

## Original Article

# Target Product Profile: A renaissance for its definition and use

Received (in revised form): 20th September 2009

**Paul W. Tebbey**

is the Managing Director at Kolabri Consulting, LLC, a life sciences product strategy consultancy.

**Charles Rink**

is an engagement manager with the Strategy & Portfolio Analysis unit at IMS Health Inc.

**ABSTRACT** The Target Product Profile (TPP) is supposed to be the cornerstone of pharmaceutical product development. But how often is it utilized or updated, and how closely does it resemble the product that originally was envisaged? At a watershed moment for a drug development industry that recognizes the need for profound change in order to increase productivity, and with the US Food & Drug Administration promoting dialogue with pharmaceutical manufacturers via a 'TPP', it is an opportune time to revisit the important role that the TPP should play in the drug development process. In its traditional form, the TPP has proven to be insufficient for effective commercial evaluation of the clinical development strategy. But, rather than redefining the currently accepted form of the TPP, the authors propose a Strategic Evaluation Framework that encompasses the TPP, the vision for the brand and the prevailing needs of the marketplace. The Strategic Evaluation Framework augments the TPP with the additional information necessary for the assessment of a product's commercial potential. The Strategic Evaluation Framework constitutes the yardstick to track the developing product's actual clinical profile versus that necessary for commercial success and thereby serves as the guide for strategic clinical development decision making.

*Journal of Medical Marketing* (2009) 9, 301–307. doi:10.1057/jmm.2009.34;  
published online 30 October 2009

**Keywords:** Target Product Profile; pharmaceutical development; commercial value; Strategic Evaluation Framework

## BACKGROUND

Drug discovery is increasingly expensive and high risk, with some reports proposing that it takes approximately \$500 million dollars and up to 12 years of research just to get drug candidates into clinic.<sup>1</sup> In order to emerge successfully from the entire pharmaceutical product

development process, estimates suggest total capitalized costs of \$1.3 billion.<sup>2</sup> These huge investments are caused partly by declining productivity for new drugs: fewer drugs are being approved, while R&D costs keep rising.<sup>3,4</sup> But even regulatory approval is no guarantee of success. The most commonly cited

**Correspondence:**  
Paul W. Tebbey  
Kolabri Consulting, LLC,  
PO Box 508, Chalfont,  
PA 18914, USA  
E-mail: ptebbey@  
kolabricsconsulting.com

example is Pfizer's Exubera, the inhaled insulin therapy. After Exubera failed to meet the expectations of physicians and patients, Pfizer removed it from the market in 2007, resulting in a \$2.8 billion financial charge.<sup>5</sup> In this environment, companies cannot afford to succeed in gaining approval, only to fail in the marketplace. But what forces have combined to result in this deteriorating productivity of commercially viable new products delivered to the market? One component is certainly an increasingly competitive and constrained health-care environment, wherein translating innovation into medicines that are both approvable and commercially viable is difficult. Additionally, theorists point to fragmented and overcomplicated company structures with misaligned functional groups that preclude the efficient integration of marketplace needs into the developing entity.<sup>6</sup> Thus, there is widespread acknowledgment of the need for change in pharmaceutical product development. As a recent example, GlaxoSmithKline resolved to shake-up its approach to research and development by splitting its drug development teams into smaller and more focused groups that incorporate a focus on results with a view to creating and sustaining value.<sup>7</sup> Such adjustments are an all too familiar occurrence in the current atmosphere within the pharmaceutical industry, which demands reassessment of the structure of the traditional model to one more streamlined and versatile. The hope is that this will support a more holistic market-driven approach to drug development and thus increase the value delivered by the pharmaceutical industry.<sup>8,9</sup> To achieve this goal, it is acknowledged that a marketplace focus be central to any guiding document for development, thereby enhancing the numbers of commercially viable products entering the market. But

are the guiding documents as currently defined and used up to the task?

