

Anil Kumar Singh and Muqbil Burhan

Factors influencing organizational change and health - Evidences from the Indian pharmaceutical sector

Verena Zimara and Sebastian Eidam

The benefits of social sustainability reporting for companies and stakeholders – Evidence from the German chemical industry

Azamat Ali and Kunal Sinha

Biomedical research and development in the Indian therapeutic drug industry

Gert Müller

Managing risk during turnarounds and large capital projects: Experience from the chemical industry

Editorial Board

Editor-in-Chief

Prof. Dr. Jens Leker, Institute of Business Administration at the Department of Chemistry and Pharmacy, University of Münster, Germany

Editors

Prof. Dr. Mattia Bianchi, Dr. Clive-Steven Curran, Prof. Dr. Federico Frattini, Dr. Carsten Gelhard, Lars Hahn, Prof. Dr. Sebastian Kortmann, Prof. Dr. Thomas Lager, Dr. Stefan Picker, Dr. Carsten Schaffer, Prof. Dr. Stefan Seeger

Executive Editor

Birte Golembiewski

Subscription

The Journal of Business Chemistry (ISSN 1613-9623) is published every four months by the Institute of Business Administration at the Department of Chemistry and Pharmacy, University of Münster.

Online-Subscription is possible at:
subscription@businesschemistry.org.
The articles are available for download free of charge at www.businesschemistry.org.

jaAims and Scope

The Journal of Business Chemistry examines issues associated with leadership and management for chemists and managers in chemical research or industry. This journal is devoted to the improvement and development of the field of business chemistry.

The Journal of Business Chemistry offers a means for researchers and practitioners to present their results in an international forum.

Abstracting and Indexing

The Journal of Business Chemistry is covered by the following abstracting and indexing services:
- EBSCO Publishing (www.ebsco.com)

- Hamburg Institute of International Economics (online databases and print archive)
- German National Library of Economics
- Chemical Business NewsBase (CBNB) by Elsevier Engineering Information, Inc.

Copyright

Copyright © 2015 Institute of Business Administration, University of Münster

All rights reserved. No part of this publication may be reproduced or transmitted, in any form or by any means, electronically, mechanically, by photo-copying, recording, scanning or otherwise, except as described below, without the permission in writing of the publisher.

Copying of articles is not permitted except for personal and internal use, to the extent permitted by national copyright law. Requests for permission should be addressed to the publisher.

Statements and opinions expressed in the articles and essays are those of the individual contributors and not the statements and opinions of the Institute of Business Administration, University of Münster. The Institute and the University of Münster assume no responsibility or liability for any damage or injury to persons or property arising out of the use of any materials, instructions, methods or ideas contained herein. The Institute and the University of Münster, expressly disclaim any implied warranties or merchantability or fit for a particular purpose. If expert assistance is required, the services of a competent professional person should be sought.

Publisher

The Journal of Business Chemistry (ISSN 1613-9623) is published by the Institute of Business Administration at the Department of Chemistry and Pharmacy, University of Münster, Leonardo-Campus 1, 48149 Münster, Germany.

Contents

Letter from the Editor

Research Paper

Factors influencing organizational change and health - Evidences from the Indian pharmaceutical sector

Anil Kumar Singh and Muqbil Burhan..... 69

The benefits of social sustainability reporting for companies and stakeholders – Evidence from the German chemical industry

Verena Zimara and Sebastian Eidam..... 85

Practitioner's Section

Biomedical research and development in the Indian therapeutic drug industry

Azamat Ali and Kunal Sinha..... 105

Managing risk during turnarounds and large capital projects: Experience from the chemical industry

Gert Müller..... 117

Letter from the Editor

Pharmaceutical companies in emerging countries

Consulting firms and many scholars currently try to explain recent developments within the pharmaceutical sector. Established multinational pharma firms are under pressure and rethinking their strategies and business models. Although growth in emerging markets seems possible, capturing this opportunity is yet challenging due to regional differences requiring adaptation e.g. regarding the value proposition, designed distribution systems (levels of integration) and prices. If an engagement, for instance, in Indian pharmaceutical markets is worthwhile, thus needs to be analyzed for every specific case. Local Indian firms have started to make use of the dynamics and benefit from their existing market knowledge and flexibility. At the moment, the business with generics still prevails the Indian pharmaceutical market but own capabilities in drug development have been generated. As many open questions regarding the ability of multinational players to exploit the (profit) potential of emerging markets, the capacity of local firms to compete in drug design and the distribution of power remain, it will be exciting to observe future developments.

Thus, we are pleased to welcome the first research paper of this issue “Factors influencing organizational change and health – Evidences from the Indian pharmaceutical sector” by Anil Kumar Singh and Muqbil Burhan. The authors present results from a survey conducted in pharmaceutical companies in India and examine the influence and interaction of several factors such as structural flexibility, information management, decision making and shared leadership on competitive advantage. The authors thus provide evidence that integrating these organizational characteristics and developing the capability to change are necessary in order to achieve organizational health and success in dynamic environments.

The second paper “Benefits of social sustainability reporting for companies and stakeholders – Evidence from the German chemical industry” by Verena Zimara and Sebastian Eidam addresses the dimension of social sustainability which is often neglected by companies, particularly in reporting. By comparing social sustainability reports of 14 German chemical companies with regard to their conformity with the Global Reporting Initiative (GRI) guidelines, the authors reveal insights on the companies’ aims, benefits and different foci, and discuss the comparability of reporting social activities and associated performance indicators.

The first paper of our Practitioner’s Section “Biomedical research and development in the Indian therapeutic drug industry” by Azamat Ali and Kunal Sinha deals with the current and future situation of R&D in the pharmaceutical sector, particularly focusing on biomedical drug development in India. By analyzing research as well as market information, the authors identify the main drivers for growth in this field. Moreover, the different magnitudes of R&D investments, routes and outcomes in drug development of six large Indian pharmaceutical firms are compared and also set in relation to the public sector’s research efforts.

Gert Müller presents an overview on risk management challenges and tools for turnaround projects in his article “Managing risk during turnarounds and large capital projects: Experience from the chemical industry”. After elaborating on the need for a different approach to risk management, the author suggests to consider various factors such as the probability and frequency of a risk to occur, barriers preventing hazards from becoming risks, the severity of consequences for different areas and countermeasures in order to evaluate and handle risks adequately. Reporting on practical experiences complements the insights on managing risks in turnaround projects.

Please enjoy reading the third issue of the twelfth volume of the Journal of Business Chemistry. We are grateful for the support of all authors and reviewers for this new issue. If you have any comments or suggestions, please do not hesitate to contact us at contact@businesschemistry.org.

Birte Golembiewski, Executive Editor

Research Paper

Factors influencing organizational change and health - Evidences from the Indian pharmaceutical sector

Anil Kumar Singh* and Muqbil Burhan*

* FORE School of Management, B-18, Qutab Institutional area, New Delhi: 110016, India, anil.singh@fsm.ac.in

Dynamics and interplay among various drivers and competencies in any organizational set-up shape the configurations of the systems black box. Structural flexibility, information management, decision making and leadership are critical components which manage the intra-organizational interactions for a collective meaningful outcome in terms of organizational change capability and superior performance. In the recent past, the Indian pharmaceutical sector has witnessed impressive global consolidation and expansion. The organizational health recipes which have been designed by the Indian pharmaceutical sector for its healthy growth need to be explored and understood. Identifying how these variables interact and how they have contributed to the success of the pharmaceutical sector is the key research agenda of this paper. The responses obtained from 216 mid- and senior-level executives of the Indian pharmaceutical industry have been processed by structural equation modeling to investigate interactive dynamics. Therefore, the outcomes are of value to scholars as well as practitioners.

1 Introduction

The scholarly and intellectual interest in pharmaceutical industry results from its highly 'closed' innovation model, pricing policies, regulatory barriers and dynamics of boundaries of the firm (Foss and Rasmussen, 2014). The Indian pharmaceutical industry will grow to US\$ 55 billion by 2020 driven by steady rise in affordability and a steep jump in market access. Articulating the insights and revelations by transcending through the 150 years old history of Indian pharmaceutical industry, it is not very surprising to find that ability to change and adopt are the key survival instincts which this industry has exhibited. The current state of its health is due to existing capabilities to change, adopt and reconfigure its competencies in light of external happenings. This magnitude of growth will lead towards a market size at par with developed markets other than the US, Japan and China and in terms of volumes it will be next to the US (McKinsey, 2013).

The pharmaceutical and medical report by McKinsey & Company (2013) and its research related to

the Indian pharmaceutical sector has embarked upon four fundamental questions: How can the industry stimulate the growth drivers? What are the most attractive opportunities in Indian markets? Which capabilities will differentiate the leaders of tomorrow? Would the way organizations are structured and managed need to change as the range of opportunities becomes diverse?

This complexity calls for an investigation into the status of organizational health of the Indian pharmaceutical sector identifying the key enablers which have catapulted this industry from a weak health configuration to global recognition. Before we proceed with the framework, model and empirical investigation, it is important to trace the enablers of this development in the industry so far. Researchers dealing with business and industry history have divided the evolutionary path in four stages with an objective to explain the industry dynamics in minutest detail. The objective of this research is to examine the internal firm-specific dynamism and more recent trends. Once research broadly understands the challenges and obstacles faced by this industry, it is possible to explore the

concept of organizational health and the constructs contributing to this central theme. We scan the literature examining the key variables associated with this unexplored phenomenon and propose a framework based on extensive literature review. We hypothesize relationships within a constructed model on the basis of existing theory and then constructs are modeled based on empirical data to validate the theoretical understandings.

2 Theoretical background

2.1 Organizational health

"[...] the health of an organization is based on the ability to align around a clear vision, strategy, and culture; to execute with excellence; and to renew the organization's focus over time by responding to market trends. Health also has a hard edge: indeed, we've come to define it as the capacity to deliver - over the long term - superior financial and operating performance". (Smet et al., 2014)

Similar to humans, a healthy organization can sustain its existence in longer runs. Therefore, it is implicit that organizational health is a powerful lever in a dynamic business environment where coping with change is an instinct linked with survival. Organizational health according to Smet *et al.* (2014) can be achieved by following one of the following four ways ("organizational health recipes"):

A. Leader-driven:

This refers to presence of talented and high-potential leaders at all levels in the organization who can exercise autonomy and are accountable. The ability to create something from nothing is materialized if this health driver is aptly nourished and nurtured.

B. Market-focused:

This refers to a firm's external orientation not

only towards the customers but also towards regulators, partners, competitors and the community. This approach directs the ability of organization to be shapers of market trends, innovators and creators of robust brand equity.

C. Execution-edge:

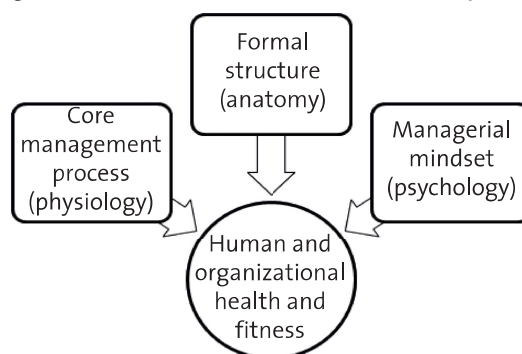
This describes the ability to sense the environment, reconfigure and deploy resources. Thus, the thrust is on the ability to swiftly act with a stout mechanism of decision making.

D. Talent and knowledge core:

This lever refers to the ability of organizations to build competitive advantage by assembling and managing a high-quality talent and knowledge base.

Following the inductive reasoning to the concept of organizational health as proposed by Smet *et al.* (2014), the theory of organizational health can be configured around the following facets. The talent and knowledge core constitute the essence of effective organizational processes, reconfiguration and deployment of resources hinge on organizational structure, the issues of market focus correspond to the sensing abilities of organizations for change and the drive comes from the organizational leadership. The health of business organizations can thus be viewed to rest upon three fundamental pillars, i.e. core management processes, formal structures and managerial mindset. If we compare these aspects of organizations with humans, they can be interpreted as synonyms for anatomy, physiology and psychology. Organizational health as interpreted and modeled in this paper (figure 1) focuses on organizational structure (anatomy), mechanism of transparency in information sharing and decision making (physiology) and shared leadership and change friendly identity (psychology). The human architecture is structured by nature and its health depends upon a balanced

Figure 1 The pillars of human and organizational health (Source: Researchers' own presentation).



interactive dynamics among the three key variables. Organizations are socio-economic units purposefully structured to bridge the value gaps. These value delivery propositions are interpreted as (parts of) business models in management literature.

2.2 Business models

Organizations and living entities are configured around the structural domains of inter- and intra-relationships. The efficiency in management of these interfaces provides benefits which are aimed at. In business context, the organizational pattern of relationships can be termed as business model. Research exists in abundance but concurrence and concreteness in the understanding of the term business model is lacking (George and Bock, 2011 and 2012). The best way to interpret and understand a business model for any firm is in terms of value propositions towards customers (Doz and Kosonen, 2010; Teece, 2010; Tikkanen *et al.*, 2005).

What makes a business tangible, is the anatomical foundation interpreted as organizational structure (Baden-Fuller and Morgan, 2010). The management processes coupled with shared leadership act as an enabler for organizational health and thus configure the organizational change ability (Gulati and Puranam, 2009; Hall and Saias, 1980). Since business models need continuous reconfigurations, any random or planned fluctuations in the environment call for realignment (Ho *et al.*, 2011; McGrath, 2010; Sosna *et al.* 2010; Teece, 2010) of processes and structure. Leadership acts as a facilitator in adjusting and coping with changes. It becomes apparently evident that changes in environment call for a reconsideration of the business model. The (re)configurations will revolve around the organizational capability of leadership, process and system dynamics and the structural organization (Najmaei, 2011).

Research by PricewaterhouseCoopers (PWC, 2009) states that the conventional integrated business model (from discovery to customer) will become distant reality in future times (Gilbert *et al.*, 2003; PWC, 2009). They suggest that alternative business models are needed to ensure effectiveness of the business value delivery.

O'Reilly and Tushman (2004) have contributed to the understanding of innovations in business models and organizational principle structural (anatomical), operational (physiological) and conceptual (psychological) components, but their work is limited to manifested organizational structures in light of business model innovations. As shown by firms in the Indian pharmaceutical sector, there has been continuous innovation in the business models over time (Foss and Stieglitz 2014, Foss and

Rasmussen 2014). Whenever an organization innovates its business models, it requires the inclusion of new tasks inside the company in order to address requirements and reshaping the coordination requirements with this new practice initiation (Foss and Rasmussen 2014). This refers to a shift in organization's health constructs by reconfiguring its structure, processes and leadership.

Changes in business models and business configuration are done to exploit unique and novel opportunities with a balance of coordination, control and expectations of better gains (Johnson *et al.*, 2008). This study draws from these key issues and correlates it to an aggregated term of organizational health. Whelan-Berry *et al.* (2003) have proposed culture, vision, leadership and communication as facilitators to the change process. These change ingredients have a high degree of dependence on structure, process and leadership. The research constructs employed in this paper have sound foundations to explore the relationships among the exogenous and outcome variables and are introduced in the following.

2.3 Hypotheses development

When linking performance with strategy and organizational structure, they can be seen as resultant and drivers (Chandler, 1962; Davis *et al.*, 2009). Structure can be interpreted as a macro-level, multifunctional system with an implicit objective of creating and capturing value (Bock *et al.* 2012). *Structural flexibility* as an organizational capability can be defined as simplification, expansion or reconfiguration of the constituent elements in light of a reorientation of a practiced business model. Structural flexibility can drive performance by reducing the coordination costs and increasing cooperation among the units leading to enhanced ability for exploration and exploitation (Mom *et al.*, 2009). Structural flexibility when viewed closely with a conceptual lens involves consolidation, removal, delegation and devolution which enable managers to resolve critical issues and exploit opportunities arising out of changes in environment (George and Bock, 2012; Ocasio, 1997; Rothaermel *et al.*, 2006).

The key role of organizational leadership is to perceive and share the impact of exogenous changes on the organization's competitive position (Ocasio, 1997) and this calls for *shared leadership and collective identity*. *Transparent information and decision making* act as glue to hold structural needs and the understanding of leaders concerning the organization and its environment together. Managers must pay attention to the roles and significance of knowledge sharing, dissemination and communication in discovering, penetrat-

ing into and exploiting new markets as well as assessing the progress of their revolutionary initiative (Najmaei, 2011).

Leadership is therefore responsible to define and design the organizational characteristics for superior performance, success and ultimately organizational health (Davis *et al.*, 2009; Glick *et al.*, 1990). Adapting and changing to the needs of the future, results in superior performance in complex and dynamic environments (Nadkarni and Narayanan, 2007). Interpreting planned organizational change as a generic phenomenon might mask important idiosyncrasies associated both with the different activities involved in the change implementation process and with the unique functions that leadership competencies might play in the execution of these activities (Battilana *et al.*, 2010). Therefore, it is essential to integrate the enablers which enhance the firm's ability to change and thus become different from others in terms of performance which is used as a proxy for *competitive advantage*.

In this paper, we propose that the firm's ability to change (CC) is linked with superior performance (CA), which is an indicator of better organizational health. In addition, the change capability (CC) depends on the organizational abilities: structural flexibility (SF), transparent information and decision making (ID) and shared leadership and identity (SLI). Furthermore, an attempt to identify the role of change capability as a mediator in the proposed relationships is made.

Studies in the area of organizational design have established relationships between structure and change. Structure can facilitate and act as an enabler resulting in better ability to control and to have a clear focus (Ethiraj *et al.*, 2008; Lee and Makhija, 2009). Reduction in cost of coordination and broad-

ening the range of offerings for better-off position among rivals is enabled by increasing the availability of information and the ability of organization to share (Puranam *et al.*, 2006; Sanchez and Mahoney, 1996). The explicit questions addressed here are:

1. How structural flexibility is related to organizational change capability and contributes to the firm's competitive advantage.
2. How transparent information and decision making is related to organizational change capability and contributes to firm's competitive advantage.
3. How shared leadership and change friendly identity is related to organizational change capability and contributes to firm's competitive advantage.

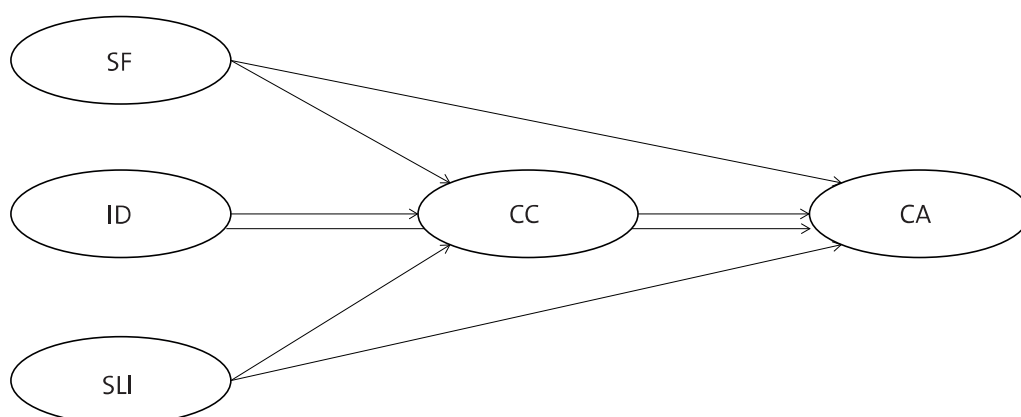
The relationships thus investigated are depicted in figure 2, where change capability (CC) is proposed as a mediating variable between the constructs of structural flexibility (SF), transparent information and decision making (ID), shared leadership and change friendly identity (SLI) and competitive advantage (CA) measured by a proxy of superior performance.

The associated research hypotheses are:

H_{SFCC} : Structural flexibility (SF) has a significant, direct and positive impact on change capability (CC).

H_{SFCA} : Structural flexibility (SF) has a significant, direct and positive impact on competitive

Figure 2 Proposed structural model.



advantage (CA).

H_{IDCC}: Transparent information and decision making (ID) has a significant, direct and positive impact on change capability (CC).

H_{IDCA}: Transparent information and decision making (ID) has a significant, direct and positive impact on competitive advantage (CA).

H_{SLICC}: Shared leadership and identity (SLI) has a significant, direct and positive impact on change capability (CC).

H_{SLICA}: Shared leadership and identity (SLI) has a significant, direct and positive impact on competitive advantage (CA).

H_{CCCA}: Change capability (CC) has a significant, direct and positive impact on competitive advantage (CA).

H_{MCA}: Change capability (CC) plays a mediating role between SF, ID, SLI and CA.

3 Research method

3.1 Sampling frame and sample characteristics

Senior level management employees from Indian pharmaceutical companies constitute the target population in this study. Our definition of the Indian pharmaceutical sector includes those firms which primarily operate in India, are incorporated and registered under the Indian Companies Act of 1956, and might be operating abroad but are not branches of a foreign company (as defined by Sharma and Singh, 2012a, 2012b; Singh, 2014). The data source for identifying the companies is CMIE (Center for monitoring Indian economy), which provides detailed and exhaustive information on 648 organizations through the database PROWESS. Data collection occurred during the years 2012 and 2013. For Indian companies, CMIE is a leading information provider and many published papers have used this database for India-specific research.

The level at which the analysis is carried out are pharmaceutical organizations (Davidsson and Wiklund, 2001; Singh, 2014). Information from top level managers provides valuable insights into the organizational systems and practices (Snow and Hrebiniak, 1980, p.320) and therefore, the information pertinent to research questions was collected from them and this data in aggregate represents the measurements at the firm level. A number of studies has previously adopted this approach, for example, Cragg and King (1988), Davidsson and Klofsten

(2003), Gadenne (1998), Kara *et al.* (2005), Sharma and Singh (2012a) and (2012b), Singh (2014). Understanding the fact that top-level executives in a firm have adequate information and understanding about the uniqueness of processes and systems followed by firms, information specific to the organizational context with reference to competitive advantage and organizational performance is obtained from them.

