

Debates surrounding CSR in pharmaceutical industry with adoption of ISO 26000

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Abstract:

Can the pharmaceutical companies confirm to better self-regulation by adopting ISO 26000 as a part of fulfilling their corporate social responsibility(CSR)? The research intends to find out how ISO 26000 built in the line of intellectual and practical infrastructure of ISO 9000 and ISO 14000 leading to certification can yield better results as opposed to serving as a mere guideline. In the context corporate self-regulation with the adoption of ISO 26000, the research further intends to unravel new perspectives into Elkington's Triple bottom line (TBL) as it is being adopted as an accounting framework with three parts -- social (people), environmental or ecological (planet) and financial (profit). Thus, the focus of the discourse is towards environmental full-cost accounting (EFCA) or true-cost accounting (TCA) that purports information about possible environmental, social and economic costs and benefits or advantages. The research deems the self-regulating attempts by the pharmaceutical industries that are susceptible to failure due to the inherent conflict of interest, such as the creation low-cost life-saving drugs through dilution of patent or cross-patenting or research involving animal bodies or even spending excessive resources on research and development.

Through different practices of CSR including the Montreal school the research in the context of pharmaceutical industry the research would like to see how the creation of shared value (CSV) unfolds in the light of adoption of ISO 26000 -- CSV is the interdependence between corporate business success and social welfare -- thus paving the way for a trade-off between profitability and social or environmental goals.

Introduction

Corporate Social Responsibility (CSR) in the context of pharmaceutical industry can be broad idea of philanthropy, for example the patents that have been reprobated and censured in the developing world, as they are considered to restrict access to life-saving drugs now can be looked at little more considerately in order to allow more lives to be touched by this. Reconciling patents and universal access to life saving drugs calls upon the pharmaceutical companies to look beyond their books of profit and loss in order to make their drugs more affordable. Notwithstanding these considerations CSR still has to come under the remit of TRIPS agreement of the World Trade Organization (WTO) -- Doha Declaration asserts that the TRIPS agreement must not take eyes off the goals of public health thus avoiding the pharmaceutical monopolies via compulsory licensing or parallel imports, even before patent expiration.

These considerations would help the actions of pharmaceutical companies contributing to social welfare, beyond what is called gross profit maximization, and thus could afford CSR practices to take root. The legitimacy of CSR, though still embroiled in debate, the consumers and investors at large have developed clear preferences for socially responsible companies.

In early 2001, some forty multi-national pharmaceutical organisations moved a litigation against South Africa for its Medicines Act, which permitted the generic production of antiretroviral drugs (ARVs) for treating HIV, denounced the patent monopoly of companies on those life-saving drugs. HIV, an epidemic in South Africa, and ARVs also rendered itself unaffordable to most victims as these drugs could cost as high as £12,000 a single consumer per

year. Soon the international consensus was built in favour of South African government's decision; the patents were ignored as the public health rights gained ground.

Big-ticket pharmaceutical companies, due to their own compulsion always not have responded positively in making CSR a key element of strategic management, but now may be forced to act differently more frequently than in the past in the climate of socially responsible investment and global corporate citizenship.

The CSR commitment of big ticket companies can be evidently found in many examples. "Merck's Gift", known as free distribution of new river blindness drug that can cure river blindness, a disease caused by infection with a parasitic worm, came as a donation in Africa alongside Pfizer's gift of free/discounted fluconazole and other drugs for AIDS in South Africa. GSK committed itself to free distribution of albendazole tablets to WHO (World Health Organisation) until the elimination of lymphatic filariasis worldwide became a household story. Novartis in the year 2006 expended US\$755 million in corporate citizenship initiatives around the world, with a particular emphasis on improving availability of medicines in the developing world through its 'Access to Medicine' projects, that comprised distribution of medicines to patients affected by leprosy, tuberculosis, and malaria or through its Glivec patient assistance programs. The company also provided relief to support major humanitarian organisations with emergency medical needs to sustain their operations on the ground.