## **TARGET PRODUCT PROFILES (TPPs) – A PROBLEM OF DEFINITION**

A universally accepted definition for a TPP remains to be elusive owing to the multiple constituents involved, differing opinions on its reason for existence and a lack of ownership. One example definition broadly describes the TPP as demonstrating how the intended product will be differentiated from competitor products in some future marketplace and thus, shows what the product labeling needs to look like to support use in that environment.<sup>10</sup> Although this definition may include the notion that product development has to 'start with the end in mind' to ensure that better products are delivered to the market, it does not explain how to achieve this through the development phases of the program. Too often the questions regarding commercial viability are asked too late in the process to allow improvements to the clinical development program.<sup>11</sup> In a misguided attempt to support drug development, pharmaceutical companies tend to adjust the form and content of the TPP to accommodate the needs of clinical development, strategic marketing, manufacturing, regulatory affairs, pricing and reimbursement, health and economics outcomes research, and all the other functions that support and guide the development of a new drug. Consequently, in some cases the traditional TPP has evolved from being an R&D tool used to guide the clinical program to serving as a business tool for determining asset value and capital commitment.<sup>12-14</sup> As an extension of this concept, many companies have implemented their own versions of the TPP to serve these multiple functions

and constituents.<sup>13</sup> Therefore, in practice, the definition of the TPP varies between and within organizations. But this often generates confusion, fragmentation, problems with version control, and an inherent conflict with the format, content and use.

It is easy to comprehend how the TPP might evolve from its originally intended purpose based upon the broad functions that it must fulfill. Steinmetz, for example, described the TPP as ‘a framework to ensure that the preclinical development program supports the intended clinical trial design and therapeutic use’. This definition has to assume that appropriate commercial input is provided sufficiently early in the process, that is at the pre-clinical stage, when in fact organizations do not sufficiently invest commercial expertise or finances until later in the development cycle.<sup>13</sup> Moreover, the notion that the TPP continues to evolve as the drug development program progresses implies frequent changes based upon accumulating knowledge of the developing product candidate.<sup>13</sup> This, itself, portends the potential for a product development plan to deviate from its intended goal because the activities become focused upon updating the TPP with the new data, rather than benchmarking the new knowledge of the product to that which was originally intended to define a differentiated product within the marketplace. Unintentionally adding to the confusion, the Center for Drug Evaluation and Research (CDER, part of the US Food and Drug Administration (FDA)) in 2007 issued draft guidance that defined the content and format of the TPP. To quote that document, ‘The purpose of a TPP is to provide a format for discussions between a sponsor and the FDA’ and refers to the TPP as a ‘dynamic summary’ of the product characteristics.<sup>15</sup> Indeed the TPP, in the FDA format, performs a vital role

in those discussions and in the ensuing tactical decisions for clinical trial design. But this definition detracts from the true purpose of the TPP, which is to provide an ineradicable point of reference for the development of a value-added contribution to the therapeutic treatment paradigm. As suggested by Wilkins, the temptation to mould the TPP to the unfolding properties of the compound must be resisted as it can lead to errant investment into an uncompromising molecule that will not provide a solution to the needs of the market.<sup>16</sup> It is precisely this type of opportunity cost that compromises the efficiency of pharmaceutical product development thus warranting the adoption of a market-led rather than product-led perspective.

## TPPs – CURRENT PRACTICE

The FDA positioned its draft guidance on the TPP as facilitating better communication between the sponsor and the regulatory body because it summarizes the drug development program in terms of intended labeling content and claims. But while the framework of the FDA guidance facilitates efficient discussion with regulatory bodies, the product’s profile usually does not embody the market insights necessary to determine the commercial viability of developmental programs. For example, achieving a statistical primary endpoint in pivotal clinical trials may well be sufficient for regulatory approval, but may not provide a compelling addition to the therapeutic armamentarium: the result might yield a marketed product that does not deliver a good return on investment for the company. The cessation of Roche’s HIV program is a good example of decision making regarding the evolving characteristics of actual products in relation to the marketplace needs and anticipated return.

*Marketplace needs, not only approvability, dictate the progress of drug candidates.*

Roche to drop HIV Research. *The Financial Times* (London, UK, 12 July 2008).

*While we had initially been hopeful about their potential, we now have concluded that none would provide a true incremental benefit for patients compared to medicines currently on the market.* (Global Leader of the HIV Franchise).

The move reflects Roche's strategic decision to focus only on medicines that provide a significant improvement to existing rival drugs available in the market at a time of growing demand for value for money from governments and healthcare systems.

The FDA-defined TPP contains only limited anticipation of market needs in the form of promotional claims and is devoid of pricing assumptions and other important information that is necessary to properly evaluate a drug's value in the portfolio. Returning to the Exubera example, had Pfizer accurately understood the marketplace needs for insulin products, hundreds of millions of dollars in development and marketing costs could have been re-allocated to other projects. The authors do not suggest that Pfizer (or the other companies pursuing inhaled insulin) made an easily avoidable mistake – market needs have to be anticipated many years in advance. However, this example is provided to demonstrate the consequences of misreading the market needs, and hence the importance of gauging them as accurately and early as is possible.

