

## Associate Editor's Commentary : Measuring Responsibility

Peter J. Pitts

*Therapeutic Innovation & Regulatory Science* published online 25 March 2013

DOI: 10.1177/2168479013483135

The online version of this article can be found at:

<http://dij.sagepub.com/content/early/2013/03/25/2168479013483135.1>

---

Published by:



<http://www.sagepublications.com>

On behalf of:



Drug Information Association

**Additional services and information for *Therapeutic Innovation & Regulatory Science* can be found at:**

**Email Alerts:** <http://dij.sagepub.com/cgi/alerts>

**Subscriptions:** <http://dij.sagepub.com/subscriptions>

**Reprints:** <http://www.sagepub.com/journalsReprints.nav>

**Permissions:** <http://www.sagepub.com/journalsPermissions.nav>

>> [OnlineFirst Version of Record](#) - Mar 26, 2013

[OnlineFirst Version of Record](#) - Mar 25, 2013

[What is This?](#)

# Associate Editor's Commentary: Measuring Responsibility

Therapeutic Innovation  
& Regulatory Science  
00(0) 1-3  
© The Author(s) 2013  
Reprints and permission:  
sagepub.com/journalsPermissions.nav  
DOI: 10.1177/2168479013483135  
tirs.sagepub.com

**Peter J. Pitts**

## Abstract

The Access to Medicine Index (ATMi) is an attempt to measure and compare the corporate social responsibility of both innovator (20) and generics (7) companies based on a number of different (and often quixotic) indicators. According to the Access to Medicine Foundation, the index “aims to help poor people in developing countries gain access to medicine by encouraging the pharmaceutical industry to improve its commitments and practices related to this issue.” Since it’s a comparison, the theory is that competition amongst companies will drive desirable “socially responsible” behaviors. A noble goal—but the devil is in the details. As Abraham Lincoln said, “You cannot escape the responsibility of tomorrow by evading it today.”

## Keywords

drug pricing, access to medicines, rational use of drugs, intellectual property, patents, generic drugs, corruption, innovation

If you can’t measure it, the saying goes, it doesn’t count. But what if you’re measuring the wrong things? The Access to Medicines Index<sup>1</sup> (ATMi) is an attempt to measure and compare the corporate social responsibility of both pharmaceutical medicine innovator (20) and generics (7) companies based on a number of different (and often quixotic) indicators. It was developed by Netherlands-based nonprofit Access to Medicines Foundation (ATMF) with funding from the Dutch Ministry of Foreign Affairs, the UK Department for International Development, and The Bill and Melinda Gates Foundation. It was launched in 2008, and it comes out every 2 years. The ATMi analyzes the following 7 technical areas across 4 pillars:

### *Technical Areas:*

1. General Access to Medicine Strategy and Governance
2. Public Policy and Advocacy
3. R&D for Index Diseases
4. Patients & Licensing
5. Equitable Pricing & Registration
6. Technology Transfer (Capability Advancement)
7. Drug Donations and Philanthropic Activities

### *Pillars:*

1. Commitment (30% weight)
2. Transparency (30% weight)
3. Performance (30% weight)
4. Innovation (10% weight)

The index concentrates on the global list of low- and medium-development countries based on the UN Human Development

Index and World Bank Country Income level categories. The index has historically covered 33 diseases, including the World Health Organization (WHO) Neglected Tropical Diseases as well as the top 10 infectious diseases and top 10 chronic diseases based on disability-adjusted life years (DALYs) from the WHO Global Burden of Diseases for the low- and medium-development countries. The next index will likely broaden the disease scope to additional categories including noncommunicable diseases (NCDs), women’s health, and some cancers. They also plan to place increased weight on companies’ actual performance (versus their commitments).<sup>2</sup>

According to the Access to Medicine Foundation, the index “aims to help poor people in developing countries gain access to medicine by encouraging the pharmaceutical industry to improve its commitments and practices related to this issue.”<sup>3</sup> Since it’s a comparison, the theory is that competition among companies will drive desirable “socially responsible” behaviors. That’s a noble goal, but the devil is in the details. As Goran Tomson, professor of international health systems research at Karolinska Institute points out, the Index’s methodology cannot be reproduced, and hence it cannot be considered statistically valid (G Tomson, panel discussion, Third International Conference for

<sup>1</sup> Center for Medicine in the Public Interest, New York, NY, USA

### **Corresponding Author:**

Center for Medicine in the Public Interest, 757 Third Avenue, 20th Floor, New York, NY 10014, USA.  
Email: ppitts@cmpi.org

Improving Use of Medicines; Antalya, Turkey; November 17, 2011).

There are also troubling issues relative to the index's metrics for success. According to the Index's methodological designer, Afshin Mehrpouya (an assistant professor of accounting and management control at the international business school Hautes Études Commerciales de Paris (HEC Paris) recently said, the only current measurements are "web hits and media coverage." That's not very exciting, plausible, or helpful from a health policy analysis perspective.

Another metric is the opinion of patient groups. When asked why certain patient groups were chosen (they are not named in the index), the answer was that groups were chosen based on their "credibility." That seems to equate to groups who do not accept funding from the pharmaceutical industry or who may share an anti-free market bias. At minimum, it's a dubious selection bias. The Karolinska Institute's Tomson also pointed out that the index's "review committee" consisted almost entirely of "familiar faces," thus creating an issue of normative bias (G Tomson, panel discussion).