However, the big-ticket pharmaceutical companies' free distribution of drugs or relenting on their patent rights to make life-saving drugs available should go beyond this. They must come to terms with the special rules for certain rare diseases (better known as "orphan diseases") in several major drug regulatory territories. The list of these diseases can be endless. For example, diseases involving fewer than 200,000 patients in the USA, or larger populations in certain circumstances in certain countries, are subject to the Orphan Drug Act or equivalent. Since to embark on any medical research and development of drugs to treat such diseases is financially draining the pharmaceutical companies must be accorded with tax reductions, fee waivers, and market exclusivity on that drug for a limited time (can vary depending upon the country), but nevertheless the drug companies must consider it is their responsibility to contribute to set their feet in orphan diseases.

The social responsibility (SR) agenda is gaining its momentum in the space of production and development of markets drugs or pharmaceuticals for the purpose of medications, so to say the pharmaceutical organisations that identify themselves with generic or brand medications and medical devices.

As these companies are subject to a diversified range of laws and regulations pertaining to patenting, testing, safety, efficacy and marketing of drugs their subsequent allegiance to ISO 26000, the de facto international standard on SR can now create larger accountability as it provides necessary guidelines for SR (also popularly known as ISO SR). Its goal is to contribute to global sustainable development, by motivating the companies to practice social responsibility to improve their impacts on their employees, immediate natural environments and communities, and also expanding all these stakeholders to a larger global context.

Discourse (Literature Review included):

ISO 26000 intention to create a de facto industry standard to promote CSR based on known reference documents without curbing creativity and development within a social system ISO particularly recognises the fact that the pace of development worldwide calls for increasing actions by organizations, including pharmaceutical businesses, to wind down their harmful impacts on people and communities, and touch their lives with some positivity.

For pharmaceutical industry the ISO 26000 guidance can make them to exhibit socially responsible behaviour and possible actions. ISO 26000, however, sits at a variance in many ways from other prevailing standards that are called upon to meet industry requirements for activities including manufacturing, managing, accounting and reporting.

Being held as a voluntary guidance standard ISO 26000 does not confirm to requirements for the purpose of certification. Not linking ISO 26000 to certification, may in certain cases take the sting out of an exercise, but the learning curve associated with the same cannot be ignored as it brings in 'corporate good will' while integrating social responsibility into company's values and practices.

Since ISO 26000 can fit into a wide range of business context the small pharmaceutical start-ups and companies in developing economies can immensely gain from its flexibility. As ISO 26000 was developed through a multi-stakeholder process involving industries, states/governments, non-governmental organization, employees and consumers at various levels, and SSRO (Service, Support, Research and Others - primarily academics and consultants) the standard now keeps itself open to future participation and development accommodating the perspectives from different economic and cultural contexts. Since a parliamentary consensus-building process has been adopted into the mechanism of ISO 26000, the resultant standard underpins deliberation and negotiations. The modus operandi of pharmaceutical industry, which is always debated, can immensely gain from this ISO 26000 since it reflects the goals and concerns of each and all of the stakeholders in its final compromise form.

The pharmaceutical companies putting ISO 26000 into practice need to wade through ISO's released document containing the definitions, examples, and suggestions on how to identify and communicate with stakeholders, and how to identify and address specific issues in each Core Subject area.

The key mantras put forward as the basis of socially responsible behaviour in ISO 26000, are as following:

- Accountability
- Transparency
- Ethical behaviour
- Appreciation for all stakeholders' interest
- Approbation for the rule of law
- Obeisance to international norms of behaviour
- Consideration for human rights

The Core Subjects recommended for each ISO 26000 user are as following:

- Organizational governance
- Human rights
- Labour practices
- Environment
- Standard operating practices must incorporate fairness and level-playing field for all
- Consumer issues
- Involvement in Community development

Probably it would not be sufficient to refer ISO 26000 as a mere standard. Pojasek (2011) correctly points out that it provides the 'missing link' that can allow a company to convert its environmental management system into a truly integrated sustainability management system.

However, the key challenge is how to integrate CSR into all areas of organisational activities, particularly in the context of pharmaceutical industry. Despite the acceptance of ISO 26000 as a note of guidance Hahn (2012) emphasis on the need to obtain a consistent

understanding of what corporate sustainability and social responsibility (CSSR) encompass believed to have contributed towards a formal strategic planning improving the operational efficiency.

