities relative to paid work activities. This is calculated by **dividing** the gender-weighted **unpaid working hours by** the gender-weighted **paid working hours**:

$$Time\ use\ ratio_{c,t} = \frac{\left[\left(\frac{P_{c,t,m}}{P_{c,t}}\right) * WHU_{c,m}\right] + \left[\left(\frac{P_{c,t,f}}{P_{c,t}}\right) * WHU_{c,f}\right]}{\left[\left(\frac{P_{c,t,m}}{P_{c,t}}\right) * WHP_{c,m}\right] + \left[\left(\frac{P_{c,t,f}}{P_{c,t}}\right) * WHP_{c,f}\right]}$$

Where:

$P_{c,t,m}$ *is the male (m) population in the corresponding country and year;*
$P_{c,t}$ *is the population in the corresponding country and year;*
$P_{c,t,f}$ *is the female (f) population in the corresponding country and year;*
$WHU_{c,m}$ *are the unpaid working hours for males in the corresponding country;*
$WHU_{c,f}$ *are the unpaid working hours for females in the corresponding country;*
$WHP_{c,m}$ *are the paid working hours for males in the corresponding country;*
$WHP_{c,f}$ *are the paid working hours for females in the corresponding country.*

The following sources can be consulted to determine the paid and unpaid working hours (in descending priority):

- → United Nations time use survey[38] country *c*
- → National statistical office
- → United Nations time use survey proxy country

The following sources can be consulted to determine the gender share of population (in descending priority):

- → World Bank in *t*
- → National statistical office in *t*

GVA ADJUSTMENT RATIO (UNPAID/PAID)

Including only a time adjustment ratio would assume that an unpaid working hour has the same monetary value as a paid working hour. Thus, the GVA per economic active person is adjusted

38 United Nations (UN), Statistics Division. Time Use Data Portal. Collection of National Time Use Surveys.; 2017. Accessed September 2020. https://unstats.un.org/unsd/gender/timeuse/

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considering the average GVA contribution of paid work activities which are comparable to unpaid work activities[39] relative to the average GVA sectorial contributions in the overall economy. Therefore, data on sector-specific GVA and employment from the WIOD and EORA database are used. To estimate the GVA per employee in the household sector for the corresponding year, the proportion of the household sector is held constant (in terms of GVA and employment) and the following proportion to the corresponding year is applied:

$$GVA\ per\ emloyee\ sector\ HH_{c,t} = \frac{\left(\frac{GVA\ Sector\ HH_c}{\sum_{j=1}^{n} GVA_{c,j}}\right) * GVA_{c,t}}{\left(\frac{L\ Sector\ HH_c}{\sum_{j=1}^{n} L_{c,j}}\right) * L_{c,t}}$$

Where:

$GVA\ Sector\ HH_c$ *is the GVA in the household sector in the corresponding country in t;*
$\sum_{j=1}^{n} GVA_{c,j}$ *is the sum of GVA over all sectors (j) in the corresponding country in t;*
$GVA_{c,t}$ *is the GVA in the corresponding country and year;*
$L\ Sector\ HH_c$ *is the labor force in the household sector in the corresponding country in t;*
$\sum_{j=1}^{n} L_{c,j}$ *is the sum of the labor force over all sectors in the corresponding country in t;*
$L_{c,t}$ *is the labor force in the corresponding country and year.*

The following sources should be used for the inputs to calculate the GVA adjustment ratio (in descending priority):

- → WIOD country *c*
- → EORA country *c*
- → WIOD proxy country
- → EORA proxy country

Setting this into relation to the average GVA contribution in the overall economy, we calculate a ratio indicating the relative **welfare contribution of unpaid activities relative to paid activities**:

$$GVA\ ratio_{c,t} = \frac{GVA\ per\ economic\ active\ person\ HH_{c,t}}{GVA\ per\ economic\ active\ person_{c,t}}$$

39 Defined by the sector of "Activities of Households as Employers; Undifferentiated Goods and Services Producing Activities of Households for Own Use" according to the International Standard Industrial Classification revision 4 (ISIC Rev. 4) used in the WIOD database or the Eora26 sector classification used in the EORA database.

