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POLICY PERSPECTIVES

Pharmaceutical Portfolio Management: Global Disease Burden and Corporate Performance Metrics



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ABSTRACT

Background: Biopharmaceutical companies face multiple external pressures. Shareholders demand a profitable company while governments, nongovernmental third parties, and the public at large expect a commitment to improving health in developed and, in particular, emerging economies. Current industry commercial models are inadequate for assessing opportunities in emerging economies where disease and market data are highly limited. **Objective:** The purpose of this article was to define a conceptual framework and build an analytic decision-making tool to assess and enhance a company's global portfolio while balancing its business needs with broader social expectations. **Methods:** Through a case-study methodology, we explore the relationship between business and social parameters associated with pharmaceutical innovation in three distinct disease

areas. The global burden of disease-based theoretical framework using disability-adjusted life-years provides an overview of the burden associated with particular diseases. The social return on investment is expressed as disability-adjusted life-years averted as a result of the particular pharmaceutical innovation. Simultaneously, the business return on investment captures the research and development costs and projects revenues in terms of a profitability index. **Conclusions:** The proposed framework can assist companies as they strive to meet the medical needs of populations around the world for decades to come. **Keywords:** burden of disease, pharmaceuticals, portfolio management.

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Introduction

Medicines prevent and treat diseases, enabling people to live longer, healthier, and more productive lives, and consequently contribute significantly to social and economic advances. Research-based biopharmaceutical companies remain the prime innovators of drugs, vaccines, and diagnostics to help countries and regions improve the health of both their people and their economies.

Companies recognize that market demand and market need are not the same thing. In a 2004 study, Acemoglu and Linn [1] reported a direct link between a market's size and the level of innovation within the biopharmaceutical industry's products in that market. A perfect example of this connection is neglected tropical diseases. There is an unmet need within developing markets for medical solutions to neglected tropical diseases but little demand for these products due to patients' inability to pay. Nevertheless, companies recognize the need to address these challenges in a way that reconciles financial return with corporate social responsibility.

Today's biopharmaceutical companies strive to maintain a balanced portfolio of products that benefit society with those that

benefit business. Strategic sustained investments in research and development (R&D) are critical to ensuring this balance, but limited market data for emerging markets can limit a company's ability to assess opportunities across the globe. Current indices used to gauge performance in business and societal measures—specifically the Access to Medicines Index (ATMI) [2] and the Productive Innovation Index [3]—operate in silos.

The ATMI measures the pharmaceutical industry's progress in better enabling access to medicines. The ATMI uses a weighted analytical framework to consistently capture and compare company data across seven technical areas of focus, namely, general access to medicine management, public policy and market influence, R&D, pricing manufacturing and distribution, patents and licensing, capability advancement, and product donations. Within each area, the index assesses four aspects of company action: commitment, transparency, performance, and innovation. The ATMI focuses on products targeting high-burden diseases but does not include data on the impact each product has had, or may have, on the burden of disease itself.

The Productive Innovation Index measures and scores the companies' ability to deliver innovation to market, by objectively

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measuring their performances in successfully commercializing, not necessarily discovering, new molecules. The index is based on publicly available data and ranks innovation in terms of such factors as the speed with which a product is brought to market and whether it achieved reimbursement. This index does not incorporate societal value factors.

The purpose of this study was to identify a new conceptual framework that combines measurements of societal value with those of business returns. This approach of evaluating the combined returns on investment has not been investigated yet. The proposed framework provides a novel way of defining the overall impact of a company's product portfolio. The advantages of net present value (NPV) and capital budgeting are covered in the business management literature, and the societal impact measured in disability-adjusted life-years (DALY) is covered in epidemiology and health policy literature. Although the study builds on these respective insights, the joint framework develops a new business lens through which companies can better optimize their portfolio. It also provides better insight into potential R&D investments and helps identify opportunities to partner on innovative products targeting neglected diseases and other emerging market needs.

Methods

The development of this framework requires identifying separate measures for the societal return on investment (SRI) and the business return on investment (BRI) before overlaying these concepts to identify commercial opportunities and areas for R&D investment.