The overall study design is adapted from Singh (2014). The sampling design followed the approach suggested by Short *et al.* (2002) for studies of this kind. To add relevance to the research, the list of pharmaceutical firms was analyzed on the basis of consistency in the sales turnover over a period of the past eight years (2005-2012). On this basis, we derived thirty firms eligible for data collection and analysis. In an attempt to resolve existing disparities in sampling processes in place, this census was chosen. These thirty firms were targeted for 15 responses from key informants which totaled to a size of 450 responses.

Data analysis was carried out through structural equation modeling (SEM) by using AMOS 19. The final sample size depends upon reliability, strength in effects and complexity in model (Bearden *et al.*, 1982; Bollen, 1990). There is lack of consensus on the recommended sample size for SEM, Gerbing and Anderson (1985) have suggested a sample size of 150 for a convergent and proper solution whereas Garver and Mentzer (1999), Hoelter (1983) as well as Sivo *et al.* (2006) have proposed a critical sample size of 200. If we adapt the study to the sample size prescribed, any sample size equal to or above 200 is accepted as it may provide sufficient statistical power for data analysis (Singh, 2014).

Data was collected for this study by hosting an online questionnaire on Google documents, sent to the targeted organizations by collecting details from their websites and other sources like a directory of NPPA (National Pharmaceutical Pricing Authority). Studies which have used online surveys consider 20% responses as valid (Hitt *et al.*, 2004; Malhotra and Grover, 1998). Considering the response rate of 38% by Subramaniam and Venkatraman (2001), 21% by Paxson *et al.* (1995), 41% by Dyer and Hatch (2006), Dyer and Nobeoka (2000), Kotabe *et al.* (2003), 25% by Kale *et al.* (2002), 32% by Hoskisson *et al.* (2000), this study has a higher response rate, i.e. 48%. Among a total of 216 responses obtained, 168 out of 250 were obtained by physical follow-ups and 48 out of 200 were obtained online. The item completion rate was 99% indicating a high survey effectiveness.

3.2 Measures

The focus of this study is on exploring the strength of relationship between SF, ID, SLI, change capability and competitive advantage. In absence of existing scales, a new instrument (table 1) has

been developed in two stages as suggested by Menor and Roth (2007).

Table 1 Constructs and their measure.

Construct	Construct description	Measure (Seven point scale: 1 – strongly agree; 7 – strongly disagree)
Structural flexibility: <i>Ability of the structure to expand to maximizes the surface area of the firm.</i>	<i>Structural flexibility</i> as an organizational capability can be defined as simplification, expansion or reconfiguration of the constituent elements in light of reorientation of practiced business model (Mom <i>et al.</i> , 2009).	1. Cross-functional teams with more authority than departmental managers in daily decisions. 2. Allocation of resources to improve and adapt. 3. Awareness and categorization of level of risk acceptable to the organization. 4. HR practices which enhance understanding of change.
Transparent information and decision making: <i>Availability of relevant information across various decision making domains which provides for a mechanism which facilitates goal setting, decision making and implementation</i>	Refers to roles and significance of knowledge sharing, dissemination and communication in discovering new markets, penetrating into them, exploiting them and assessing the progress of their revolutionary initiative (Najmaei, 2011).	1. Mechanism to allow critical information about trends, opportunities, and issues to flow into decision making. 2. Effective communication and implementation of strategy. 3. Easy access to information of interest to customers and associates. 4. Mechanism to encourage Employees for solving problems they encounter. 5. Approach to treat mistake as opportunities for learning and improve. 6. Frequent goal setting reviews.
Shared leadership and change friendly identity: <i>Focus on leadership as an individual trait, leadership as an organizational capacity, which integrates the organization with its environment</i>	Leadership which is responsible to define and design the organizational characteristics for superior performance, success and ultimately organizational health (Davis <i>et al.</i> , 2009; Glick <i>et al.</i> , 1990).	1. Team work to support the overall objectives. 2. Ability to translate vision to employee action by strong leadership. 3. Capacity to quickly respond to changes as and when required.
Change capability: <i>Defined as the ability to sustainably integrate, reconfigure, gain and release resources to ensure alignment with changing organizational environments.</i>	Definitions of change typically suggest it is composed of three main elements, a current state, a desired future state, and a set of transition processes to shift from the current state to the desired future state (Beckhard and Harris, 1987).	1. Leadership with consensus based direction setting. 2. Focusing change simultaneously on systems and corporate culture. 3. Valuing to be proactive than to be reactive. 4. Emphasis on new practices to suite changes. 5. Ability to align with need of change in case of shifting business priorities.
Competitive advantage: <i>Competitive Advantage is not just a function of how one plays the game; it is also a function of the assets that one has to play with and how these assets can be deployed and re-deployed in a changing market.</i>	The capability of an organization to create a defensible position over its competitors (Li <i>et al.</i> , 2006).	1. Ability to change swiftly than the competitors. 2. Better change ability ensured by shared leadership for superior performance. 3. Configuring structure to drive change capability and thus superior performance. 4. Transparency in information and decision making for change thus superior performance. 5. Change linked to performance.

3.3 Testing the measurement model

3.3.1 Exploratory Factor Analysis (EFA)

Uni-dimensionality and reliability was checked at the onset by carrying out exploratory factor analysis. The concept of uni-dimensionality is one of the basic assumptions in measurement theory which a research shall meet before proceeding for analysis (Steenkamp and Van Trijp, 1991). This refers to the existence of one construct which underlines a complete set of items (Anderson and Gerbing, 1987; Kumar and Dillon, 1987; Steenkamp and Van Trijp, 1991). Confirmatory factor analysis was carried out after conducting exploratory factor analysis on each scale separately so that factor loadings on each construct are verified. As the research scales were hypothesized to be uni-dimensional, it was expected that all items will load highly on one factor. This can be verified when the KMO (Keiser Meyer Olkin) test values are greater than 0.5. Following the above rules, the results for EFA were interpreted, and it was found that the scales were uni-dimensional on the basis of the eigenvalues greater than 1 heuristic

(Delgado-Ballester *et al.*, 2003), one principal component was extracted which accounts for more than 50% of the total variance of the scale.

3.3.2 Confirmatory Factor Analysis (CFA)

For carrying out the confirmatory factor analysis of the structural model, maximum likelihood method was chosen as it is statistically well-founded and is least affected by the sampling error. The convergent reliability and the validity of alignment are checked by examining the adjustment level of the model and the causality coefficients which linked various constructs (see Sharma and Singh, 2012a and 2012b; Singh, 2014). Since all the scales were uni-dimensional, a CFA is carried out to check further reliability and validity of scales (table 3). Values of indicator reliability are within the accepted limits (Long, 1983; Schumacker and Lomax, 2004; Wu, 2005).

Cronbach's alpha values are calculated to check reliability. All values for the constructs are above 0.7, which are meritorious (Hair *et al.*, 1998; Nunnally and Bernstein, 1994). When values of construct

Table 2 Results of KMO and Bartlett's test of sphericity.

Construct	KMO measures of sampling adequacy	Bartlett's test of sphericity		
		Approx. Chi.-Sq.	Df	Sig.
Structural flexibility	.746	147.311	6	0.000
Transparent information and decision making	.840	283.871	15	0.000
Shared leadership and change friendly identity	.746	70.830	3	0.000
Change capability	.815	274.640	6	0.000
Competitive advantage	.822	163.591	10	0.000

Table 3 Results for indicator reliability.

Indicators	SF	ID	SLI	CC	CA
1	.49	.53	.67	.54	.48
2	.55	.46	.47	.46	.65
3	.47	.52	.48	.57	.56
4	.48	.55		.48	.47
5		.52			.47
6		.48			

Table 4 Results for construct reliability.

Measures	No. of items	Cronbach's alpha	Construct reliability	AVE
Structural flexibility	4	.711	.81	.51
Transparent information and decision making	6	.780	.88	.56
Shared leadership and change friendly identity	3	.739	.83	.57
Change capability	4	.787	.84	.51
Competitive advantage	5	.839	.87	.53

Table 5 Goodness of fit indices for the model.

χ^2	df	χ^2/df	GFI	CFI	IFI	RMSEA
347.459	190	1.829	.904	.941	.938	.056

reliability are calculated, they are found to be higher than 0.5, which is well accepted (Fornell and Bookstein, 1982). The values of average variance extracted (AVE) are higher than 0.5 which indicate appropriateness (table 4) of the internal consistency and construct reliability (Fornell and Larcker, 1981). One way to interpret discriminate validity is to look at the estimated correlation between factors (Klin, 2010) which is not greater than 0.85%. To reinforce the presence of discriminate validity, AVE and shared variance are compared. It is found that AVE is greater than the shared variance conclusively proving presence of discriminate validity (Singh, 2014). Since the constructs should relate with each other to provide logical relationships, the calculated correlational values are observed to be positive and significant (Ahire *et al.*, 1996; Dunn *et al.*; Graver and Mentzer, 1999 and 1994; Mentzer and Flint, 1997), providing sufficient evidence of predictive validity.

4 Results

4.1 Structural model

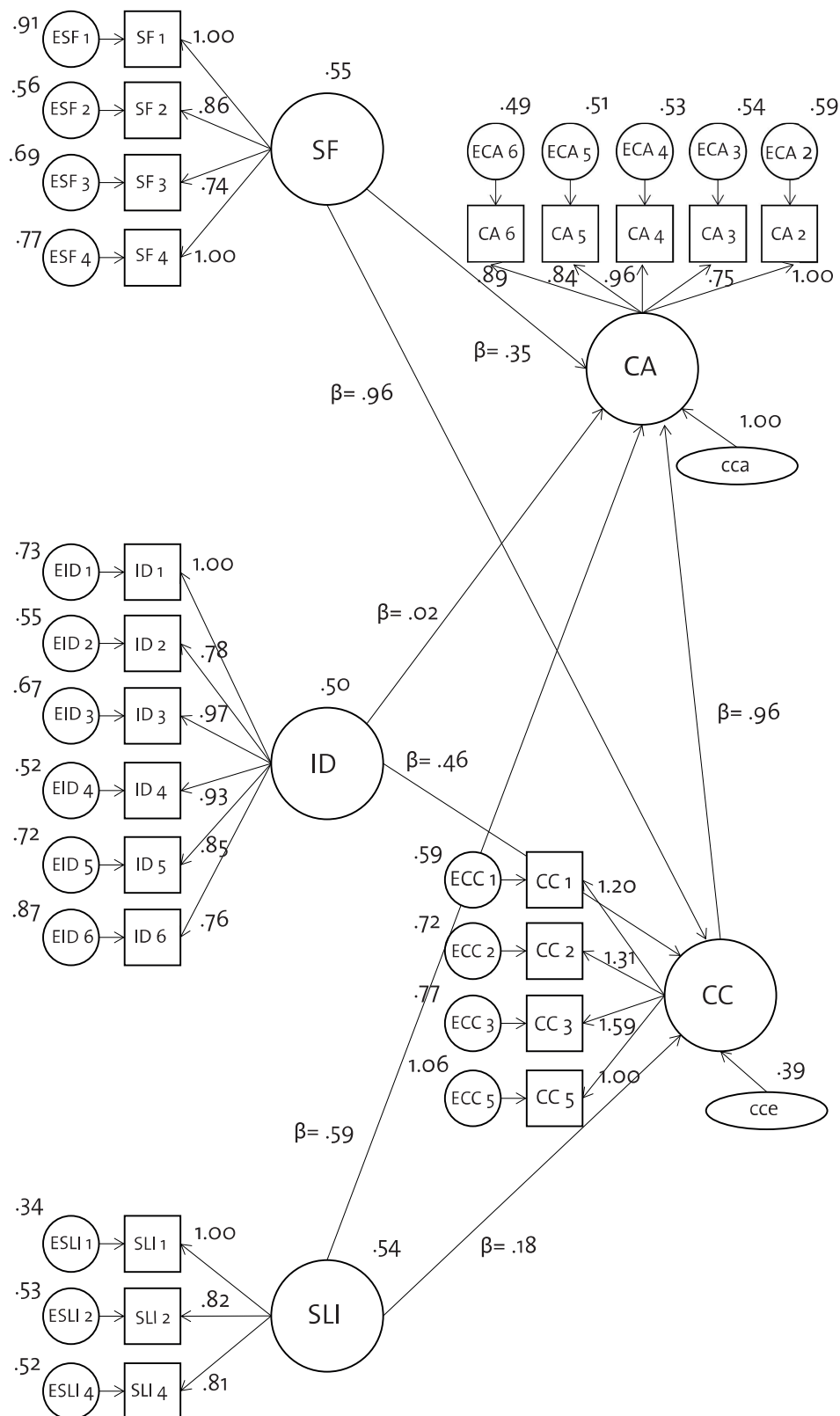
The statistical software Analysis of Moment Structures (AMOS 19) is used to test the conceptual model as shown in figure 2. In this study SF, ID, SLI are independent variables and the dependent variable is CA measured by a proxy of superior performance proxy (Barney, 1991 cited by Clulow *et al.*, 2003; Christensen and Fahey, 1984; Kay, 1994; Passe-

mard and Calantone, 2000; Porter, 1980 cited by Chaharbaghi and Lynch, 1999). Change capability as proposed was hypothesized to be a mediating variable. The tested model is shown in figure 3. It demonstrates good fit (table 5), as the values of CFI (comparative fit index) and RMSEA (root mean squared approximation of error) fall within the prescribed acceptable limits (Garver and Mentzer, 1999). Based on the inferences and recommendations about model fit, we have used the commonly accepted fit indices, CFI (>0.90 indicates good fit), RMSEA (<0.08 indicates acceptable fit) along with commonly used χ^2 statistic (χ^2/df ratio of 3 or less).

4.2 Mediation analysis

Direct effects measure the change in the dependent variable when the independent variable increases by one unit and indirect effects are compounded effects wherein the independent variable is held fixed and a change of the dependent variable is observed, considering the changes in the mediator variable by the amount it would have changed if the independent variable increased by one unit (Pearl, 2001; Robins and Greenland, 1992; Singh, 2014). According to Zainudin (2010), mediation in social sciences can be of three types. Full mediation occurs when the regression coefficient between the independent and mediating as well as between independent and dependent variable is significant. Partial mediation occurs when all three regression coefficients are significant, there is no mediation

Figure 3 Structural model including β path coefficients.



when the direct effect is higher than the indirect effect.

Properties of AMOS 19 are used to calculate the direct and indirect effects. Mediation is said to be established if the coefficient of the direct path between the dependent and independent variable remains significant when the indirect path via the

mediators is introduced in the model (Bontis *et al.*, 2007; Singh, 2014). In accordance with the study of Baron and Kenny (1986) which inherits the technique of Sobel (1982), the indirect effect should be higher than the direct effect to indicate a mediation effect in structural modeling (Wan Mohamad *et al.*, 2014). As proposed by Cheung (2007) and

Table 6 Path coefficients and hypotheses testing.

	Hypothesis	β	Result
H_{SFCC}	Structural flexibility (SF) has a significant, direct and positive impact on change capability (CC).	.96	Accepted
H_{SFCA}	Structural flexibility (SF) has a significant, direct and positive impact on competitive advantage (CA).	.35	Accepted
H_{IDCC}	Transparent information and decision making (ID) has a significant, direct positive impact on change capability (CC).	.46	Accepted
H_{IDCA}	Transparent information and decision making (ID) has a significant, direct and positive impact on competitive advantage (CA).	.02	Rejected
H_{SLICC}	Shared leadership and identity (SLI) has a significant, direct and positive impact on change capability (CC).	.18	Accepted
H_{SLICA}	Shared leadership and identity (SLI) has a significant, direct and positive impact on competitive advantage (CA).	.59	Accepted
H_{CCCA}	Change capability (CC) has a significant, direct and positive impact on competitive advantage (CA).	.96	Accepted

Table 7 Mediation analysis.

	Direct effect on change capability (CC) (β)	Direct effect on competitive advantage (CA) (β)	Indirect effect on competitive advantage (CA) (β)	Interpretation
Structural flexibility (SF)	.957	.354	.921	Indirect effect > Direct effect: Full mediation
Transparent information and decision making (ID)	.462	.021	.444	Indirect effect > Direct effect: Full mediation
Shared leadership and change friendly identity (SLI)	.183	.589	.176	Indirect effect < Direct effect: No mediation

MacKinnon (2000), the indirect effect can be estimated by the product of the direct effect β -value of the independent variable on the mediator variable and the direct effect β -value of the mediator variable on the dependent variable. The direct, indirect and total effects among the constructs as depicted in the model are presented in table 7. It reveals that change capability mediates the relationship between the structural flexibility of the firm and its ability to extract superior performance and thus contributes to competitive advantage. Similar is the case when we interpret results concerning the relationship between transparent information and decision making and the competitive advantage. Here, change capability acts as well as a mediator between the independent and the dependent variable. This reinforces the assumption that the ability to morph the organizational structure according to the needs of changes and also the information sharing and decision making positively contribute to the organizational ability to change and thus enhance the competitive advantage of firms. In case of shared leadership and change friendly identity, there is no evidence of a mediating role of change capability. Instead, it directly contributes to the competitive advantage of firms and also influences their change capability (figure 3). Therefore, the hypothesis H_{MCA} : *Change capability (CC) plays a mediating role between SF, ID, SLI and CA* is rejected and we infer that change capability only mediates the relationship between structural flexibility and the transparent information and decision making.

4.3 Discussion and conclusion

The results concerning the values of path coefficients (table 6 and figure 3) along with the model fit provide a sound and logical foundation for the theoretical constructs. The β -value is a measure of how strongly each predictor variable influences the criterion (dependent) variable. β is measured in units of standard deviation. As SEM path analysis provides no straightforward tests to determine model fit (Suhr, 2000), this relationship is to be examined in light of multiple tests e.g. chi-square, comparative fit index (CFI), Bentler-Bonett non-normed fit index (NNFI), root mean squared error of approximation (RMSEA) (Hu and Bentler, 1999).

As hypothesized in the theoretical constructs, strong relationships are exhibited between structural flexibility and organizational change capability and between change capability and superior performance (β -value of 0.96 in both cases), leading towards the conclusion that the role of organizational structure is paramount when organization faces exogenous shocks and a need for change.

Structure can be therefore interpreted as an enabling mechanism assisting organizations to adapt in response to the requirements of change. Change is significantly linked to the ability to perform better than rivals and thus providing an organization with a competitive edge resulting in unique advantages. Thus, the ability of organizations to change is a significant contributor towards gaining competitive advantage. This finding conforms to earlier researches exploring relationships between the organizational structure, change and competitive advantage (Bock *et al.*, 2012; Chandler, 1962; Davis *et al.* 2009; George and Bock, 2012; Mom *et al.*, 2009; Ocasio, 1997; Rothaermel *et al.*, 2006).

The hypothesized relationship between transparent information and decision making (ID) and change shows a moderately strong β -value (0.46), thus leading to an interpretation that this ability is positively and directly related to its ability to change. The relationship between the construct of transparent information and decision making (ID) and competitive advantage is feeble (β -value of 0.02), the possible reason for this effect can be due to the assessment of impact of decisions. The role of this construct is to act as glue, holding together the structural configurations and the other attributes (factors) for organizational success but the relationship with competitive advantage is not pounced. An important understanding which therefore emerges enhances our arguments proposed in the theoretical construct that transparent information and decision making does not contribute significantly to the construct of competitive advantage but it is an enabler positively contributing to organizational change capability. The results of this study therefore support the earlier findings of scholars (e.g. Ethiraj *et al.*, 2008; Lee and Makhija, 2009; Najmaei, 2011; Puranam *et al.*, 2006; Sanchez and Mahoney, 1996).

The relationship between shared leadership and change friendly identity (β -value of 0.59) with competitive advantage is strong, in line with the role of leadership in organizational success as proposed by various researchers. The relationship between the construct of shared leadership and change friendly identity with change capability (β -value of 0.18) shows to be positive and thus reinforces our belief that leadership has a significant role to play when it comes to an organizational capability to change as shown by Battilana *et al.* (2010), Davis *et al.* (2009), Glick *et al.* (1990), Ocasio (1997), Nadkarni and Narayanan (2007) and Whelan-Berry *et al.* (2003).

All in all, the relationships explored in this research contribute to our understanding of organizational health (Smet *et al.*, 2014) as a construct. As discussed in figure 1, compared to living organ-

isms, any formal organization can also be characterized by its anatomy (organizational structure), physiology (organizational systems and processes) and psychology (leadership and thought process). A healthy state of any living entity depends upon integrative and balanced functioning of the three key components. A healthy organization will therefore need a balanced integrative mix of structure, decision making and leadership (Ho *et al.*, 2011; McGrath, 2010; Sosna *et al.*, 2010; Teece, 2010). As observed in living entities, the three attributes of health reconfigure in response to changes and if the attributes resemble, organizational ability to change will also be conditioned by its attributes of structure, decision making and leadership. Healthy entities as well as organizations have definitely advantages over their counterparts. This implies that the attributes of success, survival and health are rooted in the organizational attributes as proposed in this research.

An objective appraisal of the research reveals its contributions to the discipline of business management in three ways. First and foremost, this research contributes towards an understanding about the construct of organizational health and the attributes associated with it. Subsequently, this research is valuable since it sheds light on the theoretical basis for change management strategies which experts recommend for competitive advantage. The third important contribution is to the creation and establishment of a link between three distinct bodies of research: organizational health, change capability and competitive advantage.