## THE STRATEGIC EVALUATION FRAMEWORK

The primary goal for the Strategic Evaluation Framework is to ensure that pharmaceutical product development is driven by a marketplace need to facilitate strategic product go/no-go decision making and to enhance development

programs so that they better incorporate marketplace value drivers. Moreover, the Strategic Evaluation Framework provides a clear format for intra-company project team progress discussions as well as serves to better communicate a product's value to investors, portfolio managers and senior management.

Building the framework around the FDA's TPP definition removes the need for multiple versions of a TPP for different purposes. Thus, the framework incorporates the FDA's definition of the TPP,<sup>15</sup> but adds to it to capture other essential parameters that place the patients, doctors and payers top-of-mind.<sup>17,18</sup> No single part of the framework should be utilized in isolation, as it is the collective body of information that supports the decision-making function.

The Strategic Evaluation Framework functions by enforcing a constant benchmarking of the evolving product in development relative to the original characteristics of a therapy that would be both differentiated and solve some as yet unmet market need. The components of the Strategic Evaluation Framework are illustrated in Figure 1, and consist of the following:

1. The Target Market Profile (TMP) is the foundation for the framework. Without understanding the market, any product profile will only be an unsubstantiated guess at the capacity of the product to be successful. While the details may be enhanced as more is learned about

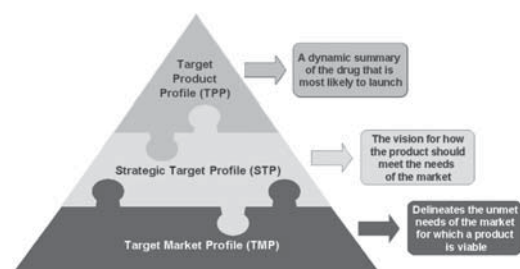


Figure 1: Strategic Evaluation Framework.

the market, the key facts contained in the TMP should change only when there is a major market shift.

2. The Strategic Target Profile (STP) is the vision for the product and is created based upon the unmet needs of the market as defined in the TMP. While staying within the realistic bounds of the company's core capability, it is the profile of the desired product to be built. Since it is important to maintain a consistent strategy, it should change only when an update to the TMP makes it absolutely necessary.
3. The TPP is the profile of the drug you *expect* to launch. At first, this profile will be the same as that in the STP. However, per the FDA's guidance, it will be updated as clinical data comes in to reflect the latest characteristics of the drug you want the regulatory authorities to approve.

To use the Strategic Evaluation Framework to guide the strategic clinical development decisions that set the foundation for commercial success, companies must evaluate how the most likely drug candidate (the latest version of the TPP) fits versus the original vision

for the product (the STP). In this comparison, it will quickly emerge how far the clinical trial results deviate from the original vision for the product (the STP), and therefore how well or how poorly the resulting drug will serve the market's unmet needs.

## THE COMPONENTS OF THE STRATEGIC EVALUATION FRAMEWORK

The *TMP* captures all the key information about the market and provides the foundation for the Strategic Evaluation Framework (Table 1). Creating the TMP is dependent upon understanding of the market's unmet needs. Contemporary viewpoints hold that products should be co-created with the targeted customer in order to provide meaningful experiences.<sup>17</sup> With this in mind, comprehensive information is garnered from different potential customer groups to build a market-needs profile that reveals how the product can achieve sustained marketplace differentiation, significant market share and profitability. This can be performed via extensive market research with various constituents (physicians, patients, payers)

**Table 1:** Key information contained within the strategic evaluation framework

	<i>Target Market Profile (TMP)</i>	<i>Strategic Target Profile (STP)</i>	<i>Target Product Profile (TPP)</i>
Purpose	Captures all of the key information about the market	A vision for a product that will meet the needs of the market	A record of the drug that is most likely to launch
Content	Therapeutic area/disease Unmet needs Patient populations Drivers of use Competitive assessment Economic cost of disease	Target attributes (desired label) Value drivers Pricing Patient share Revenue – Profitability Pharmacoeconomics Investments (R&D, COGS, SGA) Cost of goods Licenses, Royalties	Indications and usage Dosing and administration Contraindications Warnings and precautions Adverse reactions Description Clinical pharmacology Clinical studies Storage and handling
Rigidity	Created before the STP or TPP. Details are updated as findings emerge, but core facts change only in response to major market events	Set at the beginning of clinical development and updated only when necessitated by changes in the TMP	Updated as clinical and pharmacologic findings emerge and in response to guidance from regulatory authorities

to gain the necessary understanding of the prevailing unmet needs and the key requirements for a new therapeutic advance. The TMP answers questions on how the potential product would fit into medical practice by computing the needs of the current and future stakeholders and understanding the pharmacoeconomic benefits.