To offer better balance and some reference, shouldn't the index create a parallel metric that measures the policies and political environments of low- and middle-income countries to determine whether they facilitate or hinder their citizens' access to health care? How about creating an index that addresses the lack of transparency in the Less Developed Countries (LDCs) public sector and (the 800-pound gorilla in the room) corruption. These are all polite ways of saying that the design criterion stacks the deck. Karolinska's Tomson put the discussion about the index—as well as the entire ICIUM (International Conferences on Improving Use of Medicines) enterprise—into perspective when he said the index lacked for "higher ambitions." "Higher ambitions" requires that the index do more than read its own press releases and talk with its friends in nongovernmental organizations (NGOs). "Higher ambitions" requires honesty beyond one's own cognitive mapping.

According to ATMi CEO and founder Wim Leerveld, "Today all companies have teams to deliver us the requested data as they see the relevance for them."<sup>1</sup> Maybe. Maybe not. Interviews conducted by the Center for Medicine in the Public Interest (CMPI) with participating companies showed much displeasure with both the index questionnaire, the volume and type of information being requested by the index, and the "normative bias" of the ATMi staff. In some cases, participating companies are spending hundreds of hours to collect, verify, and prepare final submissions. Is it worth it? Here are some tough questions the indexers must ask themselves:

**Q:** Is the index moving the needle? Is there evidence that this is worth the effort that companies put into it and does it justify donor funding? Have they had an impact on financial

investment patterns? (Web hits and press clippings are not the most objective measures here.)

**Q:** What work has ATMf done to validate that their metrics are in fact the right drivers to improving access? Are they selecting an agenda being pushed by activist constituents without assessing a more full-bodied picture of what is happening in the real world?

To take one particularly notable example, the index operates from the assumption that the innovator pharmaceutical industry can improve access to essential medicines. But, when one examines the WHO's model Essential Drug List, very few of the 400 or so drugs deemed essential are new, or patented (or ever patented) in the world's poorest countries. In category after category, from aspirin to Zithromax, in almost every case and in almost every country, these medicines have always been (or have been for many years) in the public domain. That is, the medicine is fully open to legal and legitimate generic manufacture.

There are important implications for the world's poorest patients. If these patients had reliable and affordable access to these several hundred essential medicines, all available *theoretically* as multisource (ie, from generics companies), global mortality and morbidity might be cut as much as 10% to 20%—a huge gain for populations around the world (Center for Medicine in the Public Interest estimates based on current WHO statistics). Strangely, the index gives a pass to the world's largest producers of generics drugs in India and China. Those companies are not asked to spend hundreds of hours assembling data on their contributions to medicines access. Given the potential hugely positive impact on access to medicines, any reasonable person might ask "why not?"

Additional questions to be asked include the following:

**Q:** Is it time to reassess the index's bias for certain mechanisms and tools? Its focus on the medicines patent pool, for example unfairly demoting companies that aren't in negotiations. This doesn't seem fair. The pool is only one part of a broader landscape of what's happening around access to HIV/AIDS and other treatments, and it's unfair to use one tool as a measure of companies' commitment when there are other things happening that are very relevant and important.

There are, arguably, ideological assumptions within the questionnaire's section on technology transfer questions. Is the index looking at technological transfer as a measure of access to medicines or are they promoting industrial policy? Why isn't in-country capacity building measured? What about efforts to fight counterfeiting? What about commitments to global Good Manufacturing Practices?

**Q:** How does the index ensure each company answers the questions in the same way to allow for an apples-to-apples comparison? Is the index able to objectively compare companies? One

corporate participant in the CMPI interviews commented as follows:

*Some of the questions were just too difficult to understand and required too much interpretation. In the Pricing & Distribution section (Q1.9), we're asked to provide product-specific registration status. When I asked for clarification, our Index contact told us to indicate if the product is patented in the countries in which it's registered. This is not inherent in the question. Also, we think it would be useful for the Index to know where we have filed for registration but where the application may be stuck in a bottleneck since the speed of registration is highly dependent on the speed and efficiency of local countries' regulatory processes. But our contact indicated this information was not necessary.* (interview, August 14, 2012)

Does industry want the ATMi? They certainly value being recognized for their good work—and the competitive rankings are appreciated (and flaunted). But the implicit agenda of the ATMi isn't appreciated. So, perhaps it's inaccurate to say that industry wants the index. Maybe a better statement is that industry wants *an* index.

Recognizing both inherent flaws and bias of the ATMi and the importance of measuring industry's commitment to social responsibility and access, Business for Social Responsibility's<sup>4</sup> Healthcare Working Group has launched an effort to provide an industry-wide lens on this important issue. The working

group's efforts center on the group's acknowledgement that solving this challenge is a human need, and a business priority that requires a close collaboration with other actors from industry, public, and NGO sectors. It will be interesting to see how these two programs compare—and which one survives.

### **Declaration of Conflicting Interests**

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

### **Funding**

The author(s) received no financial support for the research, authorship, and/or publication of this article.

### **References**

1. Access to Medicine Index website. [www.accesstomedicineindex.org](http://www.accesstomedicineindex.org). Accessed November 6, 2012.
2. The World Bank website. How we classify countries. <http://data.worldbank.org/about/country-classifications>. Accessed November 6, 2012.
3. World Health Organization website. Access to Medicine Foundation [abstract]. <http://apps.who.int/medicinedocs/en/m/abstract/Js17077e/>. Accessed November 6, 2012.
4. Business for Social Responsibility website. <http://www.bsr.org/>. Accessed November 6, 2012.