5 Limitations and implications for future research

The focus of this research is on the Indian pharmaceutical industry which has catapulted itself from a small home-based, inconspicuous sector to a global scale. Since a lot of characteristics are industry-specific, it is advisable that results are interpreted with caution as they require to be tested in different industry contexts. However, the broad constructs underlined on organizational health may not differ considerably across industries or even if they differ, the difference may be marginal. The nature of this study is proving association not causality in true sense. Since the data was obtained from the same respondent, common method variance can emerge. It is true that the respondents were compatible with the purpose of this research and they possessed sufficient knowledge for meaningful data collection and analysis. Still, a multiple respondent survey would have been more meaningful. Even if the existing literature stipulates the sample size as adequate, a greater amount of data

would have revealed even more appropriate results and enabled sound interpretation.

The three constructs attributed to organizational anatomy, physiology and psychology are used to define the concept of organizational health. Its relationships with change and competitive advantage are explored. It is our belief that this study and the model add more granularities to the constructs operationalized. This constructs might be strengthened by adding a few more independent variables. Also qualitative aspects via case study methods can be explored to link the quantitative with qualitative revelations in order to enhance an enlightened understanding of this subject. One extension might be to look at specific antecedents to change capabilities such as firm's external networks, similar group analysis, regulatory pressures, their change capacity, and the role of information architecture and software. Another approach can be to conduct this study in different industries, different geographies and in contexts to mature the concept of organizational health.

References

- Ahire, S.L., Golhar, D.Y., Waller, M.A. (1996): Development and validation of TQM implementation constructs, *Decision Science*, **27** (1), pp. 23-56.
- Afthanorhan, W. M. A. B. W., Ahmad, S., Mamat, I. (2014): Testing the mediation effect using covariance based structural equation modeling with AMOS, *American International Journal of Research in Humanities, Arts and Social Sciences*, **6** (2), pp. 186-190.
- Anderson, J.C., Gerbing, D.W. (1987): Structural equation modeling in practice: a review and recommended two-step approach, *Psychological Bulletin*, **103** (3), pp. 411-423.
- Baden-Fuller, C., Morgan, M. S. (2010): Business models as models, *Long Range Planning*, **43** (2), pp. 156-171.
- Baron, R. M., Kenny, D. A. (1986): The moderator-mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations, *Journal of Personality and Social Psychology*, **51**, pp. 1173-1182.
- Battilana, J., Gilmartin, M., Sengul, M., Pache, A., Alexander, J. A. (2010): Leadership competencies for implementing planned organizational change, *Leadership Quarterly*, **21** (3), pp. 422-438.
- Bearden, W.O., Sharma, S., Teel, J.E. (1982): Sample size effects on chi-square and other statistics used in evaluating causal models, *Journal of*

- Marketing Research*, **19**, pp. 425-430.
- Beckhard, R., Harris, R. (1987): *Organizational Transitions: Managing Complex Change*, Addison-Wesley Pub. Co., Reading, MA.
- Blalock, H.M. (1979): *Social Statistics*, 2nd ed., McGraw-Hill, Kogakusha, Tokyo.
- Bock, A. J., Opsahl, T., George, G., Gann, D. M. (2012): The Effects of Culture and Structure on Strategic Flexibility during Business Model Innovation, *Journal of Management Studies*, **49** (2), pp. 279-305.
- Bollen, K.A. (1990): Political democracy: conceptual and measurement traps, *Studies in Comparative International Development*, **25** (1), pp. 7-24.
- Bontis, N., Hardie, T., Serenko, A. (2007): Self-efficacy and KM course weighting selection: Can students optimize their grades?, *International Journal of Teaching and Case Studies*, **1** (3-4), pp.189-199.
- Casadesus-Masanell, R., Ricart, J. E. (2010): From Strategy to Business Models and onto Tactics, *Long Range Planning*, **43** (2-3), pp. 195-215.
- Chaharbaghi, K., Lynch, R. (1999): Sustainable competitive advantage: towards a dynamic resource-based strategy, *Management Decision*, **37** (1), pp. 45-50.
- Chandler, A. (1962): *Strategy and Structure: Chapters in the History of American Industrial Enterprise*, MIT Press, Cambridge, MA.
- Cheung, M. W. L. (2007): Comparison of approaches to constructing confidence intervals for mediating effects using structural equation models', *Structural Equation Modeling*, **14**, pp. 227-246.
- Christensen, K., Fahey, L. (1984): Building distinctive competences into competitive advantage, *Strategic Planning Management*, February, pp. 113-123.
- Clulow, V., Gerstman, J., Barry, C. (2003): The resource-based view and sustainable competitive advantage: the case of a financial services firm, *Journal of European Industrial Training*, **27** (5), pp. 220-232.
- Cragg, P.B., King, M. (1988): Organizational characteristics and small firms' performance revisited, *Enterprise Theory and Practice*, **12**, pp. 49-64.
- Davidsson, P., Klofsten, M. (2003): The business platform: developing an instrument to gauge and to assist the development of young firms, *Journal of Small Business Management*, **41**, pp. 1-26.
- Davidsson, P., Wiklund, J. (2001): Levels of analysis in entrepreneurship research: current research practice and suggestions for the future, *Entrepreneurship Theory and Practice*, **25** (4), pp. 81-100.
- Davis, J. P., Eisenhardt, K. M., Bingham, C. B. (2009): Optimal structure, market dynamism, and the strategy of simple rules, *Administrative Science Quarterly*, **54** (3), pp. 413-452.
- Delgado-Ballester, E., Munuera-Aleman, J.L., Yague-Guillen, M.J. (2003): Development and validation of a brand trust scale, *International Journal of Market Research*, **45** (1), pp. 35-53.
- Doz, Y. L., Kosonen, M. (2010). Embedding strategic agility: A leadership agenda for accelerating business model renewal, *Long Range Planning*, **43** (2), pp. 370-382.
- Dunn, S.C., Seaker, R.F., Waller, M.A. (1994): Latent variables in business logistics research: scale development and validation, *Journal of Business Logistics*, **15**, pp. 145-145.
- Dyer, J.H., Hatch, N.W. (2006): Relation-specific capabilities and barriers to knowledge transfers: creating advantage through network relationships, *Strategic Management Journal*, **27** (8), pp. 701-719.
- Dyer, J.H., Nobeoka, K. (2000): Creating and managing a high-performance knowledge-sharing network: the Toyota case, *Strategic Management Journal*, **21** (3), pp. 345-367.
- Ethiraj, S. K., D. Levinthal, R. R. Roy. (2008): The dual role of modularity: Innovation and imitation, *Management Science*, **54** (5), pp. 939-955.
- Fornell, C., Larcker, D. (1981): Structural equation models with unobservable variables and measurement error, *Journal of Marketing Research*, **18** (1), pp. 39-50.
- Foss, N. J., Rasmussen, A. (2014): Business Model Innovation in the Pharmaceutical Industry: The Supporting Role of Organizational Design, available at: <http://ssrn.com/abstract=2400982> or <http://dx.doi.org/10.2139/ssrn.2400982>, accessed 24 February 2014.
- Foss, N., Stieglitz, N. (2014): Business Model Innovation: The Role of Leadership, in: Foss, N.J., Saebi, T. (eds.), *Business Model Innovation: The Organisational Dimension*, Oxford University Press, Oxford.
- Gadenne, D. (1998): Critical success factors for small business: an inter-industry comparison, *International Small Business Journal*, **17** (1), pp. 36-57.
- Garver, M.S., Mentzer, J.T. (1999): Logistics research methods: employing structural equation modeling to test for construct validity, *Journal of Business Logistics*, **20** (1), pp. 33-57.
- George, G., Bock, A. J. (2012): *Models of Opportunity: How Entrepreneurs Design Firms to Achieve the Unexpected*, Cambridge University Press, Cambridge.
- George, G., Bock, A. J. (2011): The business model in practice and its implications for entrepreneurship research, *Entrepreneurship Theory and Practice*, **35**, pp. 83-111.
- Gerbing, D.W., Anderson, J. C. (1985): The effects of sampling error and model characteristics on

- parameter estimation for maximum likelihood confirmatory factor analysis, *Multivariate Behavioral Research*, **20**, pp. 255-271.
- Gilbert, J., Henske, P., Singh, A. (2003): Rebuilding Big Pharma's Business Model, *In vivo-The Business and medicine report*, **21** (10), pp. 73-80.
- Glick, W. H., Huber, G. P., Miller, C. C., Doty, D. H., Sutcliffe, K. M. (1990): Studying changes in organizational design and effectiveness: retrospective event histories and periodic assessments, *Organization Science*, **1**, pp. 293-312.
- Gulati, R., Puranam, P. (2009): Renewal through reorganization: the value of inconsistencies between formal and informal organization, *Organization Science*, **20**, pp. 422-440.
- Hair Jr., J.F., Anderson, R.E., Tatham, R.L., Black, W.C. (1998): *Multivariate Data Analysis*, 5th ed., Pearson Prentice Hall, Upper Saddle River, NJ.
- Hall, D. J., Saias, M. A. (1980): Strategy follows structure, *Strategic Management Journal*, **1**, pp. 149-163.
- Hitt, M., Boyd, B., Li, D. (2004): The state of strategic management research and a vision of the future', in: Ketchen, D., Bergh, D. (eds.), *Research Methodology in Strategy and Management*, Elsevier, New York, pp. 1-32.
- Ho, Y., Fang, H., Hsieh, M. (2011): The relationship between business-model innovation and firm value: A dynamic perspective, *World Academy of Science, Engineering and Technology*, **77**, pp. 656-664.
- Hoelter, D.R. (1983): The analysis of covariance structures: goodness-of-fit indices, *Sociological Methods and Research*, **11**, pp. 325-344.
- Hoskisson, R.E., Eden, L., Lau, C.M., Wright, M. (2000): Strategy in emerging economies, *Academy of Management Journal*, **43**, pp. 249-267.
- Hu, L., Bentler, P. M. (1999): Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives, *Structural Equation Modeling*, **6** (1), pp. 1-55.
- Johnson, M. W., Christensen, C. M., Kagermann, H. (2008): Reinventing your business model, *Harvard Business Review*, **86**, pp. 50-59.
- Kale, P., Dyer, J.H., Singh, H. (2002): Alliance capability, stock market response, and long-term alliance success: the role of the alliance function, *Strategic Management Journal*, **23** (8), pp. 747-767.
- Kara, A., Lonial, S., Tarim, M., Zaim, S. (2005): A paradox of service quality in Turkey: the seemingly contradictory relative importance of tangible and intangible determinants of service quality, *European Business Review*, **17** (1), pp. 5-20.
- Kay, J. (1994): *The Foundations of Corporate Success*, Oxford University Press, London.
- Kline, R.B. (2010): *Principles and Practice of Structural Equation Modeling*, Guilford Press, NY.
- Kotabe, M., Martin, X., Domoto, H. (2003): Gaining from vertical partnerships: knowledge transfer, relationship duration and supplier performance improvement in the U.S. and Japanese automotive industries, *Strategic Management Journal*, **24** (4), pp. 293-317.
- KPMG (2006): *The Indian Pharmaceutical Industry: Collaboration for Growth*, KPMG International, The Netherlands.
- Kumar, A., Dillon, W.R. (1987): The interaction of measurement and structure in simultaneous equation models with unobservable variables, *Journal of Marketing Research*, **24**, pp. 98-105.
- Lee, S. H., Makhija, M. (2009): Flexibility in internationalization: is it valuable during an economic crisis?, *Strategic Management Journal*, **30**, pp. 537-555.
- Li, S., Ragu-Nathan, B., Ragu-Nathan, T.S., Subba Rao, S. (2006): The impact of supply chain management practices on competitive advantage and organizational performance, *Omega*, **34** (2), pp. 107-124.
- Long, J. S. (1983): *Confirmatory Factor Analysis. Sage University paper series on quantitative applications in the social science*, **33**, Sage, Beverly Hills, CA.
- MacKinnon, D.P. (2000): Contrasts in multiple mediator models', in: Rose, J.S., Chassin, L., Presson, C.C., Sherman, S.J. (ed.), *Multivariate Applications in Substance Use Research: New Methods for New Questions*, Lawrence Erlbaum Associates, London, Mahwah, NJ, pp. 141-160.
- Malhotra, M.K., Grover, V. (1998): An assessment of survey research in POM: from constructs to theory, *Journal of Operations Management*, **16** (17), pp. 407-425.
- McGrath, R. G. (2010): Business models: A discovery driven approach, *Long Range Planning*, **43** (2), pp. 247-261.
- McKinsey & Company (2013): *India Pharma 2020: Propelling access and acceptance, realising true potential*, available at <http://online.wsj.com/public/resources/documents/McKinseyPharma2020ExecutiveSummary.pdf>, accessed 27 April 2015.
- Menor, L.J., Roth, A.V. (2007): New service development in retail banking: construct development and measurement validation, *Journal of Operations Management*, **25** (4), pp. 825-846.
- Mentzer, J.T., Flint, D.J. (1997): Validity in logistics research, *Journal of Business Logistics*, **18** (1), pp. 199-216.
- Mom, T. J. M., van den Bosch, F. A. J., Volberda, H. W. (2009): Understanding variation in managers' ambidexterity: investigating direct and interaction effects of formal structural and personal coordination mechanisms, *Organization Science*

- ence, **20**, pp. 812-28.
- Nadkarni, S., Narayanan, V. K. (2007): Strategic schemas, strategic flexibility, and firm performance: the moderating role of industry clock-speed, *Strategic Management Journal*, **28**, pp. 243-70.
- Najmaei, A. (2011): Dynamic Business Model Innovation: Proposing an Integrated Organizing Framework, Doctoral working paper series, paper ID #2/2011/mgsm MGSM, Sydney, NSW, Australia.
- Nunnally, J.C., Bernstein, I.H. (1994): *Psychometric Theory*, 3rd ed., McGraw-Hill, New York.
- O'Reilly, C. A., Tushman, M. L. (2004): The ambidextrous organization, *Harvard Business Review*, **82** (4), pp. 74-83.
- Ocasio, W. (1997): Towards an attention-based view of the firm, *Strategic Management Journal*, **18**, pp. 187-206.
- Passemar, D., Kleiner, B.H. (2000): Competitive advantage in global industries, *Management Research News*, **23** (7-8), pp. 111-117.
- Paxson, M., Dillman, D.A., Tarnai, J. (1995): Improving response to business mail surveys, in: Cox, B.G., Binder, D.A., Chinnappa, B.N., Christianson, A., Colledge, M.J., Kott, P.S. (eds.): *Business Survey Methods*, John Wiley and Sons, NY.
- Pearl, J. (2001): *Direct and indirect effects, Proceedings of the Seventeenth Conference on Uncertainty in Artificial Intelligence*, Morgan Kaufmann, San Francisco, CA, pp. 411-420.
- Puranam, P., Singh, H., Zollo, M. (2006): Organizing for innovation: managing the coordination autonomy dilemma in technology acquisitions', *Academy of Management Journal*, **49**, pp. 263-80.
- PWC (2009): *Pharma 2020: Challenging business models - which path will you take?* PricewaterhouseCoopers.
- Robins, M.J., Greenland, S. (2002): Identifiability and exchangeability for direct and indirect effects, *Epidemiology*, **3** (2), pp. 143-155.
- Rothaermel, F. T., Hitt, M. A., Jobe, L. A. (2006): Balancing vertical integration and strategic outsourcing: effects on product portfolio, product success, and firm performance, *Strategic Management Journal*, **27**, pp. 1033-56.
- Sanchez R., Mahoney JT. (1996): Modularity, flexibility, and knowledge management in product and organization design, *Strategic Management Journal*, **17** (S2), pp. 63-76.
- Schumacker, R. E., Lomax, R. G. (2004): *A Beginner's Guide to Structural Equation Modeling*, 2nd ed., Lawrence Erlbaum Associates, Mahwah, NJ.
- Sharma, J.K., Singh, A.K. (2012a): Absorptive Capability and Competitive Advantage: Some insights from Indian Pharmaceutical Industry, *International Journal of Management and Business Research*, **2** (2), pp. 176-192.
- Sharma, J.K., Singh, A.K. (2012b): Change and competitive advantage: an investigative study of Indian Pharmaceutical Industry, *The IUP Journal of Business strategy*, **IX** (3), pp. 46-71.
- Short, J.C., Ketchen, D.J., Palmer, T.B. (2002): The role of sampling in strategic management research on performance: a two-study analysis, *Journal of Management*, **28** (3), pp. 363-385.
- Siggelkow, N., Levinthal, D. A. (2003): Temporarily divide to conquer: centralized, decentralized, and reintegrated organizational approaches to exploration and adaptation, *Organization Science*, **14**, pp. 650-669.
- Singh, A.K. (2014): Integrating robustness and resilience in change and competitive advantage framework: insights from Indian pharmaceutical industry, *International Journal of Strategic Change Management*, **5** (4), pp. 348-376.
- Sivo, S.A., Fan, X.T., Witta, E.L., Willse, J.T. (2006): The search for 'optimal' cutoff properties: fit index criteria in structural equation modeling, *The Journal of Experimental Education*, **74** (3), pp. 267-289.
- Smet, A.D., Schaninger, B., Smith, M. (2014): *The hidden value of organizational health - and how to capture it*, McKinsey Quarterly, April 2014.
- Snow, C.C., Hrebiniak, L. (1980): Strategy, distinctive competence, and organizational performance, *Administrative Science Quarterly*, **25** (2), pp. 317-335.
- Sosna, M., Treviño-Rodríguez, R. N., Velamuri, S. R. (2010): Business model innovation through trial-and-error learning: The Naturhouse case, *Long Range Planning*, **43** (2), pp. 383-407.
- Sobel, M. E. (1982): Asymptotic confidence intervals for indirect effects in structural equation models, *Sociological Methodology*, Vol. **13**, pp. 290-312.
- Steenkamp, J.E.M., Van Trijp, H.C.M. (1991): The use of LISREL in validating marketing constructs, *International Journal of Research in Marketing*, **8**, pp. 283-299.
- Subramaniam, M., Venkatraman, N. (2001): Determinants of transnational new product development capability: testing the influence of transferring and deploying tacit overseas knowledge, *Strategic Management Journal*, **22** (4), pp. 359-378.
- Suhr, D. D. (2000): An investigation of mathematics and reading achievement of 5- through 14-year olds using latent growth curve methodology, Dissertation Abstracts International, A (Humanities and Social Sciences), Vol 60(12-A), 4323, US: Univ Microfilms International.
- Teece, D. J. (2010): Business models, business strat-

- egy and innovation, *Long Range Planning*, **43** (2), pp. 172-194.
- Tikkanen, H., J.A. Lamberg, P. Parvinen, Kallunki, J.P. (2005): Managerial Cognition, Action and the Business Model of the Firm, *Management Decision*, **43** (6), pp. 789-809.
- Whelan-Berry, K. S., Gordon, J. R., Hinings, C. R (2003): The relative effect of change drivers in large-scale organizational change: an empirical study, in: Woodman, R. W., Pasmore, W. A (eds.): *Research in Organizational Change and Development*, **14**, pp. 99-146.
- Worren, N., Moore, K., Cardona, P. (2002): Modularity, strategic flexibility, and firm performance: a study of the home appliance industry, *Strategic Management Journal*, **23**, pp. 1123-1140.
- Wu, S. (2005): Employability and Effective Learning Systems in Higher Education, Paper Presented at Ninth Quality in Higher Education International Seminar in collaboration with ESECT and the Independent, Birmingham 27th-28th January, 2005; available at www.qualityresearchinternational.com/es e/papers/wufv.doc, accessed January 2014.
- Zainudin, A. (2010): *Research Methodology for Business and Social Science*, University Publication Centre (UPENA), UITM Shah Alam.
-

Research Paper

The benefits of social sustainability reporting for companies and stakeholders – Evidence from the German chemical industry

Verena Zimara* and Sebastian Eidam*

* Institute of Business Administration at the Department of Chemistry and Pharmacy, University of Münster, Leonardo-Campus 1, 48149 Münster, Germany, i_zimao1@uni-muenster.de

Companies' corporate social responsibility (CSR) activities respond to the increasing expectations of society. One of the three dimensions of sustainability, also known as the triple bottom line, is social sustainability. Compared to economic and environmental sustainability, the social dimension is often neglected by companies. Especially actors in the chemical industry are having a great social responsibility and are thus constantly monitored with regard to their activities and performance. Consequently, the firms need to care for their social sustainability in order to secure their license to operate. This study therefore aims at identifying the current state of social sustainability reporting within chemical companies in Germany. A data set of 14 CSR reports is tested regarding the use and fulfillment of the Global Reporting Initiative's (GRI) guidelines and indicators regarding social aspects. The results clearly indicate that social sustainability reporting is handled quite diverse concerning structure and extent among the analyzed companies. The study concludes with recommendations of how to improve the comparability of social sustainability reporting for internal and external use.

1 Introduction

CSR is a holistic term for “actions of firms that contribute to social welfare, beyond what is required for profit maximization” (McWilliams, 2015, p. 1). Integrating sustainable actions into the core business comes into focus and is frequently discussed as the *business case for sustainability* (Dyllick and Hockerts, 2002; Epstein and Roy, 2003; Salzmann et al., 2005; Schaltegger and Hasenmüller, 2005). CSR is supposed to cover the so-called triple bottom line including the dimensions economic, environmental and social sustainability (Elkington, 1997; GRI, 2011). The implementation of standards in each of these dimensions becomes more and more important for companies, particularly in Western countries (McWilliams and Siegel, 2001; McWilliams et al., 2006; Potts et al., 2014). While many guidelines concerning economic and environmental sustainability have been introduced over the past decades, e.g. for the chemical industry (Gladwin et al., 1995; Hart, 1997; Hoffman, 1999), the implemen-

tation of social sustainability is still seen as challenging by the industry (CEFIC, 2014; VCI, 2013).