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VALUE IMPACTS TO SOCIETY

THE MONETIZATION APPROACH TO ESTIMATE THE SOCIAL IMPACT OF MEDICINE

In this methodology, three different productivity effects are calculated:

- → Direct paid effects
- → Indirect paid effects
- → Unpaid effects

To derive the **direct paid GVA effects**, the QALYs gained are monetized by the average annual labor productivity (GVA contributions per economic active person) multiplied with the labor participation rate.

To obtain the QALYs gained in employment, the proportion of patients in the working age is multiplied by (i) the QALYs gained and (ii) the labor force participation rate. The QALYs gained in employment are then multiplied with the GVA contribution per economic active person:

$$GVA\ paid\ direct_{m,i,c,t,a} = Share\ in\ working\ age_{i,t,c} * QALYs\ gained_{m,i,c,a} * labor\ force\ particiaption\ rate_{c,t} * GVA\ per\ economic\ active\ person_{c,t}$$

where m = medicine, i = indication, c = country, t = time, a = age group.

To derive the **unpaid** GVA **effects**, the average monetary value equivalent for unpaid work of one QALY is estimated. This is based on the average labor productivity of one year of paid work (labor productivity).

Two adjustment factors are calculated to adjust paid labor productivity to reflect the monetary value of unpaid work activities in terms of time and value contribution. The time adjustment aims at correcting for differences in time spent in paid and unpaid work, while the value adjustment aims at correcting for differences in value creation between paid and unpaid work activities. The two adjustment factors are:

- → Time adjustment ratio: Gender-adjusted average time spent for unpaid work activities is set in relation to gender-adjusted average time spent for paid work activities. This ratio gives an estimate of how much time is spent for unpaid work activities for each hour of paid work activities.
- → Value adjustment ratio: To adjust for the lower GVA contribution of unpaid work activities, the GVA per economic active person in the household sector is set in relation to GVA per economic active person in the overall economy. This serves as a proxy for the relative value contribution of unpaid work activities and paid work activities.

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The estimate of the monetary value equivalent of one year of unpaid work activities in country *c* and time *t* is calculated by a multiplicative combination of GVA per economic active person and the two adjustment factors:

$$\begin{aligned} &Monetary\ value\ equivalent\ to\ one\ year\ of\ unpaid\ work_{c,t} \\ &\quad = GVA\ per\ economic\ active\ person_{c,t} * Time\ adjustment\ ratio_{c,t} \\ &\quad * GVA\ adjustment\ ratio_{c,t} \end{aligned}$$

Finally, the QALY gains for adult patients are monetized for unpaid work activities using the estimated monetary value equivalent of one year of unpaid work:

$$\begin{aligned} &GVA\ unpaid_{m,i,c,t,a} \\ &\quad = Share\ adults_{i,t,c} * QALYs\ gained_{m,i,c,a} \\ &\quad * Monetary\ value\ equivalent\ of\ unpaid\ work_{c,t} \end{aligned}$$

The monetization approach is summarized in Figure 8.