SRI (DALY Averted)

Prior to C.J.L. Murray and A.D. Lopez's 1997 Global Burden of Disease (GBD) Study in *The Lancet* [4], there was no way to determine leading causes of death and disability across all medical and public health concerns. Murray and Lopez developed the DALY to address that gap. As a result of the DALY measure, the researchers were able to determine the leading causes of death and disability across all health categories. To ensure consistent comparisons across therapeutic areas and geographies, our model utilizes DALYs averted to measure the impact of the intervention on disease burden. This is referred to as the SRI.

Data from the World Health Organization's 2010 GBD project were utilized as the basis of all societal return calculations [5]. Key GBD calculations incorporated were years of life lost (YLL), years of life lived with disability (YLD), residual factor, DALY, and disease-specific information (prevalence/incidence). An in-depth explanation of the methodology in calculating these estimates has been published elsewhere [4,6,7]. Table 1 provides all parameters with their respective definitions while Figure 1 provides a graphical representation of the impact of the intervention on disease mortality (ΔYLL) and morbidity (ΔYLD), collectively defined as DALY averted.

DALY (and YLL and YLD) and prevalence/incidence estimates from the WHO GBD publication were utilized for each disease state specific to geographical regions. Using these baseline (without novel intervention or DALY A) DALYs and prevalence for each disease, we calculated base DALY/patient, YLL/patient (p-mortality), and YLD/patient (p-morbidity) for the specific disease. The total DALYs averted ($\Delta DALY$) are obtained by subtracting scenario B from scenario A, where scenario A represents the base-case scenario without the intervention and scenario B represents the remaining DALYs taking into account the effect of the intervention in reducing the disease burden. A two-step approach was

Table 1 – SRI model parameters defined measure.

Variable	Definition	Source/calculation
DW	Disability weight of the relevant disease	GBD 2010 [5]
N_{Inc}	Annual incidence/prevalence of the relevant disease	GBD 2010 [5]; published literature
$P_{Mortality}$	Intervention effect on disease mortality (%)	Assumption derived from published literature
$P_{Morbidity}$	Intervention effect on disease morbidity (%)	Assumption derived from published literature
$DALY_A$	DALYs of the base-case scenario (no intervention)	$DALY_A = YLD_A + YLL_A$; GBD 2010 [5]
YLD_A	YLD of the base-case scenario (no intervention)	
YLL_A	YLL of the base-case scenario (no intervention)	
$DALY_B$	DALY of the base-case scenario (with intervention)	$DALY_B = YLD_B + YLL_B + RF$
YLD_B	YLD of the base-case scenario (with intervention)	$YLD_B = YLD_A \times (1 - P_{morbidity})$
YLL_B	YLL of the base-case scenario (with intervention)	$YLL_B = YLL_A \times (1 - P_{mortality})$
RF	RF; YLD due to extending life	$RF = YLL_A \times P_{mortality} \times DW \times (1 - P_{morbidity})$
$\Delta DALY$	Change in DALY count from the base-case scenario to a scenario with an additional intervention	$\Delta DALY = DALY_A - DALY_B$

DALY, disability-adjusted life-year; GBD, Global Burden of Disease; RF, residual factor; SRI, social return on investment; YLD, years of life lived with disability; YLL, years of life lost.

then used to calculate the potential treatment population and potential DALYs averted. First, for each calculated yearly prevalence/incidence estimate, a factor was applied to identify diagnosed patients. Second, an additional factor was applied to account for potential market share (peak share provided in the table) of the diagnosed patient population for the intervention. Assumptions were used to estimate the interventional effect on YLD and YLL of the patient population treated (p-morbidity and p-mortality, respectively). These estimates were applied to the annual DALY estimates for each year modeled to calculate the number of annual DALYs averted.

BRI (Profitability Index)

Methods for calculating R&D costs for and potential earnings from pharmaceutical products are well established. These forecasting methods are published in detail elsewhere [8,9]. All biopharmaceutical companies must consider whether the potential profits of a product will offset the costs of R&D. Further complicating this evaluation is the knowledge that most products will fail at some point during the R&D process, leading to additional costs that must be recouped during the marketing of other, successful, products.

To develop performance measures, a profitability index is first established. The profitability index is the estimated NPV

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