“Social elements relate to employment characteristics (e.g. diversity of people employed, labor rights, training) and community relations” (Epstein and Roy, 2003, p. 84) and thus address the internal staff on the one hand and the external society on the other. These aspects are of particular importance for the chemical industry (CEFIC, 2014). The safety and working conditions for the internal staff are crucial to ensure the employability of the work force (VCI, 2013). Further, it is an important asset in recruiting new employees, where chemical companies face a strong competition for skilled workers within and across industries (CEFIC, 2014). On top of protecting their human capital, chemical companies invest in further education of their staff (Robertson and Nicholson, 1996). The gap in gender equality among the workers of chemical companies is an additional field that needs to be addressed by organizations within their CSR initiatives.

At the same time, the chemical industry needs to build and maintain trust among the public to secure their license to operate (Hoffman, 1999). In addition to their environmental activities such as reducing the pollution caused by their products and processes and their economic activities providing secure employment and contributing to initiating local economic growth, chemical companies also need to show social engagement. Thereby, they can improve their image as an employer or business partner and create acceptance in the local society. To communicate sustainable activities effectively, many companies use reporting as an instrument. CSR reports have the advantage of documenting contents of sustainability activities in detail and presenting intangible social aspects of a company's behavior (Porter and Kramer, 2006).

While research on CSR reports often discusses the overall advantages and disadvantages of sustainability activities and their reporting, the two questions addressed in this paper concentrate on the specific nature of social sustainability reporting:

1. Which social sustainability aspects are most relevant for companies and why?
2. How do social sustainability reports differ and what influence results on stakeholder benefits?

In order to discuss these questions, 14 CSR reports are analyzed with regard to social sustainability indicators suggested by the GRI. To shed light on the question of relevance of social sustainability reporting for German chemical companies, the potential motivations as well as the goals of sustainability management reported by the companies are gathered and compared to the reported indicators. Further, the usage of guidelines and participating in initiatives is analyzed.

The second question addresses the differences in social sustainability reporting across companies and the benefits of social sustainability reporting for stakeholders. In order to respond to the question, the content and scope of reported sustainability aspects are first analyzed qualitatively. The companies' CSR reports are summarized according to their fulfillment of single performance indicators suggested by the GRI guidelines. Furthermore, identified gaps in reporting are critically discussed based on the reasoning given in companies' reports and in order to highlight the problems for stakeholders in interpreting social responsibility reports.

2 Theoretical background

In order to understand the background and analysis of the posed questions, it is necessary to characterize the concept of sustainability from a business perspective. Therefore, the following section describes the principle and different elements of sustainability at a corporate level. Subsequently, the special position of the social dimension is depicted and sustainability reporting is presented as a key instrument of sustainable activities.

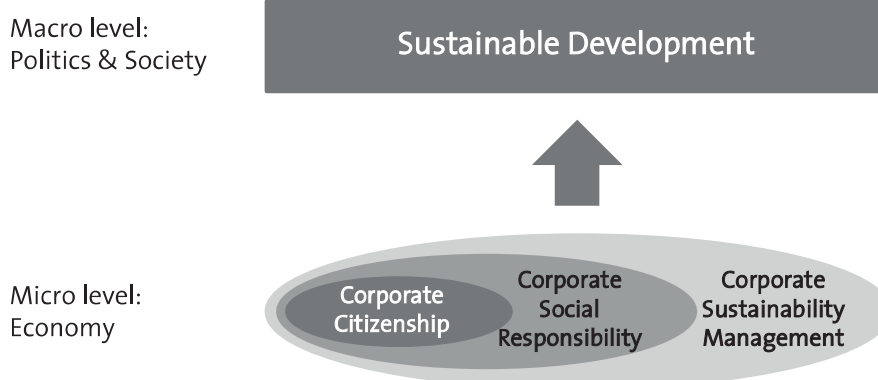
2.1 Defining sustainability at the corporate level

Sustainability is a holistic concept that applies to politics and society as well as industry (Clausen and Loew, 2009; Loew and Rohde, 2013). Accordingly, the principle of sustainability is used at the macro level as well as the micro level. The latter represents the company level and thus the contribution of enterprises and in particular their CSR initiatives to sustainable development (Clausen and Loew, 2009) as illustrated in figure 1.

Sustainable development refers to the overall impact of sustainable action and was initially only characterized as responsible use of natural resources (Beddoe *et al.*, 2009; Jahn *et al.*, 2013). Discussions on sustainability are still shaped by the definition presented within the so-called Brundtland Report of 1987: "*Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs.*" (UNGA, 1987, Chap. 2, §1). The concept addresses the three dimensions economy, ecology and society, also referred to as the triple bottom line indicating the dimensions to be interlinked and implemented together (Elkington, 1997). On the company level, this means that all three levels should be integrated into operations and handled equally.

From a business perspective, enterprises shape the ecological and social environment with their economic actions (GRI, 2013). In addition to operationalizing their business goals, aspects of sustainability need to be considered and integrated with various functional areas. In particular, this includes risk management, human resources management, innovation management and strategic management (Figge *et al.*, 2002; Loew and Braun, 2009; Schaltegger *et al.*, 2007). An entrepreneurial model of sustainability can only be effectively implemented if the sustainable concept is anchored in core business. The top management should be encouraged to make a business case for sustainability to increase financial performance and competitive advantages in the long term (Salzmann *et al.*, 2005; Weber, 2008). Sustainable measures oriented

Figure 1 Relationship between corporate sustainability and sustainable development, according to Clausen and Loew, 2009, p. 19.



toward economic goals are seen to be the key to significantly contribute to corporate success (Orlitzky *et al.*, 2003; Salzmann *et al.*, 2005; Weber, 2008).

2.2 Corporate social sustainability

The implementation and organization of sustainability-related management approaches requires a comprehensive understanding of the dimensions of sustainability as well as their respective risks and opportunities (Dyllick, 2003; Haasis, 2008). In this context, it is often criticized that insufficient attention is put on the social level of CSR and that it is rather unconsciously involved in strategic measures (Boström, 2012; Dyllick and Hockerts, 2002; Heins, 1998; Vallance *et al.*, 2011; Wagner and Henle, 2008). In many companies, ecological activities still constitute the focus of sustainable activities. However, the increasing pressure from external stakeholders urges firms to more social responsibility at all levels in order to ensure safety. Particularly the chemical industry is obliged to include aspects of social sustainability in their business strategies and activities. This presents a challenge for enterprises as social sustainability is mainly based on intangible components and includes aspects that cannot or rarely be visualized by indicators (Jörissen *et al.*, 1999). This fact complicates to control for social aspects and to measure their impact.

Social behavior is anchored in social norms and values and aims to assure socially relevant needs. Human dignity, justice and prosperity are the foundation of social sustainability in order to ensure better living and labor conditions in the future (Bundestag, 1997). Major issues of corporate social sustainability are for example ensuring diversity and

equal opportunities, health and safety, fair competition, and preventing forced or child labor and corruption. Enterprises are encouraged to address all social spheres of activity, i.e. labor practices, human rights, product responsibility and society in its entirety (GRI, 2011).

Social sustainability measures need appropriate resources. These resources mainly emanate from the intangible capital of social and human values that must be generated and accumulated by enterprises (Dyllick and Hockerts, 2002; Spangenberg and Bonniot, 1998). Thereby, social capital sets the society as a whole into focus, while human capital refers to the single individual. Thus, the employees and the social environment compose the center of business operations (Goodland, 2002; Spangenberg and Bonniot, 1998).

Overall, the challenge for enterprises is to satisfy social needs resulting in social acceptability and legitimacy (Perrini and Tencati, 2006; Porter and Kramer, 2006). Enterprises can thus benefit from living social sustainability, particularly through an improved reputation and image.

2.3 Guidelines for and reporting of sustainability aspects

In the European Union, CSR is based on a voluntary approach and can be integrated into business activities and practiced in various forms (Commission of the European Communities, 2001). Companies are confronted with many different guidelines and initiatives for their sustainable activities. Regulations and assistance for the implementation and fulfillment of CSR measures exist at both national and international level and are established by different organizations. In addition to widely

recognized guidelines for sustainability reporting, e.g. by the GRI, there are also international documents challenging companies for corporate responsibility in terms of human rights or labor safety. For the chemical industry, sector-specific initiatives focusing on corporate social and ecological responsibility, safety and sustainability are also relevant. Table 1 shows the most important guidelines and initiatives affecting the German chemical industry.

Although companies can choose of a variety of guidelines, the social aspects and practices of sustainability often remain neglected as their economic benefit is often not visible or measurable, at least not in the short-term (Jörissen *et al.*, 1999; Schaltegger *et al.*, 2007). Hence, seized CSR measures mostly result from a sense of moral or legal obligation. The increasing force from external stakeholders drives companies to more social responsibility and a social culture. At the same time, corporate actions provoke reactions from stakeholders and influence them in turn. Epstein and Roy (2003) describe this relationship as follows: “[...] *sustainability performance and actions are drivers of stakeholder reactions. It is through stakeholder reactions that managers can accurately translate actions and performance into the resultant costs and benefits. Furthermore, stakeholder reactions provide feedback to revise corporate strategy [...]*” (Epstein and Roy, 2003, p. 82).

Therefore, the stakeholder concept introduced by Freeman (1984) attracts specific interest in the field of CSR. It describes the reciprocal relationship between businesses and societal stakeholders. All stakeholders have a common interest in transparency and an open communication of the implemented sustainability measures and performance of companies (Perrini and Tencati, 2006). The involvement of stakeholders’ interests in sustainable decision-making processes is of fundamental importance (GRI, 2011; Perrini and Tencati, 2006) in order to minimize wrong choices at an early state, increase corporate success and ensure authenticity and acceptability (Hauth and Raupach, 2001; Hentze and Thies, 2014).

Reporting can be considered as an essential instrument of sustainability communications (Hentze and Thies, 2014). CSR reports enable companies to satisfy information requirements of relevant stakeholders and at the same time involve the stakeholders actively in their business decision-making processes (Perrini and Tencati, 2006). The economic benefit of a CSR report consists in both controlling and exerting a positive influence on the employees. These reports are as well supposed to facilitate benchmarking between companies.

Summing up, the internal benefits of sustain-

ability reporting according to GRI (2014) are:

- developing vision and strategy on sustainability
- improving management systems, internal processes and setting goals
- identifying strengths and weaknesses
- attracting, motivating and retaining employees.

External motivations and potential benefits are:

- enhancing reputation, achieving trust and respect
- attracting funding
- increasing transparency and dialogue with stakeholders
- achieving competitive advantage and leadership.

An overall goal of sustainability reporting for companies, especially in B2B markets, is a good sustainability rating (as provided by different sustainability rating providers, i.e. by Johnson Controls Inc. or EcoVadis SAS) to satisfy the demands of customers, suppliers (Foerstl *et al.*, 2010; Freeman and Velamuri, 2008; Lamberti and Lettieri, 2009) and institutional investors (Campbell, 2006; Wahba, 2008). However, besides these externally motivated goals there are further goals companies pursue by their sustainability reporting. Especially for the social sustainability activities in the chemical industry, these internal motivations are of higher importance and at the same time not as clear as ecological or economic motives.

For preparing and implementing a CSR report, companies primarily rely on the GRI guidelines. The GRI specifies those reports as follows: “*Sustainability reporting is the practice of measuring, disclosing, and being accountable to internal and external stakeholders for organizational performance towards the goal of sustainable development.*” (GRI, 2011, p. 3). Besides the successful implementation of sustainability strategies, the disclosure of shortcomings and complications should be part of a transparent report. It should be a balanced and reasonable representation of the sustainability performance (GRI, 2011).

Table 1 Guidelines and initiatives of (social) sustainability.

Guidelines and initiatives for CSR reports and/or sustainable action	Aim and content	Source
DNK (Deutscher Nachhaltigkeitskodex)	“Der Nachhaltigkeitskodex ist nicht nur ein Instrument zur Berichterstattung, [...], sondern gibt Ihnen auch Orientierung zum Nachhaltigkeitsmanagement. Mit seinen 20 Kriterien für nachhaltiges Wirtschaften, [...], hilft der DNK den Unternehmen klarzusehen, was mit dem Begriff Nachhaltigkeit gemeint ist, den Fokus auf das Wesentliche zu bewahren und zugleich ihre Verantwortung für Umwelt und Gesellschaft wirksamer und ehrgeiziger wahrzunehmen.”	RNE (2014), p. 4
GHS (Globally Harmonized System of Classification and Labelling of Chemicals)	“Given the reality of the extensive global trade in chemicals, and the need to develop national programs to ensure their safe use, transport, and disposal, it was recognized that an internationally-harmonized approach to classification and labelling would provide the foundation for such programs.”	UN (2013), p. 3
GPS (Global Product Strategy)	“The International Council of Chemical Associations (ICCA) launched the Global Product Strategy (GPS), in 2006, to advance the product stewardship performance of individual companies and the global chemical industry as a whole.”	ICCA (2006)
GRI Guidelines	“The GRI Reporting Framework is intended to serve as a generally accepted framework for reporting on an organization’s economic, environmental, and social performance. It is designed for use by organizations of any size, sector, or location. [...] The GRI Reporting Framework contains general and sector-specific content that has been agreed by a wide range of stakeholders around the world to be generally applicable for reporting an organization’s sustainability performance.”	GRI (2011), p. 3
ILO (International Labour Organization) Declarations	“The main aims of the ILO are to promote rights at work, encourage decent employment opportunities, enhance social protection and strengthen dialogue on work-related issues.”	ILO (2009)
ISO (International Organization for Standardization) 26000	“ISO 26000 provides guidance on how businesses and organizations can operate in a socially responsible way. This means acting in an ethical and transparent way that contributes to the health and welfare of society.”	ISO (2011)

Guidelines and initiatives for CSR reports and/or sustainable action	Aim and content	Source
OECD Principles	“The mission of the Organisation for Economic Co-operation and Development (OECD) is to promote policies that will improve the economic and social well-being of people around the world. [...] We work with governments to understand what drives economic, social and environmental change. We measure productivity and global flows of trade and investment. [...] We set international standards on a wide range of things, from agriculture and tax to the safety of chemicals.”	OECD (2015)
OHSAS 18001 (Occupational Health and Safety Assessment System)	“OHSAS 18001 is an Occupation Health and Safety Assessment Series for health and safety management systems. It is intended to help an organizations to control occupational health and safety risks. It was developed in response to widespread demand for a recognized standard against which to be certified and assessed.”	OHS Group (2007)
RC (Responsible Care)	“Responsible Care is the global chemical industry’s environmental, health and safety (EHS) initiative to drive continuous improvement in performance. [...] It focuses on new and important challenges facing the chemical industry and global society, including the growing public dialogue over sustainable development, public health issues related to the use of chemical products, the need for greater industry transparency, and the opportunity to achieve greater harmonization and consistency among the national Responsible Care programs currently implemented.”	ICCA (2010), p. 4
SA8000	“The intent of SA8000 is to provide an auditable, voluntary standard, based on the UN Declaration of Human Rights, ILO and other international human rights and labour norms and national labour laws, to empower and protect all personnel within an organisation’s control and influence who provide products or services for that organisation, including personnel employed by the organisation itself and by its suppliers, sub-contractors, sub-suppliers and home workers.”	SAI (2014), p. 4
UNGC (United Nations Global Compact)	“Corporate sustainability starts with a company’s value system and a principled approach to doing business. [...] By incorporating the Global Compact principles into strategies, policies and procedures, and establishing a culture of integrity, companies are not only upholding their basic responsibilities to people and planet, but also setting the stage for long-term success.”	UN (2015)

Table 2 Basic data on the chemical companies in the sample, according to companies' annual reports of 2013.

Companies	Number of employees 2013	Sales 2013 (€ million)
Altana AG	5,700	1,765
Aurubis AG	6,600	12,346
BASF SE	112,000	73,973
Bayer AG	113,000	40,157
Brenntag AG	13,000	9,769
Evonik Industries AG	33,500	12,874
H. C. Starck GmbH	3,000	900
Henkel AG & Co. KGaA	47,000	16,355
K+S AG	14,400	3,950
Lanxess AG	17,000	8,300
Merck KGaA	39,000	10,700
Messer Group GmbH	5,400	1,027
Symrise AG	6,000	1,830
Wacker Chemie AG	16,000	4,479

3 Empirical evidence

3.1 Research approach

A sample of 14 CSR reports from German chemical companies for the year 2013 is collected from the GRI database (GRI, 2015). These reports have been submitted according to the sustainability reporting guidelines (version 3.0 and 3.1) issued by the GRI. For companies that publish reports in a two-year rhythm, the most recently available publication has been selected. The CSR reports are first investigated qualitatively regarding their contents and then quantitatively based on their fulfillment of social performance indicators by the GRI. Information on the companies is provided in table 2.

3.2 Discussing the results regarding qualitative content analyses

The CSR reports of the 14 companies are firstly compared according to their extent

and structure. Table 3 provides an overview about different attributes and specific social topics included in the table of contents in the reports of the analyzed companies. The analysis of the reporting structure, i.e. the table of contents, does not allow drawing conclusions on the absence of any sustainability issues in the full report. However, as the table of contents gives a quick outline for interested readers where to find relevant information, it makes the report an easy to use document for stakeholders.

It can be seen that many CSR reports miss to address certain social topics in their table of contents. For instance, substantial attributes recommended within the GRI guidelines are partly absent. Further, a materiality matrix is missing in 6 of 14 reports. A materiality matrix is the graphical presentation of essential sustainability aspects which companies identify for themselves as relevant and are willing to report. Thus, reports are not consistent in their composition across companies. Additionally, only 6 of the 14 reports have received an external audit by a third party.

The reports have as well been examined in terms of being in conformity with the different guide-

Table 3 Overview of the contents of the CSR reports.

Companies	Altana		BASF*		Brenntag		H.C. Starck		K+S*		Merck		Messer Group		Symrise*		Wacker	
	Aurubis	68	252	351	✓	✗	✓	150	24	54	98	208	114	61	102	141	✓	✓
Scope (number of pages)	74	68	252	351	✓	✗	✓	150	24	54	98	208	114	61	102	141	✓	✓
Summary and introduction to report	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Structure (table of contents)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sustainability as a separate component	✗	✓	✓	○	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Personnel	✓	✓	✓	○	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Safety	✓	○	✓	○	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Social commitment	✓	✓	✓	○	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Product (responsibility)	✓	✓	✓	○	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Compliance	✓	○	✓	○	✓	✓	✓	✓	○	✓	✓	✓	✓	✓	✓	✓	✓	✓
Stakeholder dialog	✓	○	✓	○	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Materiality matrix	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
External audit by third party	✗	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Note: *Sustainability report is included in annual report; ✓ Attribute is included in the report; ✗ Attribute is not included in the report;
○ Attribute is included in a subdirectory

lines and initiatives for corporations displayed in table 1. Figure 2 shows the frequency of application of the different guidelines detected by a keyword search within the CSR reports. Due to the data source, all reports use the GRI guidelines and most of them include voluntary commitments, such as the chemical industry's RC initiative mentioned in 12 of 14 cases. More than 70% of the companies state that they commit themselves to the 10 principles on human rights, labor standards, environmental protection and fight against corruption codified in the UNGC. Concerning the responsibility for products and services, half of the companies follow the GHS or GPS. Only little use is made of the ISO 26000, SA 8000 and the German sustainability codex (DNK).

The usage of different guidelines might result from the various goals the reporting companies want to achieve with their reporting. Therefore, a closer look is taken on the purposes stated in the CSR reports. Unfortunately, not all of the 14 companies state their aims of sustainability management as recommended by the GRI guidelines.

3.3 Results concerning the fulfillment of social indicators

Ten companies comply with the GRI classification of relevant sustainability topics. Nine of those reports also list the goals of their company's sustainability management. Table 4 shows the prevalence of topics and goals among German chemical companies. The topics *work safety* and *social*

commitment are named in every report of the sample and therefore seem to play a central role in social sustainability management. The *reduction of work accidents and support of social projects* are some of the most mentioned goals. Overall, the goals and major topics named in the CSR reports seem to be aligned in all reports in the sample. Goals like the support of social projects are displayed in the report when elaborating on social commitment like sponsoring and local responsibility. The same is true for responsible supplier management, fostering diversity and equal working opportunities and the further training for employees.

Table 5 provides an overview about the fulfillment of indicators organized by categories according to the GRI guidelines (only indicators that are included in both version 3.0 and 3.1 are analyzed). Definitions for every indicator are included in the appendix and sorted by the categories labor practices and decent work, human rights, society and product responsibility. The most frequently fulfilled indicators for each category are highlighted in grey in the respective columns.

It has to be kept in mind that some indicators are core indicators (bold) and some indicators are designated as additional indicators (italic). The analysis shows that core indicators are more often fulfilled than additional indicators, which are reflecting emerging practices or topics only affecting some organizations. However, it is striking that none of the core indicators is met by all 14 companies in the sample. Another issue is that "fulfillment" of

Figure 2 Guidelines and initiatives used in the CSR reports.