If a company loses sight of the original desired target as driven by the unmet market needs, then there is a risk that assessment of the product is colored by data that emerges from the clinical trials. Thus, the TMP should change only when substantial environmental or competitive events take place. Examples could include major government-mandated changes in the treatment of a disease or the appearance of unforeseen technology advances such as the launch of imatinib (Gleevec/Glivec) in chronic myeloid leukemia, or a major finding in a competitor's clinical trial such as atorvastatin's (Lipitor) higher efficacy than pravastatin (Pravachol) in the PROVE IT trial. In the absence of these types of major events, the vision for the brand should remain unchanged.

The *STP* provides a record of the vision for how the product should meet the needs of the market. The *STP* describes the specific solution needed by the marketplace, as described in the *TMP*. The *STP* should also be consistent with company core competency, mission and strategy. For example, it is inconsistent for a biotech company whose mission is dedicated toward providing innovative therapies for underserved high-need patients to then target a broader population with mild disease in need of standard topical emollients. The *STP* builds a vision for the product benefits needed to meet the marketplace needs. In contrast to the *TPP*, the *STP* contains pricing, forecast, investment and pharmacoeconomic assumptions. It is the

*STP* that should possess the valuation for the developmental program in order to substantiate investment decisions. Consequently, a basic component toward developing the *STP* is a quantitative assessment of prescribing intent of physicians and the potential for reimbursement by payers. The *STP* is therefore a valuable decision-making tool determining, for instance, the viability of a program from the outset, and is the benchmark to assess continuing investment at each stage gate.

The *TPP*, using the FDA's definition, provides a record of the drug that is most likely to launch, incorporating the latest data from the clinical program and the evolving product pharmacology. As the *TPP* focuses on the product rather than on the needs of the marketplace, it can serve to provide a record for the clinical development program to guide the number, design and timing of clinical trials; as well, it captures clinical findings and product attributes (for example, purity, stability) as they emerge.<sup>19</sup> As the *TPP* is updated to reflect the latest estimate for the product's profile at launch, it provides a 'dynamic summary that changes as knowledge of the drug increases'.<sup>15,13</sup> As the *TPP* is updated with new information, and most notably at key clinical stage gates, it is imperative to continually assess its performance relative to the static *STP* to quantify differences in value. Invariably, in clinical programs, unexpected information is collected on the evolving compound. Without a framework to benchmark the impact of this new data, decisions have to be made in the absence of evidence. The benchmarking can be achieved via competitive market modeling and choice model market research studies that measure the impact of individual product attribute levels as a function of the forecasted market share of the compound. In this way the impact of attribute

differences of the compound contained within the TPP can be directly measured against the original need for the product in the STP, thus focusing discussion on the specific areas that have most impact on the program.

Collectively, the components of the Strategic Evaluation Framework support the objective of guiding the strategic clinical development decisions that set the foundation for commercial success. To implement it, a process is needed whereby the actual developing entity (TPP) can be evaluated against the TMP and STP for the degree of fit. Such a process would consider all of the parameters of the TMP to assess a developing product's deviation from the original vision (by contrasting the TPP with the STP) in order to support continuous investment decisions. Although some companies have groups that fulfill aspects of these objectives, for the most part they invariably exist in isolation. Therefore, the collection of the requisite participants that derive from different functional capacities may require a reorganization of current pharmaceutical business models from groups sequestered by purpose to teams of multi-functional groups that work in concert. It follows that the synthesis of the Strategic Evaluation Framework be jointly governed by Marketing and R&D groups thus mandating close interaction between the classical silos from the earliest development stages through to commercialization.<sup>20</sup>

To conclude, we propose the Strategic Evaluation Framework as a scaffold that addresses explicitly the many functions and uses for product profiles, and the need to focus on the marketplace and individual customer value rather than on product attributes alone. Collectively, the components of the Strategic Evaluation Framework help guide the strategic clinical development decisions that set the foundation for commercial success.