ISO 26000 in the context of understanding the strategic management processes of diversified pharmaceutical companies spreading across geographies allowing the potential of ISO 26000 for guiding organisations on their road to sustainability particularly has proved to be useful for start-ups in CSSR. Since the ISO 26000 does not hold the sway over the entire gamut of strategic management processes the standard can be narrowed down to internal and external analyses providing a head start to implement sustainability strategies.

Possibly the CSR method can be put into practice to the pharmaceutical start-ups better than companies in existence for some time, as allegedly it is easier to engage the stakeholders at the time inception. A host of CSR resources may as well be developed from multiple initiatives for pharmaceutical companies, both public and private, at the beginning. It is largely witnessed in practice that the CSR theories and methods of applying social responsibility in pharmaceutical as well other industries are always focused on medium and large organisations, whose attributes are strikingly dissimilar to start-ups and newly created firms.

On contrary to Retolaza (2009) suggested idea of demonstrating the possibility to put into practice a CSR method to tackle all of the interests of future and potential stakeholders in business start-ups, and then subsequently to expand this to big-ticket and old companies to see if ideas would hold the ground. Castkaa and Balzarovab (2008) raise questions of 'why' and 'under what circumstances' these companies and their domestic and global supply chains will adhere to ISO 26000. They have identified a clutch of propositions about diffusion of ISO 26000 and how some of these SR practices have come to bear upon the companies. Propositions, which certainly can prove to be relevant for the pharmaceutical companies, are made in relation to SR orientation of companies/networks, differences in regulatory systems across geographies, and the role of governments and national/regional environments. The current industry efforts should follow Castkaa and Balzarovab (2008)' empirical studies in order to determine how the SR aided by ISO 26000 can set out the SR agenda for companies.

As sustainable development has become a key metaphor for all industries the pharmaceutical industry is no exception to this. The immediate reference point for the same has been the American Chemical Society Green Chemistry Institute's Pharmaceutical Roundtable that has zeroed in on the process mass intensity (PMI) as the key, high-level metric for evaluating and benchmarking progress towards more sustainable manufacturing. Jimenez-Gonzalez et al (2011) combine a long treatise of philosophical and technical arguments on why PMI is chosen above other related metrics such as mass efficiency, reaction mass efficiency, E factor, atom economy, space-time yield, E factor or atom economy in order to drive business, government, and communities towards more sustainable practices.

As aptly pointed out that since sustainability, by its very definition, is a multivariable optimization exercise, the task identified by Jimenez-Gonzalez *et al* (2011) is to choose a handful of metrics that would drive the correct behaviours towards more sustainable, greener practices in pharmaceutical industries. In the context of mass-based metrics, there has been ground swell opinion about whether the best approach for a simple high-level mass metric is to lay emphasis on the total mass of materials used (e.g., PMI or Mass Efficiency) or on the mass of the waste generated from any given process (e.g., E factor).

Jimenez-Gonzalez et al (2011) identified metrics to relate well to the sustainable development that is frequently an object of standardization in the view of increasing number of pharmaceutical and chemical companies that are confirming to legitimate environmental management systems. Such identified metrics can be considered to be the new world order.

The pharmaceutical and chemical companies, which may initially have considered some *social* responsibility practices as mere guidelines, these are now the object of standardization. The emerging ISO 26000 standard bears a testimony to this phenomenon.

However, from the viewpoint of pharmaceutical industry it certainly needs to be known the rationale behind developing ISO 26000. Such an investigation must follow Schwartz and Tilling (2009)'s study on companies' tendency to decouple complex CSR issues in the organizational context. It particularly has a relevance in pharmaceutical companies in emerging economies and low-income nations that fraught with problems of poor working conditions, weak regulatory compliance, and corruption often encountered in the production context.