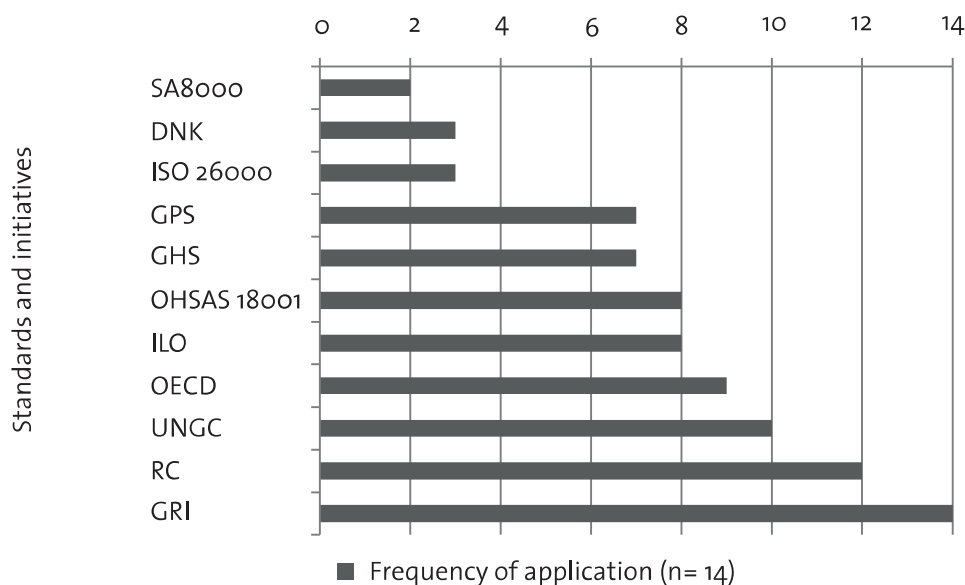


Table 4 Topics and goals named in companies' reports.

Sustainability topics	Frequency of occurrence	Goals of sustainability management	Frequency of occurrence
Occupational safety and health protection	10	Reduction of occupational accidents	8
Social commitment ¹	10	Support of (local) social projects and social responsibility	5
Education, further training and employee development	7	Development and expansion of a responsible supplier management	5
Compliance (fight against corruption and fair competition)	7	Increase of the female share	5
Megatrends ²	7	Increase of product performance and product security	4
Human rights	6	Trainings for employees	3
Diversity and equal opportunity	6	Compliance training	2
Responsible supplier management	6	Talent Management	2
Product responsibility and product security	6	Increase of the employee satisfaction	1
Employee satisfaction	4	Support of diversity	1
Job security	3	Development of a compensation system	1
Trust and reputation as well as transparency and credibility	3	Increase of the job attractiveness	1
Cooperation (communication) with stakeholders	3	Expansion and receipt of employee's know how	1
Youth development and personal commitment	3	Increase of life quality	1
Attractiveness of the employer	2	Improvement of working conditions	1
Compensation	1	Flexibility of working hours	1
Increasing regulations	1		
Increasing consumption	1		
Σ	86	Σ	42

¹ Social commitment includes fundraising/sponsoring, social progress, sustainable value creation for the society, health and security for the population, local responsibility.

² Megatrends include urbanization, demographic change, population growth, poverty, globalization.

an indicator is not necessarily enabling a valuation of a company or pointing to a “good” social performance, but only indicating the provision of the required information.

From a total of 350 core indicators in the sample, 65% are fully reported. The percentage of reported additional indicators (n= 210) sums up to only 34%. More than half of the additional indicators (60%) are not considered in the social sustainability reports under analysis. The share of reported core indicators in relation to the total number of

indicators (n= 560) is 40% and 13% for fulfilled additional indicators. The low values indicate that the additional social indicators have little relevance for companies.

Figure 3 shows the fulfillment of 40 social performance indicators by company. There is a difference between a total, partial and non-fulfillment. As can be seen, results range from 31 fulfilled and 2 unfulfilled indicators for Aurubis to Brenntag with only 8 fulfilled and 30 unfulfilled performance indicators. It is obvious that there are major differences

Table 5 Fulfillment or lack of the GRI's social indicators in companies' reports.

Number of companies fulfilling the indicators	Performance indicators of the category: <i>Labor practices & decent work</i>													
	LA1	LA2	LA3	LA4	LA5	LA6	LA7	LA8	LA9	LA10	LA11	LA12	LA13	LA14
fulfilled	9	7	5	9	11	5	8	12	4	3	9	8	7	7
partly fulfilled	4	5	-	1	-	1	6	1	1	7	-	3	6	3
not fulfilled	1	2	9	4	3	8	-	1	9	4	5	3	1	4
	Performance indicators of the category: <i>Human rights</i>													
	HR1	HR2	HR3	HR4	HR5	HR6	HR7	HR8	HR9					
fulfilled	5	6	4	12	10	10	10	3	4					
partly fulfilled	3	3	4	1	-	2	2	1	-					
not fulfilled	6	5	6	1	4	2	2	10	10					
	Performance indicators of the category: <i>Society</i>													
	SO1	SO2	SO3	SO4	SO5	SO6	SO7	SO8						
fulfilled	11	11	12	8	12	6	8	9						
partly fulfilled	1	2	-	3	1	-	-	1						
not fulfilled	2	1	2	3	1	8	7	4						
	Performance indicators of the category: <i>Product responsibility</i>													
	PR1	PR2	PR3	PR4	PR5	PR6	PR7	PR8	PR9					
fulfilled	10	2	12	2	6	9	1	4	7					
partly fulfilled	1	-	2	-	3	2	-	-	-					
not fulfilled	3	12	-	12	5	3	13	10	7					

in the scope of addressed fields. Companies fulfilling more indicators give a deeper insight into their social responsibility management and can be seen as a positive example in relation to other companies. However, the scope does not always directly reflect the status of social responsibility management within a company.

Reasons for not fulfilling or rather not report-

ing individual social indicators are only rarely stated in the CSR reports. In the majority of cases, the non-fulfilled indicators are not listed in the GRI index at all. Justifications for non-fulfillment can only be found in the reports of Altana, BASF, Evonik, K+S and Merck and are summarized in table 6. Repeatedly stated reasons for non-fulfillment are a high effort for the acquisition of appropriate data

Figure 3 Fulfillment of social indicators by company.

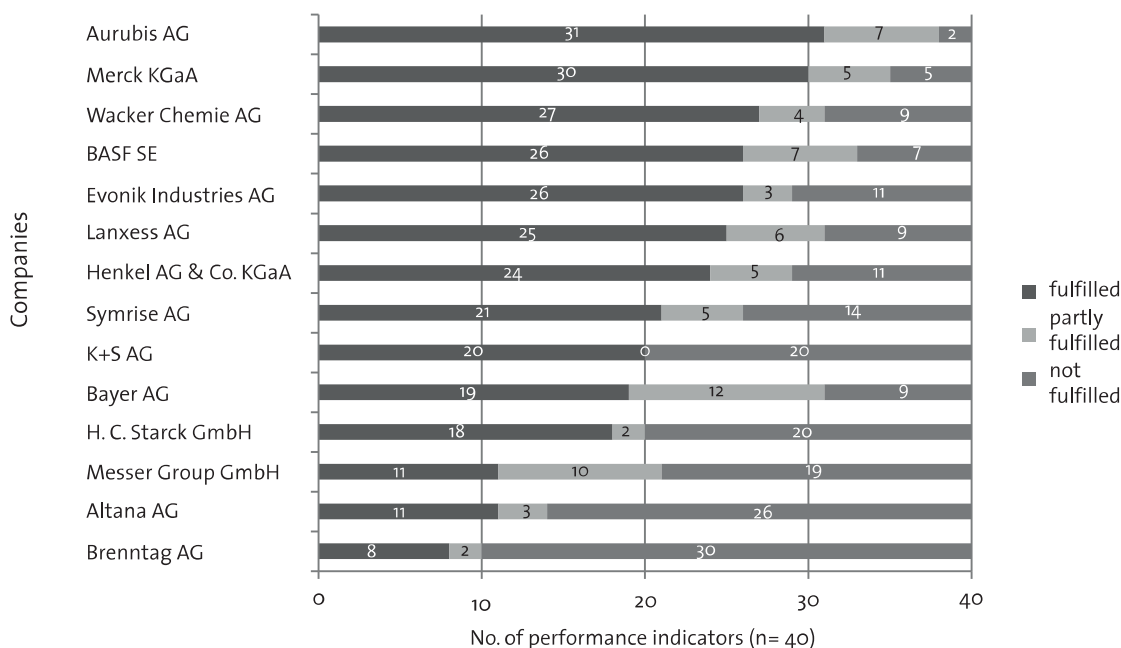


Table 6 Influences and reasons for non-fulfillment of social indicators.

Influences and reasons for not complying with the GRI guidelines	Performance indicators (company)
Too high/inadequate effort	LA1, LA2, LA3, LA4, HR3, SO1 (Altana)
Implementation and registration does not present an improvement potential	LA6, PR1 (Altana)
Requirements are not asked resp. are not known	LA10, HR 8 (Merck) HR2, PR6, PR9 (K+S) HR8, PR2, PR4, PR7, PR8 (Altana)
The result of the indicator is not significant and/or too global	LA5, LA10, LA14, HR4 (Altana)
Indicator is not relevant (e.g. due to the business activity in the B2B-sector)	LA9, HR7, HR9, SO6 (Altana) PR6 (K+S) PR7, PR8, PR9 (BASF)
For reasons of trust	HR1 (Evonik) HR1, SO8 (K+S) SO4 (Altana)
Information is placed elsewhere (e.g. annual report)	SO7, SO8, PR2, PR4 (BASF) SO7, SO8, PR9 (Evonik) PR2, PR4, PR7 (Merck)

or lacking relevance for the own company. Some social indicators are also published in other documents such as annual reports. The only reason mentioned for fulfilling indicators is that there are no incidents within the company and therefore the indicator is fulfilled. These statements are utilized by Aurubis, Lanxess and Merck.

4 Discussing implications and concluding remarks

The analysis of CSR reports by German chemical companies has shown that the social dimension is seen as an essential part of sustainable development in terms of their strategies and goals. The reporting of social aspects is preferably based on the GRI guidelines. Still, many other guidelines are referred to as well when preparing reports. However, the results indicate a high discrepancy in social sustainability reporting relating to the scope and focus of social topics or performance.

4.1 Which social sustainability issues are most relevant for companies and why?

Although not all companies analyzed have clearly stated their sustainability issues or objectives in their reports, some social elements seem to have a higher priority and are reported more often. Occupational health and safety as well as social commitment are most frequently listed, and play therefore a central role in social sustainability management. The goals of CSR measures named in the reports are consistent with the frequency of appearing topics in CSR reports as companies primarily intend to reduce work accidents and to support (local) social projects. These CSR activities can help companies to gain decisive competitive advantages, as both, the internal and external corporate level are addressed. Overall, the abovementioned aspects aim to enhance the company's attractiveness and thereby facilitate recruiting new employees and protecting existing human capital. Particularly in the chemical industry, ensuring safety is of high importance due to handling hazardous materials and operating highly complex technological systems.

Further, the education and training of employees as well as fostering diversity and equal opportunities are frequently presented as social sustainability goals. This shows that motives of social actions aim to increase the working atmosphere and employee satisfaction in order to strengthen its own competitive position. In addition, social commitment generates trust and credibility. Social sustainability measures allow companies to counteract the unpleasant image of chemical compa-

nies in the public and to cooperate with their environment. Still, the activities within the sample are mainly directed towards employees and therefore have an internal character.

4.2 How do social sustainability reports differ and what influence results on stakeholder benefits?

GRI indicators are divided into four categories in order to give companies a structural guideline to measure and report social aspects. The analysis of the reports shows that the degree of fulfillment between individual performance indicators differs strongly (see figure 3). Even within the narrow sample of German chemical companies, large differences between reported indicators can be observed. Furthermore, there is no single indicator which is fulfilled by all of the companies.

It is striking that the category of product responsibility is overall the field with the fewest fulfilled indicators. With regard to the industrial sector, this empirical evidence seems rather unexpected since many chemical products or their production processes provide a rather high risk potential. However, due to the different interpretation by companies, it is not identifiable if the reporting of indicators should be assessed positively or negatively. For example the content of unfulfilled GRI indicators in the product sector partly includes incidents of disrespect regarding the product safety. On the one hand, not reporting those indicators could imply that the company has not recorded any incidents or on the other hand, that it does not want to report about incidents. Furthermore, a fulfillment of these indicators does not automatically mean that negative incidents within the company are present as fulfilling an indicator occurs by giving a positive or negative feedback. Therefore, an assessment and adequate comparability cannot solely be based on the GRI Index. Especially for stakeholders, the comparison of social sustainability activities will be affected if the company has not reported any reasons for non-fulfilled indicators. The transparency and accountability of social sustainability reports is thus limited. Companies should enhance the credibility of reporting by also declaring their weaknesses or shortcomings concerning the social indicators. A mere listing of reported guidelines and initiatives provide stakeholders just a rough view of the orientation of policies, but state little about whether and how they are implemented within the company. This is also referred to as bluewashing (Voegtlin and Pless, 2014).

In summary, the benefits achieved through reporting on the social dimension of sustainability are mostly non-monetary, at least in the short-term. Transparent and detailed reports can lead to

improved reputation of the company among stakeholders. These advantages enable companies to expand and secure their social and human capital and provide an enhanced competitive position, for example in the field of employer attractiveness. However, a reliable analysis and comparability of CSR reports is hardly possible as reported guidelines and indicators as well as the content of the CSR reports presented by companies differ widely.

It can be concluded that social sustainability reports could create more transparency and present a good tool for communication towards stakeholders in general. However, until reliable guidelines which are more straightforward and clear in their content emerge, the usability of these reports for companies, stakeholders, experts and inter-company comparison is rather limited. The next step is already introduced by the GRI's G4 guidelines which further structure and improve the existing guideline. It will be highly interesting to see to which extent future CSR reports will adopt this guideline and if it is capable to increase comparability of social sustainability reporting.

References

- Beddoe, R., Costanza, R., Farley, J., Garza, E., Kent, J., Kubiszewski, I., Martinez, L., McCowen, T., Murphy, K., Myers, N., Ogden, Z., Stapleton, K., Woodward, J. (2009): Overcoming systemic road-blocks to sustainability: the evolutionary redesign of worldviews, institutions, and technologies, *Proceedings of the National Academy of Sciences of the United States of America*, **106** (8), pp. 2483-2489.
- Boström, M. (2012): A missing pillar? Challenges in theorizing and practicing social sustainability: introduction to the special issue, *Sustainability: Science, Practice, & Policy*, **8** (1), pp. 3-14.
- Campbell, J.L. (2006): Institutional analysis and the paradox of corporate social responsibility, *American Behavioral Scientist*, **49** (7), pp. 925-938.
- CEFIC (2014): *Social Responsibility in the European chemical industry*, available at <http://www.cefic.org/Documents/Learn%20and%20Share/Social-Responsability-Brochure/Social-Responsability-in-the-european-chemical-Industry.pdf>, accessed on 01. September 2015.
- Clausen, J., Loew, T. (2009): *CSR und Innovation: Literaturstudie und Befragung*, available at www.4sustainability.org, accessed on 01 September 2015.
- Commission of the European Communities (2001): *Green Paper - Promoting a European framework for Corporate Social Responsibility (DOC/01/9)*, Brussels.
- Deutscher Bundestag (1997): *Konzept Nachhaltigkeit. Fundamente für die Gesellschaft von morgen, Zwischenbericht der Enquete-Kommission „Schutz des Menschen und der Umwelt – Ziele und Rahmenbedingungen einer nachhaltig zukunftsverträglichen Entwicklung“*, Deutscher Bundestag, Berlin.
- Dyllick, T. (2003): *Konzeptionelle Grundlagen unternehmerischer Nachhaltigkeit, Handbuch Nachhaltige Entwicklung*, Springer, pp. 235-243.
- Dyllick, T., Hockerts, K. (2002): Beyond the business case for corporate sustainability, *Business Strategy and the Environment*, **11** (2), pp. 130-141.
- Elkington, J. (1997): *Cannibals with forks, The triple bottom line of 21st century*, Capstone Publishing Ltd., Oxford.
- Epstein, M.J., Roy, M.-J. (2003): Making the business case for sustainability, *Journal of Corporate Citizenship*, **2003** (9), pp. 79-96.
- Figge, F., Hahn, T., Schaltegger, S., Wagner, M. (2002): The sustainability balanced scorecard—linking sustainability management to business strategy, *Business Strategy and the Environment*, **11** (5), pp. 269-284.
- Foerstl, K., Reuter, C., Hartmann, E., Blome, C. (2010): Managing supplier sustainability risks in a dynamically changing environment—Sustainable supplier management in the chemical industry, *Journal of Purchasing and Supply Management*, **16** (2), pp. 118-130.
- Freeman, R. E., Velamuri, S. R. (2008): *A new approach to CSR: Company stakeholder responsibility*, available at <http://ssrn.com/abstract=1186223> or <http://dx.doi.org/10.2139/ssrn.1186223>, accessed on 01 September 2015.
- Freeman, R. E. (1984): *Strategic management a stakeholder approach*, Pitman series in business and public policy, Pitman publishing Inc., Boston, MA.
- Gladwin, T.N., Kennelly, J.J., Krause, T.-S. (1995): Shifting paradigms for sustainable development: Implications for management theory and research, *Academy of Management Review*, **20** (4), pp. 874-907.
- Goodland, R. (2002): *Sustainability: Human, social, economic and environmental*, available at http://www.balticuniv.uu.se/index.php/component/docman/doc_download/435-sustainability-human-social-economic-and-environmental.pdf, accessed on 1 September 2015.
- GRI (2015): *Sustainability disclosure database*, available at <http://database.globalreporting.org/search>, accessed on 30. January 2015.
- GRI (2014): *Ready to Report - SME booklet*, available at <https://www.globalreporting.org/resource/library/Ready-to-Report-SME-booklet-online.pdf>,

- accessed on 01 September 2015.
- GRI (2013): *Global Reporting Initiative - G4 Leitlinien zur Nachhaltigkeitsberichterstattung*, available at <https://www.globalreporting.org/resource/library/German-G4-Part-One.pdf>, accessed on 01 September 2015.
- GRI (2011): *Global Reporting Initiative - Sustainability Reporting Guidelines*, available at <https://www.globalreporting.org/resource/library/G3.1-Guidelines-Incl-Technical-Protocol.pdf>, accessed on 01 September 2015.
- Haasis, H.-D. (2008): *Produktions- und Logistikmanagement*, Gabler Verlag, Wiesbaden.
- Hart, S.L. (1997): Beyond greening: strategies for a sustainable world, *Harvard Business Review*, **75** (1), pp. 66-77.
- Hauth, P., Raupach, M. (2001): Nachhaltigkeitsberichte schaffen Vertrauen, *Harvard Business Manager*, **23** (5), pp. 24-33.
- Heins, B. (1998): *Soziale Nachhaltigkeit*, Analytica, Berlin.
- Hentze, J., Thies, B. (2014): *Stakeholder-Management und Nachhaltigkeits-Reporting*, Springer-Verlag, Wiesbaden.
- Hoffman, A.J. (1999): Institutional evolution and change: Environmentalism and the US chemical industry, *Academy of Management Journal*, **42** (4), p. 351-371.
- ICCA (2006): *Global Product Strategy*, available at <http://www.icca-chem.org/en/home/global-product-strategy/>, accessed on 01 September 2015.
- ICCA (2010): Responsible Care Global Charter, available at <http://www.cefic.org/Documents/ResponsibleCare/RC-global-charter.pdf>, accessed on 01 September 2015.
- ILO (2009): *International Labour Organization Declarations*, available at <http://www.ilo.org/global/about-the-ilo/lang--en/index.htm>, accessed on 01 September 2015.
- ISO (2011): *ISO 26000:2010 - Social responsibility*, available at <http://www.iso.org/iso/home/standards/iso26000.htm>, accessed on 01 September 2015.
- Jahn, G.A., Sächsische Hans-Carl-von-Carlowitz-Gesellschaft (ed.) (2013): *Die Erfindung der Nachhaltigkeit - Leben, Werk und Wirkung des Hans Carl von Carlowitz*, oekom-Verlag, München.
- Jörissen, J., Kopfmüller, J., Brandl, V., Paetau, M. (1999): *Ein integratives Konzept nachhaltiger Entwicklung*, Forschungszentrum Karlsruhe.
- Lamberti, L., Lettieri, E. (2009): CSR practices and corporate strategy: Evidence from a longitudinal case study, *Journal of Business Ethics*, **87** (2), pp. 153-168.
- Loew, T., Braun, S. (2009): *CSR-Handlungsfelder-Die Vielfalt verstehen, Ein Vergleich der Handlungsfelder aus den Perspektiven Unternehmen, Politik, GRI und ISO 26000*, available at http://www.4sustainability.de/fileadmin/redakteur/Publikationen/Loew-Braun2009_CSR-Handlungsfelder-im-Vergleich.pdf, accessed on 02 September 2015.
- Loew, T., Rohde, F. (2013): *CSR und Nachhaltigkeitsmanagement*, available at: http://www.4sustainability.de/fileadmin/redakteur/bilder/Publikationen/Loew_Rohde_2013_CSR-und-Nachhaltigkeitsmanagement.pdf, accessed on 02 September 2015.
- McWilliams, A. (2015): Corporate Social Responsibility, in: *Wiley Encyclopedia of Management*, 12, pp. 1-4.
- McWilliams, A., Siegel, D. (2001): Corporate social responsibility: A theory of the firm perspective, *Academy of Management Review*, **26** (1), pp. 117-127.
- McWilliams, A., Siegel, D.S., Wright, P.M. (2006): Corporate social responsibility: Strategic implications, *Journal of Management Studies*, **43** (1), pp. 1-18.
- OECD (2015): Organisation for Economic Co-Operation and Development (OECD) Principles, available at <http://www.oecd.org/about/>, accessed on 01 September 2015.
- OHS Group (2007): Occupational Health and Safety Assessment System (OHSAS) 18001, available at <http://www.ohsas-18001-occupational-health-and-safety.com/what.htm>, accessed on 01 September 2015.
- Orlitzky, M., Schmidt, F.L., Rynes, S.L. (2003): Corporate social and financial performance: A meta-analysis, *Organization Studies*, **24** (3), pp. 403-441.
- Perrini, F., Tencati, A. (2006): Sustainability and stakeholder management: the need for new corporate performance evaluation and reporting systems, *Business Strategy and the Environment*, **15** (5), pp. 296-308.
- Porter, M.E., Kramer, M.R. (2006): The Link between Competitive Advantage and Corporate Social Responsibility, *Harvard Business Review*, **84** (12), p. 78-92.
- Potts, J., Lynch, M., Wilkings, A., Huppe, G., Cunningham, M., Voora, V. (2014): The State of Sustainability Initiatives Review 2014: Standards and the Green Economy, available at <https://www.fastinternational.org/files/The%20State%20of%20Sustainability%20Initiatives%20Review%202014.pdf>, accessed on 01 September 2015.
- RNE (2014): *Leitfaden zum Deutschen Nachhaltigkeitskodex*, available at https://www.berthelmann-stiftung.de/fileadmin/files/Projekte/31_Nachhaltigkeitsstrategien/Leitfaden_zum_