## REFERENCES

- 1 Frearson, J.A., Wyatt, P.G., Gilbert, I.H. and Fairlamb, A.H. (2007) Target assessment for antiparasitic drug discovery. *Trends in Parasitology* 23(12): 589–595.
- 2 DiMasi, J.A. and Grabowski, H.G. (2007) The cost of biopharmaceutical R&D: Is biotech different? *Managerial and Decision Economics* 28(4–5): 469–479.
- 3 Del Llano, J. (2007) Discussion point: Should governments buy drug patents? *European Journal of Health Economics* 8: 173–177.
- 4 Niles, S. (2008) 22nd annual report – 73 new medicines. *MedAdNews* 27(3): 6–31.
- 5 Bowe, C. (2007) Pfizer takes a \$2.8 billion write-down after failure of insulin treatment. *Financial Times*, London (UK), 19 October: 13.
- 6 Finn, B.M. and Sutherland, C.F. (2004) The pharmaceutical industry: Where it is, how it got here, where it needs to go, how to get there. *International Journal of Medical Marketing* 4(4): 361–369.
- 7 Jack, A. (2009) GSK to shake-up research strategies. The Financial Times Limited, London, 9 June 2008, Vol. 23: 18.
- 8 Rao, S.K. (2002) Pharmaceutical marketing in a new age. *Marketing Health Services* 22(1): 7–12.
- 9 Cacciotti, J. and Shew, B. (2006) Pharma's next model. *Pharmaceutical Executive* (March).
- 10 Kennedy, A. (2008) *Pharmaceutical Project Management*, 2nd edn. New York: Informa Healthcare USA.
- 11 Shohet, S. (2005) De-risking novel therapeutic development – Time to stop blaming the molecule? *Journal of Commercial Biotechnology* 12(1): 5–7.
- 12 Curry, S. and Brown, R. (2003) The target product profile as a planning tool in drug discovery research. *Business Briefing: PharmaTech 2003*, World Markets Research Centre, pp. 67–71.
- 13 Steinmetz, K. and Spack, E. (2009) The basics of preclinical drug development for neurodegenerative disease indications. *BMC Neurology* 9(1): S2.
- 14 Gad, S. (2007) *Handbook of Pharmaceutical Biotechnology. Pharmaceutical Development Series*, Vol. 2. Hoboken, NJ: John Wiley and Sons.
- 15 US DHHS Food and Drug Administration. (2007) Draft guidance: Target Product Profile – A strategic development process tool, <http://www.fda.gov/cder/guidance/6910df.htm>, accessed 7 October 2008.
- 16 Wilkins, M. (2003) *Experimental Therapeutics*. London, UK: Martin Dunitz – The Taylor & Francis Group.
- 17 Prahalad, C.K. and Krishnan, M.S. (2008) *The New Age of Innovation: Driving Co-created Value through Global Networks*. Columbus, OH, USA: McGraw-Hill, ISBN: 978-0071598286.
- 18 Don, R. (2005) Target product profile: Starting with patients in mind. *DNDi newsletter*, Vol. 12, November <http://www.dndi.org>.
- 19 Yu, L. (2008) Pharmaceutical quality by design: Product and process development, understanding and control. *Pharmaceutical Research* 25(4): 781–791.
- 20 Theodorou, A. (2004) Marketers, get to know your R&D colleagues: The rewards could be far reaching for you personally and for your organization. *International Journal of Medical Marketing* 4(3): 298–300.

---

#### **ABOUT IMS**

Operating in more than 100 countries, IMS Health is the world's leading provider of market intelligence to the pharmaceutical and healthcare industries. With \$2.3 billion in 2008 revenue and more than 50 years of industry experience, IMS offers leading-edge market intelligence products and services that are integral to clients' day-to-day operations, including product and portfolio management capabilities; commercial effectiveness innovations; managed care and consumer health offerings; and consulting and services solutions that improve productivity and the delivery of quality healthcare worldwide.

#### **IMS HEALTH®**

##### **CORPORATE HEADQUARTERS**

901 Main Avenue  
Suite 612  
Norwalk, CT 06851-1187  
USA  
Tel: 1.203.845.5200

##### **REGIONAL HEADQUARTERS**

###### **THE AMERICAS**

Plymouth Meeting Executive Campus  
660 West Germantown Pike  
Plymouth Meeting, PA 19462-0905  
USA  
Tel: 1.610.834.5000

###### **EUROPE/MIDDLE EAST/AFRICA**

7 Harewood Avenue  
London NW1 6JB  
United Kingdom  
Tel: 44 020 3075 5000

###### **ASIA PACIFIC**

10 Hoe Chiang Road  
Keppel Towers # 23-01/02  
Singapore 089315  
Tel: 65 6227 3006

###### **JAPAN**

Toranomon Towers  
4-1-28 Toranomon  
Minato-ku, Tokyo 105-0001  
Japan  
Tel: 81 03 5425 9000

[www.imshealth.com](http://www.imshealth.com)



**ims®** INTELLIGENCE.™  
APPLIED.