Following the direction of Schwartz and Tilling (2009) the research intends to find the existing codes of conduct that are frequently decoupled from actual company's performance and how CSR standardization risks isolating complex and contested social issues, or the more radical attempts at change conflicting with aiming for legitimacy. Yet it is to be seen in the context of pharmaceutical industry across geographies like the decontextualizing tendency proceeding from the standardized treatment of complex sustainable development issues in organizations -- how the CSR issues risk becoming decontextualized with the application of standardized approaches, particularly the ISO 26000 as a *de facto* standard.

Pharmaceutical industry is a closely fought social space involving patent, competition and market outreach. The creation of new institutional practices and arrangements reflecting settlements reached by companies should confirm to existing to norms and practices, however, this must not leave out the focus on how these settlements need to be negotiated in the first place.

As pointed out by Helms *et al* (2012) based on their study of the formal negotiation of, and settlement on, ISO 26000, the discourse unravels an emerging global standard capturing the normative domain of corporate social responsibility (CSR). There must be an effort to carry forward the cognitive perspective adopted by Helms *et al* (2012) in order to develop and test an organizational model of settlement on a new institutional practice. The findings of Helms *et al* (2012) with regard to the significant roles of logic pluralism or so called "doctrine of multiplicity" within organizations suggest at organizational negotiation frames in the context of pharmaceutical industry as determinants of settlement and the coining of new institutional practices.

Also, must be taken into consideration the suggestions put forward by Castka and Balzarova (2007) on the alleged synergies (and divergences) between quality management (and ISO quality management and environmental management standards) and CSR as they emerged during the process of ISO 26000 development.

Castka and Balzarova (2007)'s conclusions drawn from the resolutions and working materials produced by ISO Committee on Consumer Policy, the Strategic Advisory Group on Social Responsibility and ISO/TMB/WG SR - a working group in charge of the development of ISO 26000 - gives a particular slant to the quality management dimension that can be useful to establish ISO 26000 as a standard for SR in the context of pharmaceutical industry.

However, not to ignore such research limitation as evident in Castka and Balzarova (2007)'s study circumscribed by the linkages between quality management and CSR stemming from the development of ISO 26000. Hence, efforts must be made to expand to other CSR standards and tools such as Triple bottom line accounting (TBL) and creating shared value (CSV).

The current research thus anticipates the expansion of CSR standards and tools that can have a larger contribution to CSR agenda with respect to a host of key areas such as management systems, integration of strategy, operations, technology, CSR and quality;

incorporation of corporate governance; and improvements in third-party certification and internal auditing practices.

The adoption of ISO 26000, it came into being in September 2010 as a new International Guidance Standard on Organizational Social Responsibility, requires a participant company to put itself into the process of developing the standard over a five-year period in the view of the points of multiple intersection among ISO 26000 and public policy, international law, democracy, and the role of the state. The ISO 26000 must always be grounded in an analysis of the standard's negotiating history in order to develop the appropriate descriptive and normative theoretical frameworks. The current research would like to expand Halina (July 2011)'s proposed innovations underpinning the bonhomie among ISO, public policy and the role of the state.

Some of the organisations' likely misinformation of ISO 26000:2010 as a management system standard appropriated for certification purposes or regulatory or contractual use needs to be countered. A misrepresentation of the intent and purpose and a misuse of ISO 26000:2010 can undermine the efforts of other companies which are adopting this to improve their CSR mechanism. The current research direction may commit itself to investigate how ISO 26000:2010 can lead to certification upon organisations fulfilling the stated requirements as possible under other ISO certification provision.

According to ISO's own admission, for the purposes of the Marrakech Agreement establishing the World Trade Organization (WTO), ISO 26000:2010 is not intended to be understood as an "international standard", "guideline" or "recommendation", nor is it intended to offer a basis for any presumption or finding that a measure is consistent with WTO obligations. Also, ISO has made it amply clear that it is not intended to provide a basis for legal actions, complaints, defences or other claims in any international, domestic or other proceeding, nor is it intended to be referred as evidence of the evolution of customary international law. Not leading to certification may adversely impact ISO 26000:2010's credibility as it is not certain how long its credentials can be maintained as long it is merely used to provide organizations with guidance concerning CSR and as a part of public policy advocacy.