- Deutschen_Nachhaltigkeitskodex.pdf, accessed on 01 September 2015.
- Robertson, D.C., Nicholson, N. (1996): Expressions of corporate social responsibility in UK firms, *Journal of Business Ethics*, **15** (10), pp. 1095-1106.
- SAI (2014): *Social Accountability 8000 - International Standard*, available at http://sai-intl.org/_data/n_0001/resources/live/SA8000%20Standard%202014.pdf, accessed on 01 September 2015.
- Salzmann, O., Ionescu-Somers, A., Steger, U. (2005): The business case for corporate sustainability: literature review and research options, *European Management Journal*, **23** (1), pp. 27-36.
- Schaltegger, S., Hasenmüller, P. (2005): *Nachhaltiges Wirtschaften aus Sicht des "Business Case of Sustainability"*, Ergebnispapier zum Fachdialog des Bundesumweltministeriums, Centre for Sustainability Management, Lüneburg.
- Schaltegger, S., Herzig, C., Kleiber, O., Klinke, T., Müller, J., Deutschland Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit (ed.), Ecosense (ed.), Centre for Sustainability Management (ed.) (2007): *Nachhaltigkeitsmanagement in Unternehmen*, available at http://www.econsense.de/sites/all/files/nachhaltigkeitsmanagement_unternehmen.pdf, accessed on 01 September 2015.
- Spangenberg, J.H., Bonniot, O. (1998): *Sustainability indicators: a compass on the road towards sustainability*, available at <http://www.ulb.ac.be/ceese/STAFF/Tom/spangenberg.pdf>, accessed on 02 September 2015.
- UN 2015: *The Ten Principles of the UN Global Compact*, available at <https://www.unglobalcompact.org/what-is-gc/mission/principles>, accessed on 01 September 2015.
- UN (2013): *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, 5th revised ed., available at http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev05/English/ST-SG-AC10-30-Rev5e.pdf, accessed on 01 September 2015.
- UNGA (1987): *Report of the World Commission on Environment and Development: Our Common Future*, available at www.un-documents.net/our-common-future.pdf, accessed on 02 September 2015.
- Vallance, S., Perkins, H.C., Dixon, J.E. (2011): What is social sustainability? A clarification of concepts, *Geoforum*, **42** (3), p. 342-348.
- VCI (2013): *Chemiehoch3 - Sustainability Guidelines for the Chemical Industry in Germany*, available at <https://portal.vci.de/Downloads/Publikation/Sustainability-Guidelines-German-Chemical-Industry-Chemie3.pdf>, accessed on 02 September 2015.
- Voegtlin, C., Pless, N. M. (2014): Global governance: CSR and the role of the UN Global Compact, *Journal of Business Ethics*, **122** (2), pp. 179-191.
- Wagner, B., Henle, B. (2008): Die brüchige Säule der Nachhaltigkeit, *Ökologisches Wirtschaften-Fachzeitschrift*, **23** (2), pp. 30-34.
- Wahba, H. (2008): Exploring the moderating effect of financial performance on the relationship between corporate environmental responsibility and institutional investors: Some Egyptian evidence, *Corporate Social Responsibility and Environmental Management*, **15** (6), pp. 361-371.
- Weber, M. (2008): The business case for corporate social responsibility: A company-level measurement approach for CSR, *European Management Journal*, **26** (4), p. 247-261.

Appendix

Table 7 Definitions of GRI indicators in the guidelines version 3.1, according to GRI, 2011, pp. 31-39. *Indicators not included in version 3.0 are marked.

Category I: Labor practices and decent work	
Aspect: Employment	
LA1	Total workforce by employment type, employment contract, and region, broken down by gender.
LA2	Total number and rate of new employee hires and employee turnover by age group, gender, and region.
LA3	Benefits provided to full-time employees that are not provided to temporary or part-time employees, by significant locations of operation.
LA15*	Return to work and retention rates after parental leave, by gender.
Aspect: Labor/Management relations	
LA4	Percentage of employees covered by collective bargaining agreements.
LA5	Minimum notice period(s) regarding operational changes, including whether it is specified in collective agreements.
Aspect: Occupational health and safety	
LA6	Percentage of total workforce represented in formal joint management-worker health and safety committees that help monitor and advise on occupational health and safety programs.
LA7	Rates of injury, occupational diseases, lost days, and absenteeism, and total number of work-related fatalities, by region and by gender.
LA8	Education, training, counseling, prevention, and risk-control programs in place to assist workforce members, their families, or community members regarding serious diseases.
LA9	Health and safety topics covered in formal agreements with trade unions.
Aspect: Training and education	
LA10	Average hours of training per year per employee by gender, and by employee category.
LA11	Programs for skills management and lifelong learning that support the continued employability of employees and assist them in managing career endings.
LA12	Percentage of employees receiving regular performance and career development reviews, by gender.
Aspect: Diversity and equal opportunity	
LA13	Composition of governance bodies and breakdown of employees per employee category according to gender, age group, minority group membership, and other indicators of diversity.
Aspect: Equal remuneration for women and men	
LA14	Ratio of basic salary and remuneration of women to men by employee category, by significant locations of operation.

Category II: Human rights**Aspect: Investment and procurement practices**

HR1	Percentage and total number of significant investment agreements and contracts that include clauses incorporating human rights concerns, or that have undergone human rights screening.
HR2	Percentage of significant suppliers, contractors, and other business partners that have undergone human rights screening, and actions taken.
HR3	Total hours of employee training on policies and procedures concerning aspects of human rights that are relevant to operations, including the percentage of employees trained.

Aspect: Non-discrimination

HR4	Total number of incidents of discrimination and corrective actions taken.
------------	---

Aspect: Freedom of association and collective bargaining

HR5	Operations and significant suppliers identified in which the right to exercise freedom of association and collective bargaining may be violated or at significant risk, and actions taken to support these rights.
------------	--

Aspect: Child labor

HR6	Operations and significant suppliers identified as having significant risk for incidents of child labor, and measures taken to contribute to the effective abolition of child labor.
------------	--

Aspect: Forced and compulsory labor

HR7	Operations and significant suppliers identified as having significant risk for incidents of forced or compulsory labor, and measures to contribute to the elimination of all forms of forced or compulsory labor.
------------	---

Aspect: Security practices

HR8	Percentage of security personnel trained in the organization's policies or procedures concerning aspects of human rights that are relevant to operations.
------------	---

Aspect: Indigenous rights

HR9	Total number of incidents of violations involving rights of indigenous people and actions taken.
------------	--

Aspect: Assessment

HR10*	Percentage and total number of operations that have been subject to human rights reviews and/or impact assessments.
--------------	---

Aspect: Remediation

HR11*	Number of grievances related to human rights filed, addressed and resolved through formal grievance mechanisms.
--------------	---

Category III: Society

Aspect: Local communities

- SO1** Percentage of operations with implemented local community engagement, impact assessments, and development programs.
- SO9*** Operations with significant potential or actual negative impacts on local communities.
- SO10*** Prevention and mitigation measures implemented in operations with significant potential or actual negative impacts on local communities.

Aspect: Corruption

- SO2** Percentage and total number of business units analyzed for risks related to corruption.
- SO3** Percentage of employees trained in organization's anti-corruption policies and procedures.
- SO4** Actions taken in response to incidents of corruption.

Aspect: Public policy

- SO5** Public policy positions and participation in public policy development and lobbying.
- SO6** Total value of financial and in-kind contributions to political parties, politicians, and related institutions by country.

Aspect: Anti-competitive behavior

- SO7** Total number of legal actions for anticompetitive behavior, anti-trust, and monopoly practices and their outcomes.

Aspect: Compliance

- SO8** Monetary value of significant fines and total number of non-monetary sanctions for noncompliance with laws and regulations.

Category IV: Product responsibility

Aspect: Customer health and safety

- PR1** Life cycle stages in which health and safety impacts of products and services are assessed for improvement, and percentage of significant products and services categories subject to such procedures.
- PR2** Total number of incidents of non-compliance with regulations and voluntary codes concerning health and safety impacts of products and services during their life cycle, by type of outcomes.

Aspect: Product and service labeling

- PR3** Type of product and service information required by procedures, and percentage of significant products and services subject to such information requirements.
- PR4** Total number of incidents of non-compliance with regulations and voluntary codes concerning product and service information and labeling, by type of outcomes.
- PR5** Practices related to customer satisfaction, including results of surveys measuring customer satisfaction.

Aspect: Marketing communications

- PR6** Programs for adherence to laws, standards, and voluntary codes related to marketing communications, including advertising, promotion, and sponsorship.
- PR7** Total number of incidents of non-compliance with regulations and voluntary codes concerning marketing communications, including advertising, promotion, and sponsorship by type of outcomes.

Aspect: Customer privacy

- PR8** Total number of substantiated complaints regarding breaches of customer privacy and losses of customer data.

Aspect: Compliance

- PR9** Monetary value of significant fines for noncompliance with laws and regulations concerning the provision and use of products and services.

Practitioner's Section

Biomedical research and development in the Indian therapeutic drug industry

Azamat Ali* and Kunal Sinha*

* Centre for Studies in Science, Technology and Innovation Policy, School of Social Sciences, Central University of Gujarat, Gandhinagar- 382030, India, azamatcug@gmail.com

Health is a key issue in the development of a stable global social, political and economic structure in the 21st century. Better and reasonable health is a global goal. Great progress has been made during the past decades in the biomedical fields in the understanding of diseases, developing new diagnostic technologies and new medicines for better prevention and treatment of illness. The emergence of new diseases directly and indirectly affecting human activity through environmental changes is a new major scientific challenge. Research and development (R&D) is the heart of all advances and has the capacity to solve problems facing humanity. The paper aims to explore the biomedical R&D in the therapeutic segments of the pharmaceutical drug industry in India. The paper also highlights factors influencing the growth of biomedical R&D in therapeutic areas, the market and investments, and elaborates on the R&D pipeline of firms and public research for biomedical drugs in the current healthcare system in India.

1 Introduction

Biomedical research is a broad aspect of science that looks for ways to prevent and treat diseases that cause illness and death of people as well as animals. It is an evolutionary process requiring careful experimentation by many scientists, including biologists and chemists. Discovery of new medicines and therapies requires careful scientific experimentation, development, and evaluation (New Jersey Association for Biomedical Research, 2014). Therapeutics refers to treatment and care of a patient for the purpose of both preventing and combating disease or alleviating pain or injury. In a broader sense, it means, serving and caring for the patient in a comprehensive manner, preventing disease as well as managing specific problems (Rakel, 2014). Biomedical research is conducted in pharmaceutical, biotechnology and medical device firms. The paper addresses the therapeutic segments in the pharmaceutical industry, not all biomedical industries. Reducing the disease burden of the population has emerged as a major development challenge in several developing countries. R&D has always been the backbone and the underlying strength of biomedical innovation in the pharmaceutical industry. In the past decades, the Indian

pharmaceutical industry has delivered multiple life-saving medicines contributing to new treatment options for several biomedical needs. Currently, it is playing a major role in medical needs and R&D investments in neuroscience, cardiovascular, endocrine, gastrointestinal, respiratory and genitourinary research.

The Indian pharmaceutical industry was valued at US\$ 12 billion in the year 2013. Globally, India ranks 3rd in terms of volume and 14th in terms of value (Business Standard, 2014). The top 10 therapy areas (anti-infective, cardiac, gastrointestinal, respiratory, pain/analgesics, vitamins/nutrients, anti-diabetic, gynecology, central nervous system and derma) of the Indian pharmaceutical contribute to approximately 90% of the Indian pharmaceutical sales. The contribution of chronic therapies to the Indian pharmaceutical industry has raised from 27% in 2010 to 30% in 2013. Chronic therapies (cardio, gastro, central nervous system and anti-diabetic) have outperformed the market for the past four years and are growing at a rate of 14%, faster than the acute therapies (anti-infective, respiratory, pain and gynecology) which grew at 9.6% (PWC, 2013). Within the domestic formulations market the major therapeutic categories are anti-infective, gastrointestinal, cardiac, gynecology and derma-

tology. The leading drug classes were Cephalosporin, anti-peptic ulcers, oral anti-diabetic and Ampicillin or Amoxycillin, etc. (DOP, 2013).

In this backdrop, the present paper is an attempt to analyze the biomedical R&D in the therapeutic drug industry in India. The paper is divided into six sections. Section one deals with the introduction and the current market scenario of biomedical industry in therapeutic segments. Section two deals with the methods used for data collection. The third section presents the factors influencing growth of biomedical industry. Section four presents Indian biomedical firms in the therapeutic segments, and section five deals with the role of public sector units and research institutes in the biomedical R&D. Finally, section six deals with discussion and conclusion.

2 Research method

The research study is based on a quantitative research method. A quantitative method is generally used in order to collect statistical data and conduct statistical analyses (Yin, 2003). In this paper, quantitative indicators for R&D expenditure, net sales, profits, market share and registered patents have been collected. Details of R&D and innovation activities of Indian pharmaceutical firms, particularly in the therapeutic segments, were picked out through various sources such as authentic internet resources, annual reports, newspaper clippings, websites, etc. Data is mainly collected from companies' websites and annual reports: www.lupin.com, www.sunpharma.com, www.cipla.com, www.zyduscadila.com, www.torrentpharma.com and www.ipcalabs.com. We also analyzed these facts from the peer-reviewed literature and books published by academia.

We have chosen the six largest Indian pharmaceutical companies in terms of revenue from worldwide pharmaceutical sales in therapeutic segments: Lupin, Sun Pharma, Cipla, Zydus Cadila, Torrent Pharma, and Ipca. These leading Indian companies examined here have been selected on the following basis:

- They are highly profitable and fast growing.
- Their initial technical skills have been in chemistry and low cost manufacturing.
- These companies are mainly active in the generics sector and produce generics to be sold in India.
- They have significant levels of international business, including products on sale in the highly regulated markets in the western countries. They obtain approval for and

market generic drugs in the USA and Europe.

- They develop in-house skills in drug discovery and developing new patented drugs including biopharmaceuticals.

These six companies have diverse roots. Some were founded many years ago, e.g. Cipla in 1935, Zydus Cadilla in 1952, Torrent Pharma in 1959, Lupin in 1968 and some comparatively recently, e.g. Ipca in 1976, 1983 Sun Pharma in 1983. The vision of these companies is to make India self-sufficient in health-care, a leader in the pharmaceutical industry, deliver world class products and services, and make quality medicine more accessible and affordable to the common man globally.

3 Factors influencing growth of biomedical industry

3.1 Growing and ageing population

The current world population of 7.2 billion is projected to increase by over 1 billion in the next 12 years and reach 9.6 billion by 2050 (UN News, 2013). Between 2000 and 2050, the proportion of the world's population over 60 years will double from about 11% to 22%. The absolute number of people aged over 60 years is expected to increase from 605 million to 2 billion over the same period (WHO, 2014a). Most of the older people die of non-communicable diseases such as heart disease, cancer and diabetes, rather than from infectious and parasitic diseases. The growing ageing population will drive the demand for medicines and increase pharmaceutical spending.

3.2 Changing lifestyle

Rising prevalence of lifestyle diseases like hypertension, diabetes mellitus, dyslipidaemia and overweight or obesity are the major risk factors for the development of cardiovascular diseases. Cardiovascular diseases (CVD) continue to be the major cause of mortality representing about 30% of all deaths worldwide (Pappachan, 2011). With rapid economic development and increasing westernization of lifestyle in the past few decades, prevalence of these diseases have reached alarming proportions among Indians in the recent years (Pappachan, 2011).

3.3 The rising incidence of non-communicable diseases

Non-communicable diseases are the top cause of death worldwide, killing more than 36 million

people in 2008. Cardiovascular diseases were responsible for 48% of these deaths, cancer 21%, chronic respiratory diseases 12%, and diabetes 3% (WHO, 2014b). World Health Organization (WHO) forecasts that by 2020, the non-communicable diseases will account for 44 million deaths a year, increasing by 15% from 2010 (WHO, 2010).

3.4 Prevalence of communicable diseases

Although disease patterns change constantly, communicable diseases remain the leading cause of mortality and morbidity in less developed countries. According to WHO, low-income countries currently have a relatively high share of deaths from: (i) HIV infection, tuberculosis and malaria, (ii) other infectious diseases, and (iii) maternal, perinatal and nutritional causes compared with high and middle income countries (Gupta and Guin, 2010; WHO, 2004).

3.5 Rising spend on healthcare

The healthcare sector in India is expected to grow at a CAGR of 15% and touch US\$ 158.2 billion in 2017 from US\$ 78.6 billion in 2012 (IBEF, 2014a). India is a country with a growing population, its per capita healthcare expenditure has increased at a CAGR of 10.3% from US\$ 43.1 in 2008 to US\$ 57.9 in 2011, and going forward it is expected to reach US\$ 88.7 by 2015 (IBEF, 2014a). The factors behind the growth of the sector are rising incomes, easier access to high quality healthcare facilities and greater awareness of personal health and hygiene.

3.6 Growth in healthcare financing products

Development in the Indian financial industry has eased healthcare financing with the introduction of products such as health insurance policy, life insurance policy and cashless claims. This has resulted in an increase in healthcare spending, which in turn, has benefitted the pharmaceutical industry.

3.7 Health insurance is growing

Health insurance in India is a growing segment of India's economy. It is expected to grow at a CAGR of 15% over the next five years and nearly 650 million people will enjoy health insurance coverage. Around 80% healthcare is financed out of pocket (PWC, 2010). The private healthcare facilities grew rapidly and insurance coverage increased. The small percentage of Indian who has some insurance and government run insurance company is the main

provider. The government sponsored programmes largely focused on the below poverty line (BPL) segment and are expected to provide coverage to nearly 380 million people by 2020 (Bhadoria *et al.*, 2012).

3.8 Increase in domestic demand

More than half of India's population does not have access to advanced medical services and is mainly depending on traditional medicine practices. However, with the increase in awareness levels, rising per capita income, change in lifestyle due to urbanization and increase in literacy levels, demand for advanced medical treatment is expected to rise. Moreover, growth in the middle class population would further influence demand for pharmaceutical products.

3.9 Rise in outsourcing activities

Increase in the outsourcing business in India would accelerate the growth of Indian pharmaceutical industry. Some of the factors that are likely to influence clinical data management and bio-statistics markets in India in the near future include: 1) cost efficient research 2) highly-skilled labour base 3) cheaper or low cost of skilled labour 4) presence in end-to-end solutions across the drug-development spectrum and 5) robust growth in the IT industry.

3.10 High R&D expenditures

The government of India is committed to supporting the expansion of R&D in the pharmaceutical and biotechnology industries and has taken a direct role in funding R&D in both, public and private sectors. The total biomedical R&D expenditure by both public and private sectors was US\$ 10.4 billion between the year 2007 and 2012 in India (Chakma *et al.*, 2014). This R&D expenditure included expenditures by government agencies, educational or research institutions, and charitable organizations, whereas for the industries it included expenditures by biotechnology, medical-device, and pharmaceutical firms.

4 Indian biomedical firms in therapeutic segments

4.1 Overview of the major players

Biomedical innovation in the pharmaceutical industry in India is one of the largest and most advanced among the developing countries. The industry produces an entire range of products belonging to all major therapeutic segments. In

the pharmaceutical world, India's opportunities are significant in the context of medicinal development in the 21st century (Kumar and Satish, 2007). India has an existing generic based drug industry with an increasing focus on discovery. Antibiotic, cardiovascular, analgesic and antipyretic, antacids and anti-ulcerants, respiratory and anti-tuberculosis are the major therapeutic segments which account for over 90% of the domestic formulation market (Kumar and Satish, 2007). Other important therapeutic segments are anti-parasitic and anti-fungal products, non-steroidal anti-inflammatory drugs (NSAID) drugs, anti-anaemic, anti-diabetes, anti-malarial, anti-tuberculosis, central nervous system (CNS) and psychiatric products, gynaecology, nutrients and mineral supplements. Table 1 presents the figures of the six selected Indian pharmaceutical companies revealing their net sales, profit, growth rates and market share during the financial year 2013-14.

Sun Pharma has the largest share and has a strong positioning in chronic segments like central nervous system (CNS), cardiovascular and diabetology, together accounting for more than 50% of India formulation revenues. Torrent Pharma posted the highest growth in revenue; growth was primarily driven by cardiology, diabetology, CNS in chronic and gastroenterology in acute segments. The company is ranked number four in cardiovascular segment and in neuro-psychiatry therapies.

Lupin is one of the fastest growing players in high growth therapy segments like cardiology, central nervous system, diabetology, anti-asthma, and gynaecology, anti-infective, gastro intestinal and oncology. The company is the second largest player in India's respiratory (anti-asthma) segment, third largest player in the cardiovascular segment and seventh largest player in diabetes segment.