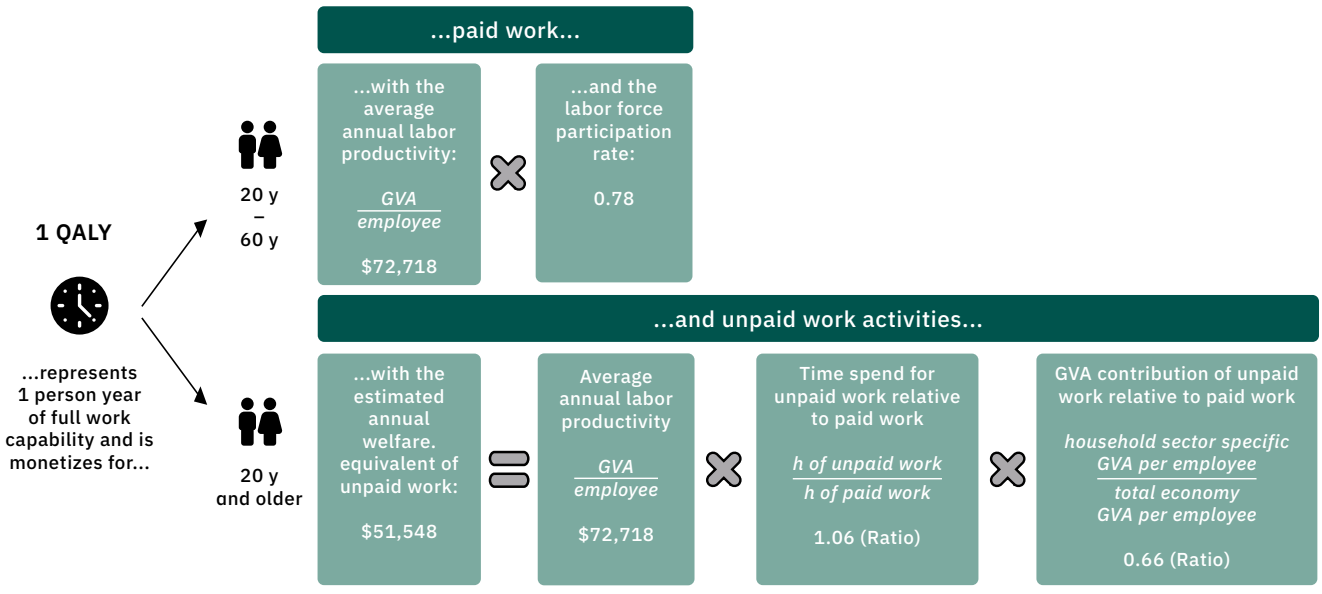

Figure 7. Illustration of the valuation approach of one QALY gained for direct effects of paid and unpaid work (Example values)

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Based on the direct productivity effects, further **indirect** value chain **effects** within the economy triggered by the initial GVA effects are estimated. These are based on industry sector specific Leontief multipliers[40] calculated from the multinational input output databases WIOD and EORA. Indirect effects are calculated by multiplying direct paid effects by the respective multiplier.

$$GVA\ paid\ indirect_{m,i,c,t,a} = GVA\ paid\ direct_{m,i,c,t,a} * Total\ economy\ average\ GVA\ multiplier_{c,t}$$

The social impact of innovative medicines ($SI_{c,m}$) calculation is performed separately by monetizing the QALYs per country, product, indication, and age group. The resulting $SI_{c,m,i,a}$ is summed up by product and country:

$$SI_{c,m} = \sum_{i=1}^{n} SI_{c,m,i,direct\ paid\ effects} + SI_{c,m,i,indirect\ paid\ effects}\ SI_{c,m,i,unpaid\ effects}$$

40 Leontief multipliers, named after economist Wassily Leontief, are coefficients used in input-output analysis to quantify the direct and indirect effects of a change in final demand on the total output of different sectors within an economy. They measure the impact of a unit change in the final demand for a specific sector's output on the total output of that sector and others through inter-industry relationships. Leontief (1972): Input-Output Economics.

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6.

USE CASES

6. USE CASES

Application of the presented methodology to capture the social impact of medicines offers a great range of use cases for actors in the health system, particularly governments, patient organizations, investors, and others who are concerned with pharmaceutical products. Future evolutions of the methodology should be expanded to cover other aspects of the health system and its actors to enable them to use the methodology, both internally and externally.

6.1 FOR BUSINESS STEERING

From an internal perspective, the use cases of the methodology bring to life the general benefits of impact valuation: its comparability across the social, environmental, and economic impact dimensions. Instead of considering a variety of "non-financial" parameters in isolation, all business activities affecting society are brought into one joint view. Monetization elevates non-financial parameters to the same level of relevance as financial parameters.