The current research concurs with the viewpoint of Henriques (2010) who holds ISO 26000 a powerful statement of the moral and practical issues facing companies and other organisations, hence this must prevail over narrow profit-centric modus operandi of organisations. But since ISO 26000 standard's development has been fraught with politics its future version must learn to negotiate its way through this adversarial politics. The current research re-examines the perspective of Henriques (2010) who dwells on the issues arising from the multi-stakeholder approach to developing a global human rights standard from a participant in the process of ISO 26000.

Methodology

As ISO 26000 initially anticipated to be built in the line of intellectual and practical infrastructure of ISO 9000 and ISO 14000, naturally leading to certification, the Advisory Group on Social Responsibility reached a consensus to develop this as a guidance standard and not a specification standard against which conformity can be assessed. The current research intends to carry forward the investigation Castka and Balzarova (2008) who view that ISO member body delegations and invited participants in international standardisation of social responsibility – some 500 delegates participated from various task groups and committees spreading across geographies -- diverged from the meta-standard approach towards a guidance standard.

The current research will not only revisit the discussions at the ISO International Conference on Social Responsibility, where ISO member body delegations and approximately 40

invited organisations commented on this matter, however, it would also suggest agenda for the future meeting in order to create better standardisation of social responsibility leading to certification.

Direction of the Research:

In the view of the above it is probably a plausible idea to take ISO 26000:2010 to its drawing board, which emerged from meeting in eight Working Group Plenary Sessions between 2005 and 2010 involving multiple stakeholders, as it would now be a more resolute guideline leading to certification and at the same time allowing the development of national standards that are more specific, more demanding, or of a different type.

A better approach towards a new version of ISO 26000:2010 standard can only be found upon knowing the dissonances that stemmed out of the year 2010 meeting in relation to policymaking, global governance and sustainable development. Ward (2012) suggested steps to maximise the positive contributions of ISO 26000:2010 with regard to global governance for sustainable development and better understanding of market governance mechanisms.

Since there are quite a few counter narratives to the triumph of ISO 26000 standard these deserve to have a mention in the current research. Roberts (2010) argues while CSR is applauded for a host of social goals such as health care, education, and infrastructure construction in developing countries, in practice it aims to devolve into a veiled threat as a form of coercion requiring organisations to transfer their earnings to a host of government authorities or their entire associated agencies.

Voices like Roberts (2010) must be listened to, in order to know how certain pharmaceutical organisations may resist any efforts to make ISO 26000 standards mandatory in the form of certification. Are these ISO standards are frequently used to buttress protectionist cases at WTO, thus have disgruntled many pharmaceutical organisations? It is good direction for the research to seek ways to keep ISO 26000 out of WTO debate, certainly not in the way some companies would like to protect their vested interest ignoring the larger social appeal of ISO 26000 as a de facto standard.

The better legitimacy of ISO 26000 can be established through a better understanding of the globalisation process engendered by a governance gap that is being addressed by transnational rule-making involving private actors among others. The current research concurs with the viewpoint of Hahn and Weidtmann (2012) who aver that the democratic legitimacy of such new forms of governance beyond nation states confronts the concept of nation-centered democracies. Hahn and Weidtmann (2012) suggest such governance cannot build, for example, on representation and voting procedures to convey legitimacy to the generated rules but instead, alternative elements of democracy such as deliberation and inclusion required for discussion to assess new instruments of governance.

Conclusion

The current research certainly views ISO 26000 in the light of Hahn and Weidtmann (2012)'s suggested new-age understanding of corporate governance tantamount to transnational governance. Since the ISO 26000 standard has stemmed out of a prolonged multi-organizational process in order to provide guidance on the social responsibility it still needs to answer the questions of its legitimacy in the context of nation-state democracy. The latter, which always regarded as the de facto social responsibility standard, must subject to this evolving discourse. The study must always find its moorings in the idea of democratic legitimacy, and must take note of normative legitimacy of the development process of ISO 26000 as and when necessary. In this process it would be able to position itself as a mandate on the most ideal interface of business and public policy.

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