Cipla holds the second largest share and it has a leading position in various therapeutic categories, including respiratory and urology, and reinforces the potential to strengthen its presence in India across other therapies. It continues to increase its focus on CNS, oncology, dermatology and gastroenterology. The company holds a dominant position in the respiratory therapy segment and grasps 70% market share in this segment.

Zydus Cadila is one of the largest market players with leading positions in key therapy areas. It has strong leadership positions in the represented markets of cardiology, gynaecology, gastrointestinal and respiratory therapy areas. The company has gained second position in the dermatology segment and shifted from the sixth rank in 2013 to the fourth rank in 2014. Ipca is a therapy leader in India for anti-malarial and it focuses on chronic therapy segments such as cardiovascular, anti-diabetics and non-steroidal anti-inflammatory drugs (NSAID)

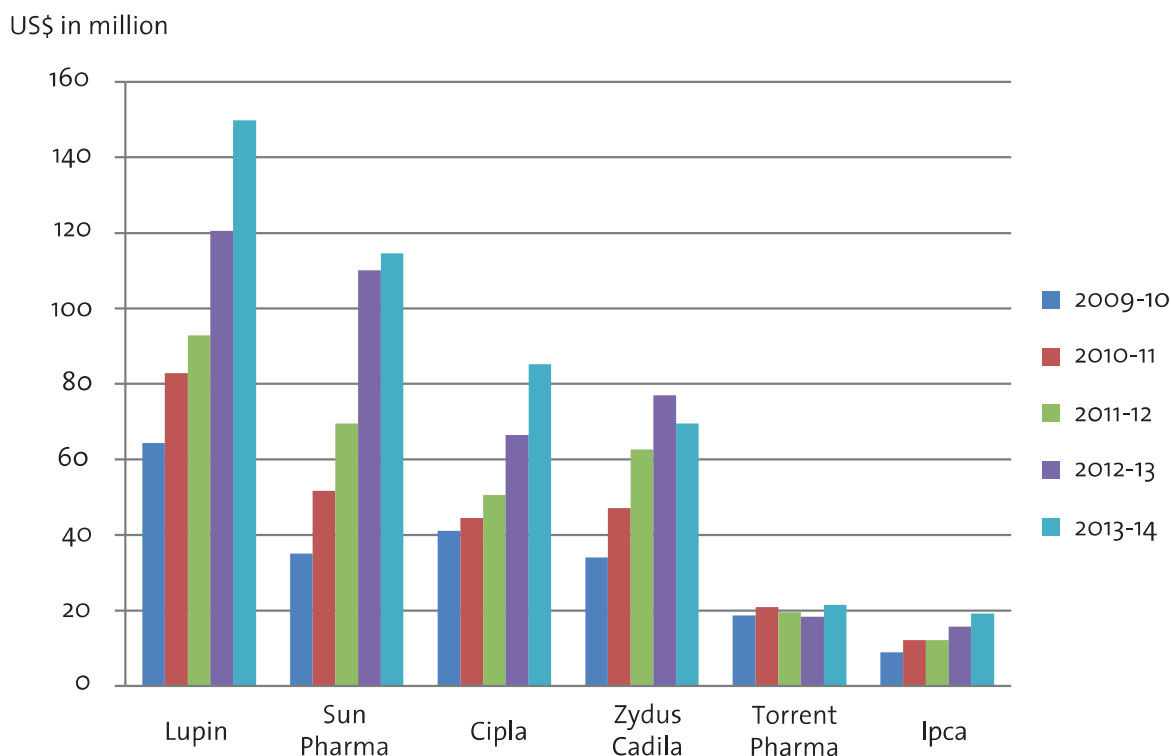
4.2 Investments into R&D

The pharmaceutical industry is knowledge intensive and R&D investment plays a crucial role in the growth of this industry (Shah *et al.*, 2010). R&D in pharmaceutical industry includes directional search solutions to existing medical problems and unmet medical requirements. The pharmaceutical R&D may be concentrated in the New Chemical Entities (NCE), Novel Drug Delivery Systems (NDDS) or in generic products. R&D is a comparatively recent phenomenon for Indian pharmaceutical firms which gained momentum only after the year 1995. India introduced the product patent regime in accordance with the Trade Related Aspects of Intellectual Property Rights (TRIPs) agreement, in January

Table 1 The six selected pharma companies by net sales, profits, growth rates and market share in 2013-14 (Source: Authors' compilation based on each company's annual report).

Company	Net sales (US\$ in million)	Profits (US\$ in million)	Growth rates (%)	Market share (%)
Lupin	1,733	287	17	2.8
Sun Pharma	2,503	501	30	5.4
Cipla	1,579	333	22	5.3
Zydus Cadila	385	126	17	4.4
Torrent Pharma	503	119	30	4.2
Ipca	509	75	16	2.0

Figure 1 R&D expenditures of selected Indian pharmaceutical companies between 2010 and 2014 (Source: Authors' compilation based on each company's annual report).



2005 with an amendment to the patent act. The allowance of product patents supported the confidence of innovator pharmaceutical companies in the Indian market (IBEF, 2014b). The cumulative figure for the top 30 companies is about US\$ 837.9 million in 2012-13. This works out to be about 7.8% of the net sales of these companies (Rao, 2014). Figure 1 shows the R&D expenditures of selected pharmaceutical companies over the past five years.

The R&D expenditure of these pharma companies has steadily increased. In the financial year 2013-14, the total R&D expenditure by these six pharmaceutical companies was US\$ 460.70 million. Currently, Lupin is the top pharma company spending for its R&D in the biomedical innovation in India. The company invested 8.6% of its net sales in R&D and related expenditure amounting to US\$ 149.80 million in the financial year 2014. The company Novel Drug Discovery and Development (NDDD) program focuses on the discovery, development and commercialization of new drugs for new therapies and various diseases that include metabolic and endocrine disorders, pain and inflammation, autoimmune diseases, CNS disorders, cancer and infectious diseases. The R&D of Sun Phar-

ma in India focuses on the chronic segments like diabetes, central nervous system, hypertension etc. The company spends around 6% of its net sales in the R&D, and has four modern R&D centres, expert scientist teams who are engaged in complex developmental research projects in process chemistry and dosage forms, including complex generics based on drug delivery systems.

The R&D wing of Cipla is involved in the development of new drug formulations for existing and new active drug substances, novel drug delivery system (NDDS) and development of products related to the indigenous systems of medicines. The total R&D expenditure as a percentage of total turnover was around 5% during the financial year 2014. The R&D of the company focuses on various therapeutic segments like respiratory, anti-viral, gynaecology and urology. Zydus Cadila focused on finding innovative therapies for diseases affecting mankind through continuous R&D. The total R&D expenditure as a percentage of total turnover was around 11% during the financial year 2014. The major areas of R&D include new chemical entities (metabolic disorders, diabetes, obesity, dyslipidaemia, inflammation and pain, rheumatoid arthritis, bac-

terial infections, and cancer) research, formulation development, process research and novel drug delivery system.

Torrent Pharma is currently working on several in-house new chemical entities R&D projects within the areas of diabetes and its related complications, metabolic, cardiovascular and respiratory disorders. The total R&D expenditure as a percentage of turnover was 4.26% during the financial year 2014. The company R&D expenses have increased by 10% to US\$ 21.57 million as compared to US\$ 19.54 million during the financial year 2013. Product development costs accounted for 71% and discovery research costs accounted for 29% in 2014 of the total R&D cost. The company has expert scientist teams who offer dedicated services in the areas of discovery research, generic drug development, new drug delivery systems and value added generics thereby transforming discoveries into the highest quality therapeutic products. Ipca is a therapy leader in India for anti-malarial and also leads in DMARDs (Disease Modifying Anti-Rheumatic

Drugs) treatment for rheumatoid arthritis. The company carries out R&D in several areas including the development of newer dosage forms and new drug delivery systems, process improvements, technology absorption and optimization of basic drugs, process simplification, etc. The company had stepped up its R&D expenditure from US\$ 15.69 million in the financial year 2013 to US\$ 19.2 million in the year under report. The total R&D expenditure as a percentage of total turnover is 3.87% during the financial year 2014. Table 2 shows the disease wise product specific R&D activities of the selected pharmaceutical companies in India.

The table shows the categorization of diseases into type I, II, and III and product wise specific R&D activities of selected companies during 2002 to 2011. This indicates that Ipca Lab and Lupin Ltd are more active in type I and type II diseases. Sun Pharma and Zydus Cadila are more active in type I diseases. In case of Cipla and Torrent Pharma are less R&D activities compared to other companies.

Table 2 Disease wise product specific R&D activities of companies active in India between 2002 and 2011, whereby 1-15 present the number of disease wise products (adapted from NHSRC Report, 2013).

	2002-2004			2005-2007			2008-2011			Total
	Disease type ¹									
	I	II	III	I	II	III	I	II	III	
Com- panies										
Lupin Ltd		1		4	4		4		1	14
Sun Pharma				2			7			9
Cipla Ltd								1	1	2
Zydus Cadila				3	1		9			13
Torrent Pharma							1			1
Ipca Lab				4	1		5	5		15
Grand total		1		13	6		26	6	2	54

1) Type I: Diabetes, cancer, metabolic diseases, hepatitis, influenza, cardiovascular, infectious diseases, inflammatory diseases, allergy, respiratory diseases. Type II: HIV/AIDS, tuberculosis, and malaria. Type III: Leishmaniasis, lymphatic filariasis, leprosy, diarrhoea (neglected diseases of the poor in developing world).

4.3 Therapeutic areas of new drug R&D

Research in the development of drugs has generally two major aspects: (i) discovery of a new drug molecule, and (ii) invention of new formulations of drugs with higher therapeutic index (Maitra, 2000). A drug discovery pipeline has various phases that can be grouped into four stages: discovery, pre-clinical, clinical trials and marketing (or post approval). It is an important indicator of the value and future prospects of a company. Usually, the more compounds in the pipeline and the more advanced stage these are in, the better. Table 3 includes a list of new molecules of selected leading pharmaceutical companies in the therapeutic segment in India which are at different stages of development.

The table shows that R&D efforts focus on chronic disease such as diabetes. Lupin's Novel Drug Discovery and Development (NDDD) program focuses on the discovery, development and commercialization of new drugs that address disease areas with significant unmet medical needs. Currently, the program in the CNS area completed phase I studies in Europe and is being advanced to Phase II clinical trials in Europe. Cipla R&D is focused towards developing new products, improving existing products as well as drug delivery systems and expanding product applications. Cipla and the Drugs for Neglected Diseases initiative (DNDi) are developing a more acceptable granule formulation of 40/10 mg lopinavir/ritonavir as part of a first-line regimen for infants and young children.

The Sun Pharma strategy has been dominating the lifestyle disease segments. SUN-597 is a topical glucocorticoid being developed for allergic rhinitis, inflammation, asthma and other applications and completed its Phase I clinical trials in India. SUN-L731 is being developed as an oral LTD₄ antagonist for treatment of Asthma & Allergic Rhinitis. SUN-K706 is a novel tyrosine kinase inhibitor (TKI), intended for the treatment of chronic myelogenous leukaemia (CML). Currently, available oral drugs like Imatinib (Gleevec®), Nilotinib (Tasigna®) and Dasatinib (Sprycel®) are quite effective chemotherapeutic agents CML. Sun 09 is a pro-drug of Baclofen and is being developed as an efficient Baclofen. Baclofen is the standard drug of choice for the treatment of spasticity. Zydus Cadila currently conducts basic new drug discovery research in cardio-metabolic, inflammation, pain and oncology therapeutic areas. During the year 2014, the company launched Lipaglyn (Saroglitazar) in India, its first NCE for treating diabetic dyslipidaemia and hypertriglyceridemia. It is the first drug discovered and developed indigenously by an Indian pharmaceutical company.

Torrent Pharma R&D is engaged in the discovery of new chemical entities and the development of new processes and suitable formulations for known Active Pharmaceutical Ingredients (APIs). The most advanced discovery program of the Company is Advanced Glycation End-Products (AGE) Breaker, of which the Phase II clinical trials for the indication of diabetes associated heart failure in India and Europe is completed. Ipca is actively engaged in the segment of new Drug Discovery Development by collaborating with various research organizations and premier institutes in India and abroad. The company's current pipeline includes pain management, anti-ulcer and anti-malarial and one of the novel molecules (CDRI- 97/78) has shown very promising anti-malarial activity and is currently in clinical Phase-I in India.

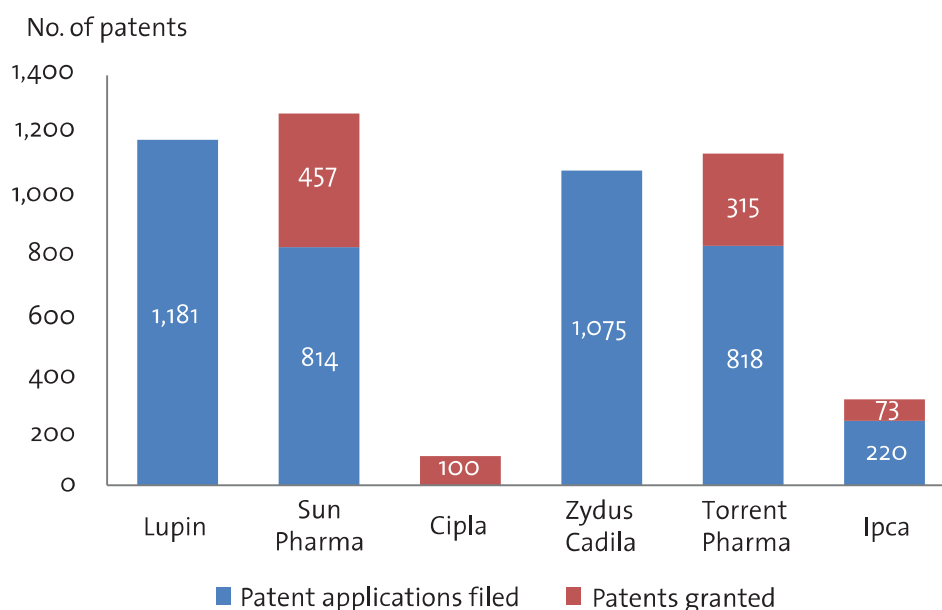
4.4 R&D outcomes

R&D investments are indicators for the main inputs into science based innovation. Publication and patent data provide complementary indicators for research and development activities, although capturing intermediate outputs (OECD, 2008). Patents are the most important way in which researchers can protect the ideas or technologies they have developed. It reflects the ability of transferring scientific results into technological applications. It is also essential for economic exploitation of research results and is thus central to any analysis which deals with economic potentials of technology and the identification of the most promising fields and actors in terms of persons, organizations or countries (Hullmann, 2006; Ali and Sinha, 2014). Figure 2 provides company wise patent applications filed and granted at different patent offices (Indian Patent Office (IPO), European (EPO) and United States Patent and Trade Office (USPTO)).

The figure shows that Sun pharma has the maximum number of patents granted. Lupin has comparably filed the highest number of patent applications in India and other countries. This included 108 formulation patents, 39 Active Pharmaceutical Ingredients (APIs) or process patents, 2 biotech and 232 new chemical entity (NCE) patents in India and other countries. Cipla has been granted about 100 patents. Patent filing includes drug substances, drug products, platform technologies, IP on polymorphs and crystallinity, and medical devices. Zydus Cadila has filed over 115 patents in the US, Europe and other countries, taking the cumulative number of filings to over 1,075. Torrent pharma has 818 patents filed for novel drug delivery systems (NDDS) technology, drug discovery projects and innovative process of API and formulations for various geographies and 315 have been granted so far. Ipca has

Table 3 Drug development pipelines of selected Indian pharmaceutical companies (Source: Authors' compilation based on each company's annual report).

Company	Identifier/ molecule description	Therapeutic area	Stage of development
Lupin		Central Nervous System (CNS)	Phase II
Sun Pharma	Sun-597	Allergic rhinitis, inflammation, asthma	Phase I
	Sun-L731	Asthma and allergic rhinitis	Preclinical
	Sun-K706	Chronic Myelogenous Leukaemia (CML)	Preclinical
	Sun-1334H	Allergic diseases	Phase II
	Sun-09	Spasticity	Phase I
	Sun-44	Neuropathic pain	Preclinical
Cipla/ DNDi	Boosted PI	Lopinavir/ritonavir (LPV/rtv)	Phase I
	Boosted PI/2NRTIs	LPV/rtv/ abacavir (ABC) or zidovudine (AZT)/ lamivudine (3TC) (4-in-1)	Phase I
Zydus Cadila	PPAR alpha; gamma	Treatment of hypertriglyceridemia	NDA
	PPAR alpha	Dyslipidaemia	Phase II
	GPR-119 agonist	Diabetes	Phase I
	Long acting DPP-IV	Diabetes	Phase I
	PEG-EPO	Anaemia of chronic renal failure	Phase I
	Rabies MAb	Rabies	Phase I
	AGE-Breaker (TRC4186)	Diabetes	Phase II
Torrent Pharma	T2 Mimetic	Cardio metabolic risk	Phase I
	DARA	Anti-hypertensive	Lead optimization
	HIF (TRC 160334)	Acute kidney injury	Lead optimization
		Diabetes	Lead optimization
		Chronic obstructive pulmonary disease (COPD)	Early discovery
Ipca	Novel molecule CDRI-97/78	Anti-malarial	Phase I

Figure 2 Number of filed and granted patents for the selected companies until 31 May 2014 (Source: Authors' compilation based on each company's annual report).

220 patent applications filed till date in India, USA and other countries. These applications relate to novel and innovative manufacturing processes for the manufacture of APIs and pharmaceutical formulations.

5 Role of public sector units and research institutes

There are five central public sector companies established by the government of India, which are Indian Drugs and Pharmaceuticals Limited (IDPL), Hindustan Antibiotics Limited (HAL), Bengal Chemicals and Pharmaceuticals Limited (BCPL), Bengal Immunity Limited (BIL) and Smith Stanistreet Pharmaceuticals Limited (SSPL). HAL and IDPL play a very important role in the biomedical R&D in India. HAL is the first public sector company in drugs and pharmaceuticals and HAL was incorporated on 30th March, 1954 in Pune. It was established to produce antibiotic with the assistance of WHO and UNICEF. It is the first company in India to manufacture of antibiotic drugs like penicillin, ampicillin, gentamicin, streptomycin, sulphate, anhydrous from the basic stage (Mazumdar, 2013). IDPL was incorporated on 5th April, 1961 for achieving India's march towards self-sufficiency and self-reliance in the field of drugs and pharmaceuticals, particularly with the primary objective of creating self-sufficiency in essential lifesaving drugs and medicines

(DOP, 2012). Presently, under different classes of therapeutic medicines, around 87 generic or branded drugs covering tablets, capsules, injections, vitamins, oral rehydration solution (ORS) pouches etc. are being manufactured in various plants of IDPL (DOP, 2012).

The publicly funded research institutes are also playing a key role in the growth of the biomedical sector in India. The government of India has created a number of research institutes under the guidance of the Indian Council of Medical Research (ICMR) and the Council of Scientific and Industrial Research (CSIR) to promote technological advancement of the country. The CSIR institutes are playing a significant role in boosting up the knowledge base in the biomedical R&D sector of India. The technologies developed by the public research institutes are also transferred effectively from laboratories to industries. The success of the CSIR laboratories in fostering the technological environment of the Indian pharmaceutical firms in the biomedical sector is also evident and shows that almost all the top pharmaceutical companies like Lupin, Ranbaxy, Cipla, Nicholas Primal, Wockhardt, Torrent Pharma, Sun Pharmaceutical, Orchid, and Aurobindo Pharma Ltd have benefited from the services of the research institutes in India in some or the other way. Table 4 shows some of the public research pharmaceutical R&D Institutes in India.

6 Conclusion

The Indian biomedical industry has been on a strong growth trajectory in the last decade. It has achieved several milestones and is well positioned to leverage emerging opportunities. The industry needs to tackle various issues related to its operations and regulations. The current Indian drug discovery pipeline offers attractive opportunities, as it illustrates that Indian pharma companies have proven their capability to build integrated drug discovery capabilities, and to drive molecules from the early discovery stage to development.

The analysis of R&D expenditures of pharmaceutical firms shows that there had been a growth in the R&D intensity. Presently, most of the company's drug development pipeline is in the stages of lead identification, preclinical research and Phase I. In the R&D for new drugs, the analysis of the new drug pipelines of leading Indian pharma firms shows that the new patent regime has not been able to become the driving force. The R&D activities of Indian firms are increasingly getting concentrated on lifestyle diseases of global nature and they do not find any opportunity in local diseases such as tuberculosis and malaria except a single pharma com-

pany, i.e. Ipca laboratory. The patenting activity is focused on new processes, new dosage forms and drug delivery systems.

There is a need for real prioritization of R&D and innovation activities by the government. The public sector companies and public sector laboratories have played a major role in augmenting the science and technology skills of the private sector industry. The discovery and development of new drugs are the result of a close collaboration between university and industry researchers. In this process, the public and private sectors pursue distinct but complementary objectives. Whereas the role of the public sector is centred on deepening our basic understanding of disease, that of the private sector is more focused on applied research aimed at converting this knowledge into effective treatments. Public research institutions play an important role in the system's positive evolution but they are dependent on the government policy and budget. The benefits that flow from public subsidies to university research can be reaped only once effective treatments have been developed – only the pharmaceutical industry is in the position to play this role.

Table 4 Public research pharmaceutical R&D institutes in India (Source: Authors' Compilation).