For practitioners of impact valuation, the social impact of innovative medicines complements the impact valuation results with the downstream perspective and hence allows for a complete view on impact valuation across the entire value chain. In view of the relevance of products for health-related businesses, they represent the key element for embedding impact valuation in this sector.

The greatest benefit of the social impact of medicines is that it translates science into more easily accessible business terms. This in turn allows for uses to non-scientific audiences and can be used, for example, in internal communication to employees beyond established financial performance and progress on Corporate Social Responsibility activities. For most larger pharmaceutical entities, social impact valuation creates a link between business performance and a necessarily qualitative statement of purpose – underpinning it quantitatively. Obviously, if used consistently, it can play an important role in providing inspiration, motivation, and focus to employees.

Furthermore, the social impact of innovative medicines helps to create awareness about the entity's impact on society. It thus sensitizes employees for stakeholder concerns. This goes hand in hand with an increased appreciation for the sources of long-term value creation, or sustainability, of the business.

As the social impact of innovative medicines provides a macro view, or an external perspective on the business, it helps anticipate stakeholder perspectives and to double-down on them by providing an easily accessible language for various engagements.

The methodology can assess the product-related impacts for past performance and enables users of the methodology to forecast future impact performance. This allows a direct link to the strategic plan of the business. Based on the same set of figures, certain aspects of forward-looking decision making support can be provided, for example, for strategic portfolio-shaping decisions and strategic and operational resource allocation decisions. Strategies anchored in a specific therapeutic or geographic setting require contextualization, which can be provided by the social burden of the disease in question. Supporting data would be sourced from reputable references, such as the Global Burden of Disease database.

With the capability available to forecast an entity's impact performance, it is possible to utilize the methodology for target setting and to track progress against such targets.

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6.2 FOR EXTERNAL COMMUNICATION AND STAKEHOLDER ENGAGEMENT

The methodology encompasses an equally wide array of external use cases. On a more general level, it allows expression of a holistic entity profile, also to non-experts in the health sector. Impacts related to the use of products of the pharmaceutical industry complement the impact information in a way that both negative and positive impacts of a corporate footprint are included. Although read-outs from clinical trials provide information on the health effects from a perspective of incremental QALYs, this methodology helps to translate empirical evidence from a language of science into easily understandable business terms. As stakeholders, including governmental representatives and investors, are not all health experts or health care professionals, it is important to provide comprehensive information in an accessible language. As innovative medicines require an improvement over the prevailing standard of care, social impacts of medicines approved for a market are thus, by definition, positive. Providing a comprehensive perspective on these positive impacts related to product use alongside other negative or positive environmental and social impacts elevates the credibility of the methodology. As illustrated by a variety of use cases, the methodology thus complements admission requirements of innovative medicines, often captured by “health-technology assessments”, with the resulting productivity gains for society.

Apart from these general uses that amplify the usability of an entity’s statement of impact, there are health sector-specific topics for which the calculation results of the methodology are particularly well suited. One such aspect is the ask of the G20 ministries of health to understand the return on their investments in health. Any entity using the methodology can directly express their social return on investment for any country in scope of the analysis. As health ministries are a key stakeholder for the health sector, this is an important consideration.

Finally, the impacts calculated with the methodology help link corporate performance to the SDGs, especially SDG 3 – Good Health and Well-being. The methodology helps in expressing how an entity contributes to achieving SDG 3. The SDG-perspective also lends itself to supporting tailored impact investing approaches. Thus, the methodology directly connects to the need and power of establishing functioning health systems in low and middle-income countries and the Global South.

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7. LIST OF ABBREVIATIONS

ATC	Anatomical Therapeutic Chemical
BSC	Best Supportive Care
EMA	European Medicines Agency
GBD	Global Burden of Disease
GDP	Gross Domestic Product
GVA	Gross Value Added
LYG	Life Years Gained
LYS	Life Years Saved
PR	Patients Reached
QALY	Quality Adjusted Life Years
SI	Social Impact
SoC	Standard of Care
SPC	Summary of Product Characteristics

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