Institutes
National Institute of Pharmaceutical Education and Research (NIPER)
Indian Institute of Chemical Technology (IICT)
Centre for Cell & Molecular Biology (CCMB)
Indian Institute of Chemical Biology (IICB)
Indian Toxicology Research Institute (ITRI)
Institute of Genomic and Integrated Biology (IGIB)
National Institute of Immunology (NII)
Indian Institute of Science (IISc)
National centre for Biological Sciences (NCBS)
National Chemical Laboratory (NCL)
Institute of Microbial Technology (IMTECH)
Central Drug Research Institute (CDRI)
Regional Research Laboratories (RRL)

References

- Ali, A., Sinha, K. (2014): Emerging scenario of nanobiotechnology development in India, *European Academic Research*, 2 (2), pp. 1707-1727.
- Bhadoria, V., Bhajanka, A., Chakraborty, K., Mitra, P. (2012): India pharma 2020: Propelling access and acceptance, realizing true potential, McKinsey & Company.
- Business Standard (2014): *Success strategies for Indian pharma industry in an uncertain world*, available at <http://www.business-standard.com/>

- content/b2b-chemicals/success-strategies-for-indian-pharma-industry-in-an-uncertain-world-114021701557_1.html, accessed 5 July, 2014.
- Chakma, J., Gordon, H., Sun, M. D., Steinberg, J. D., Stephen, M. S., Jaggi, R. (2014): Asia's ascent: Global trends in biomedical R&D expenditures, *The New England Journal of Medicine*, **370** (1), pp. 3-6.
- DOP (2012): *Annual Report 2011-2012*, Department of Pharmaceuticals, Government of India, Ministry of Chemicals & Fertilizers, New Delhi.
- DOP (2013): *Annual report 2012-2013*, Department of Pharmaceuticals, Government of India, Ministry of Chemicals & Fertilizers, New Delhi.
- Gupta, I., Guin, P. (2010): Communicable diseases in the South-East Asia Region of the World Health Organization: Towards a more effective response, *Bulletin of the World Health Organization*, **88**, pp. 199-205.
- Hullmann, A. (2006): *The economic development of nanotechnology: An indicator based analysis*, European Commission Report, available at ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nanoarticle_hullmann_nov2006.pdf, accessed 2 July 2014.
- IBEF (2014a): *Healthcare industry in India*, India Brand Equity Foundation, available at <http://www.ibef.org/industry/healthcare-india.aspx>, accessed 13 July 2014.
- IBEF (2014b): *Pharmaceuticals*, Indian Brand Equity Foundation, available at www.ibef.org, accessed 11 July 2014.
- Kumar, B. R., Satish, S. M. (2007): *Growth Strategies of Indian Pharma Companies*, The Icfai University Press, Hyderabad.
- Maitra, A. (2000): Drug delivery: Today's scenario and opportunities for Indian pharmaceutical industry, *Current Science*, **79** (10).
- Mazumdar, M. (2013): *Performance of Pharmaceutical Companies in India: A Critical Analysis of industrial Structure, Firm Specific Resources, and Emerging Strategies*, Springer, Heidelberg.
- New Jersey Association for Biomedical Research (2014): *What is biomedical research?*, available at <http://biology.unm.edu/MARC/what-is-biomedical-research.html>, accessed 11 July 2014.
- NHSRC Report (2013): *Opportunities, ecosystem requirements and road-map to innovations in the health sector*, Draft Report of the Sector Innovation Council for Health, National Health System Resource Centre, Ministry of Health and Family Welfare, Government of India. New Delhi.
- OECD (2008): *Nanotechnology innovation: An overview*, Working party on Nanotechnology, Organization for Economic Cooperation and Development, available at <http://www.oecd.org/science/sci-tech/oecdworkingpartyonnanotechnology.htm>, accessed 2 July 2014.
- Pappachan, M. J. (2011): Increasing prevalence of lifestyle diseases: High time for action, *Indian Journal of Medical Research*, **134**, pp. 143-145.
- PWC (2010): *Capitalizing on India's Growth Potential*, Price Waterhouse Coopers Private Limited, available at <https://www.pwc.in/assets/pdfs/pharma/PwC-CII-pharma-Summit-Report-22Nov.pdf>, accessed 23 May 2015.
- PWC (2013): *Changing landscape of the Indian pharma industry*, Price Water Cooper India pharma Inc., available at <http://www.pwc.in/assets/pdfs/publications/2013/changing-landscape-of-the-indian-pharma-industry.pdf>, accessed 5 July 2014.
- Rakel, R. E. (2014): *Therapeutics medicine*, available at <http://www.britannica.com/EBchecked/topic/591185/therapeutics>, accessed 5 June 2014.
- Rao, D. Y. (2014): *R&D in pharmaceuticals sector*, Paper presented at the national conference on pharmaceutical policies in India: Balancing industrial and public health interests, March 7, 2014 at ISID Auditorium ISID Complex, New Delhi.
- Shah, B. N., Nayak, B. S., Jain, V. C., Shah, D. P. (2010): *Textbook of Pharmaceutical Industrial Management*, Reed Elsevier India Private Limited.
- UN News (2013): *World population projected to reach 9.6 billion by 2050*, available at http://www.un.org/apps/news/story.asp?NewsID=45165#.U7jb3_QW3CI, accessed 06 July 2014.
- WHO (2004): *Global burden of disease 2004 update: Selected figures and tables*, available at http://www.who.int/healthinfo/global_burden_disease/GBD2004ReportFigures.ppt#2, accessed 13 July 2014.
- WHO (2010): *Global status report on non-communicable diseases*, available at http://whqlibdoc.who.int/publications/2011/9789240686458_eng.pdf?ua=1, accessed 13 July 2014.
- WHO (2014a): *Ageing and life course*, available at <http://www.who.int/ageing/en>, accessed 12 July 2014.
- WHO (2014b): *WHO maps non-communicable disease trends in all countries*, available at http://www.who.int/mediacentre/news/releases/2011/NCDs_profiles_20110914/en, accessed 13 July 2014.
- Yin, R. K. (2003): *Case study research: Design and methods*, Sage Publications, USA.

Practitioner's Section

Managing risk during turnarounds and large capital projects: Experience from the chemical industry

Gert Müller*

* T.A. Cook & Partner Consultants GmbH, Leipziger Platz 1-2, 10117 Berlin, Germany
g.mueller@tacook.com

Large capital projects such as turnarounds and shutdowns require the management of a vast number of employees and tasks simultaneously. At chemical sites, where assets are highly complex, ensuring that risks are managed properly is of vital importance both to the safety of the workforce and the success of the project as a whole. Within the framework of turnarounds and shutdowns in the chemical industry, this article looks at the key aspects of risk and outlines how different tools can be used to overcome the challenges of risk management. Using practical experience gained onsite, the most risk-prone aspects in turnarounds as well as ways in which risk management tools can aid project success are highlighted.

1 Introduction

All business activities, regardless of the underlying sector, involve some element of risk. Whether the risk is operational or strategic, concerns market failures or environmental disasters, all business processes will at some point be exposed to risk. The term “risk management” therefore describes the attempt to identify, evaluate, measure, mitigate and monitor risks and their consequences – either on a particular project or on a business as a whole.

Within the context of capital-intensive industries, whose complex assets and processes often require highly technical skills and operational know-how, the perception of risk is often limited to health and safety rules and regulations. As such, when discussing risk management with managers at chemical sites, the first notion that tends to spring to mind is the way in which his or her team will be protected from accidents at work.

During large capital projects – such as turnarounds and shutdowns, where an entire section of a plant may be taken offline for scheduled repair or renewal – the sheer number of people needed to conduct work onsite means that managers' concerns over risks to team safety are valid. During such projects, companies are forced to engage contractors to ensure that the huge volume of work can be completed on time. These contractors are

often not familiar with site processes and systems including safety protocols and therefore could be considered to be at higher risk of accident or injury than those who work at the site all year round.

While undoubtedly a crucial factor, this viewpoint excludes a number of other risks at play. The vast number of tasks being carried out by multiple workers at any one time means that one particular action (or lack of it) could completely derail the schedule and have repercussions across the rest of the planned work for that day, week or even the whole project. Managers must understand that the risk of one single delay to the schedule could put pressure on some workers to complete their tasks in less time, as well as cause confusion as to what should occur, where and when. Tasks may either then not be conducted or be carried out in a hurried or unsafe manner, which could lower efficiency and impact the safety of all employees while onsite. If the potential impact of risks to the schedule on both health and productivity is not taken seriously by managers, it could have a disastrous effect on the success of the turnaround and ultimately, the bottom line.

With specific reference to the chemical industry, this paper will look at the key aspects of risk within the framework of turnarounds and large capital projects. The term “risk management” is therefore used in this context to refer to the process

of identifying, evaluating, measuring and mitigating risks to the turnaround before they occur. The risk of not achieving the project's defined objectives – such as cost, quality, duration and safety – on time or at all is therefore a chief concern.

Beginning by outlining some of the key problems turnaround managers have when attempting to manage risk, the paper will then examine the use of risk management tools in planning, scheduling and project execution as a means of addressing those challenges. Finally, it will make use of experience obtained while onsite at a chemical plant in France to evaluate the benefits and obstacles encountered during a turnaround risk review where such a risk management tool was used. The ways in which risk is addressed and handled within the industry will be outlined and critically assessed.

2 The problem with identifying and cataloging risk

While most managers understand that risk management is important and needs to be addressed, the way in which it should be approached and dealt with is often misunderstood on a number of levels. For example, a risk register listing risks, their causes and consequences is usually compiled before a project starts and includes anything and everything that could threaten the project. This could range from bad weather to unexpected repairs, missing parts or the absence of appropriately qualified personnel. This register is then filed away and seldom referred to again, if at all.

As each event has a unique set of requirements, some risks which were present at previous projects may have disappeared due to mitigation measures, some new risks may arise which were not relevant in the past, or the impact of existing risks may be greater under new circumstances. As a result, the register provides a good starting point from which to begin the risk management process, but if risk is treated as a static “problem” which does not change over time, it will only serve to give the entire team a false sense of security and will not actually help to safeguard the turnaround's success in any practical sense.

Part of the reason for this is the sheer scope of risk: there are often so many potential events and delays to a project as complex as a turnaround that even trying to identify and quantify those possibilities can seem extremely daunting. It is also perceived to be time consuming and expensive, so managers lean towards the “so far, so good” approach, where no new actions or processes are developed as those risks have not materialized in the past. It is therefore vital that the turnaround

manager understands that the process of evaluation cannot be a one-size-fits-all approach: As the nature of risk means that it changes over time and according to location, environment and circumstances, managers must learn to move away from the idea of it as a static obstacle which can be swiftly overcome with a few meetings and a hastily written report. Dealing with risk in an effective way means taking a dynamic approach to a constantly evolving situation, which in practice means that risks need to be continuously evaluated and measured at different stages of the project.

3 The difference between hazards and risks

The key to avoiding the above mentioned problems is to take an active approach to identifying all of the risks that could occur during the project. This means that the fundamental difference between a risk and a hazard must be understood – where a hazard is latent and only develops into a risk when it directly impacts a project. A good example of this is the weather: in regions where heavy rain can stop people from working, the rain only becomes a risk when measures such as temporary roofing have not been organized in advance by management.

The identification of risks should therefore begin much sooner than most managers realize, ideally at the same time the turnaround is being planned. The use of different tools which give the process some structure tend to aid the process, and usually begin with a risk register as mentioned above. Some teams begin with a brainstorming workshop to identify potential risks to the project, while others start with a list of common risks. Where possible, using risk registers from previous turnarounds to build a list of what could potentially occur within a new project is perhaps the easiest approach. While this provides a good foundation, it can be misleading. Only using the information from previous projects ignores problems that by pure chance did not occur in the past and lays the project open to delays or even failure.

One way of overcoming this is to begin with a non-project-specific risk register; from experience, there are approximately between 100 and 150 hazards that are applicable to most turnarounds. The hazards could range from the late delivery of materials to more banal items such as a lack of parking spaces and gates. When a site normally operates with 600 workers, accounting for the access of 3,000 during a turnaround is vital.

Managers should then evaluate which hazards are relevant to the project at hand and then divide them into themes which allow them to be more easily dealt with. The nine themes to which hazards are typically assigned to include: 1. Scope, 2.

Organization, 3. Management, 4. Work planning, 5. Capex involvement, 6. Scheduling, 7. Purchasing and sourcing, 8. Environment, safety, health and quality and 9. Execution.

4 Using a risk matrix to evaluate risk severity

This is where many managers stumble, primarily because the process of risk assessment is by nature rather subjective. What is viewed as highly dangerous to one manager might seem only moderately dangerous to another. It is therefore important that the different tools discussed below are created and evaluated by a team involving not just the turnaround manager, but also managers from production, maintenance and operations who all agree on the threat level and try to give as much detail to the definitions as possible. That way, a more balanced and concrete assessment will be conducted, the results of which will be far more helpful to the turnaround manager during execution.

Once the risk register has been agreed, the most straightforward way of evaluating the severity of the risks listed in it is to apply a matrix to each one. On one side of the table, the probability of occurrence is measured against the impact on the project. On the other, the severity is assessed. When looking at figure 1, on the left hand side of the table, the severity of the impact of a particular risk is clearly defined across a number of different fields, from health, safety and environmental to media attention and financial impact. This is then measured on a scale from one to four, where one is severe and four is significant. Consequently, if a risk evaluation team considers a risk to have the potential to cause serious injury, could be reported by local news stations and has a 50% probability of occurring, it would be in the 2C category. However, if the probability of a risk occurring is high – such as between 90 and 100% – and it carries equally high human and financial costs, it would be classified as 1A and require immediate action.

This evaluation is necessary for all of the risks on the risk register and can then be used to prioritize the risks at hand in a structured and coordinated fashion. If a risk is agreed to be in the bottom right, dark green corner, mitigating actions are not necessary, whereas risks classified in the orange, red or dark red areas would need imminent or even immediate attention.

5 Preventing risks from occurring: The bow tie model

Understanding probability and the severity of risk is only half of the process. Countermeasures which prevent that risk from occurring must be defined and acted upon. The bow tie model (figure 2) is another tool which can be helpful to managers in the visualization of how the approach to risk should be structured.

On the left hand side, the hazard is described along with “barriers” which can be put in place to stop the hazard becoming a risk. In the middle, the risk is clearly defined and on the right, the consequences and countermeasures are noted – what some might call a “plan B”. To refer back to the original example of poor weather as a hazard, a typical barrier would involve putting temporary tents in place so that, should heavy rain occur, work can continue without interruption. Another barrier example would be to have a contractor on standby should another contractor not be available or is too slow. Most of the time, relatively simple, mundane things go wrong and therefore, taking the time to address even the most minor risks at an early stage can save significant time, energy and money in the future.

Once these steps have been taken, planners can then work together with maintenance and production to ensure that the most important, dangerous tasks are attended to first and action is taken to prevent them from occurring. Repairs and their actions must be written into a system which records their status as well as the nature and date of preventive action. Once that action has been taken, risks can then be reclassified to assess their criticality.

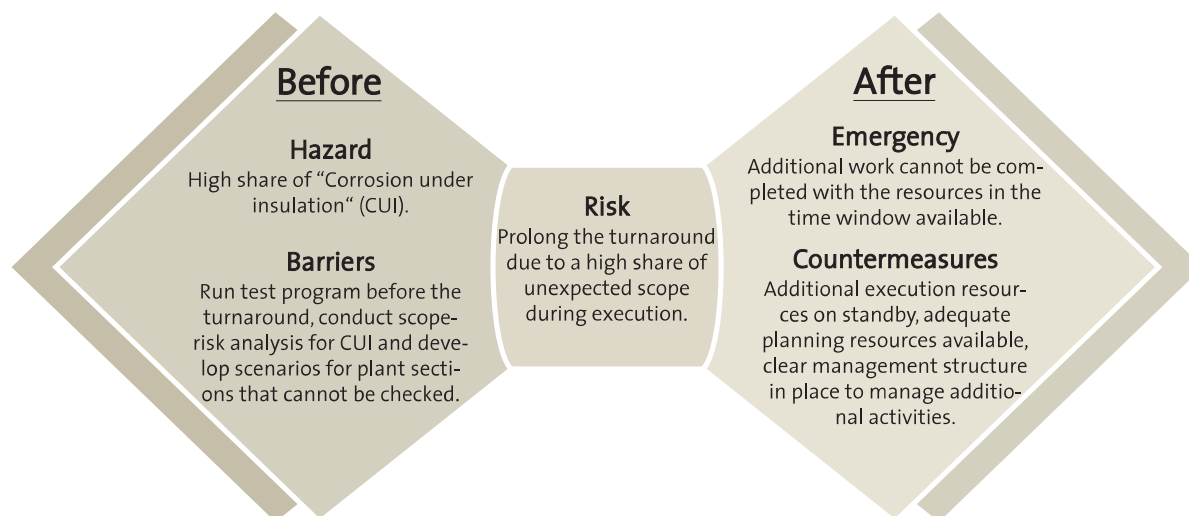
The key to the success of using this model lies in the consistent assessment of risk on a regular basis, which is where the use of risk management tools can be helpful. Beginning with the bow tie model, the onsite team or external risk experts can use detailed questions and answers to establish how critical the impact of a risk would be, usually placing it on a scale of one to five. The risk exposure index (REI) in figure 3 below is an example of this in practice, where the impacts of a documented risk on quality, costs, environment, safety and health and duration are plotted on a graph to show exactly the level of urgency with which preventive measures are needed.

Where the risk matrix helps to highlight the severity of risk – that is, the consequences the occurrence of a risk would have on health, safety, environment and business impact – the REI provides guidance as to the urgency with which a particular risk should be tackled in the function of time

Figure 1 An example of a risk matrix. The consequences are measured against the probability of a risk occurring.

Consequences						Probability				
						90-100%	60-90%	40-60%	10-40%	0-10%
						A	B	C	D	E
Severity	Health/ safety	Environ- mental	Media attention/ action by authorities	Business impact	Turnaround specific	Possibility of repeated incidents	Possibility of isolated incidents	Possibility of occurring sometime	Not likely to occur	Practically impossible
1 (Severe)	Fatality(ies); serious inju- ry requiring medical treatment to members of public	Potential widespread, long term, sig- nificant adver- se effects; sustained complaints	Significant public disruption; national or international media coverage	Corporate > \$2M	Extends turnaround duration > 2 days	1A	1B	1C	1D	1E
2 (Major)	Serious or lost time injury/ illness	Potential localized, medium term, signifi- cant adverse effects; numerous complaints	Small public disruption; extended local media coverage	Business \$500K-\$2M	Extends turnaround duration < 2 days	2A	2B	2C	2D	2E
3 (Serious)	Restricted work or medical treatment	Potential short term, minor adver- se effects; public complaints	One time local media coverage	Site \$100K-\$500K	Extends unit critical path	3A	3B	3C	3D	3E
4 (Signi- ficant)	First aid/ minor injury	Negligible or no adver- se effects	No media coverage	Other < \$100K	No impact to unit critical path	4A	4B	4C	4D	4E

Figure 2 The bow tie model is used to highlight the hazards, barriers, emergency and contingency measures should a hazard develop into a risk.



remaining, i.e. the criticality of a risk. Understanding the difference between severity and criticality of risk is vital to making pragmatic decisions in the context of a turnaround. The team is in a constant race against the clock, both in terms of the start date and the duration of the whole project. This may mean that, paradoxically, a risk of moderate severity (in terms of potential consequences) might be highly critical because mitigation measures have a throughput time that may not fit into the remaining turnaround duration. For example, the acquisition of spare parts is important for the production process, but working on that process may not be difficult, nor expensive, nor pose health, safety or environment issues. However, obtaining the part, which may have to be manufactured or imported from the Far East, will take 10 weeks with only eleven weeks remaining on the clock. It is therefore critical that the action is taken forthwith, even if the consequences of the risk as such would not rate "severe".

The REI can further be used along with different mathematical models to create a risk threat potential (RTP), which gives a snapshot calculation of impending additional costs. The example in figure 4 is taken from a project where the REI was used to estimate the impact of a risk on days of production lost. The risk was judged to have the potential to increase turnaround duration beyond what was agreed and required action, meaning that the supplemental production loss would have translated into non-generation of revenue. Based on the different cost and price information provided by the client, the figure of € 5.23 million there-

fore represents a time, site and product mix which is specific to a particular market and economic situation.

Typically, addressing a clearly identified and correctly weighted risk could entail providing supplementary resources in order to reduce the throughput time of an at-risk activity. When the financial exposure that not dealing with a risk is known, the decision process is lifted out of the emotional phase and the cost of mitigation measures can be compared to the impact that doing nothing may have on the bottom line. For example, when the activities that will be carried out during a turnaround are known to produce a given quantity of effluent over a given period, this can be set off against the available treatment capacity. Any shortfall can be identified up front and countered beforehand, either by modifying the pattern of activities to alter the outflow or by bringing in temporary treatment or storage capacity or by moving untreated effluent off-site, or a combination of these.

6 Managing schedule risk

As seen, the process of addressing continuously changing risks can be aided and structured by the use of different tools to clarify and quantify the potential impact that risks can have on a project. When it comes to ensuring that tasks are done in a timely, efficient manner and in a way that balances minimum downtime with realistic time allowance for the work to be executed, the turnaround schedule is a particular source of concern to many managers, mainly because one single day

Figure 3 A risk exposure index shows the impact of a documented risk on the quality, costs, environment, health and duration of a project.



Figure 4 The risk exposure index (REI) is used to create a risk threat potential (RTP) which shows the impact of a particular risk on the whole turnaround in Euro.



leads to significant loss in production and hence profit margin. The schedule quickly becomes redundant if it is not kept up to date and viewed as a static document which does not change over time. As with project risk management, the schedule itself must be treated as a dynamic tool which aids and structures execution. Thus, the potential impact that risks have on a schedule must also be treated in a dynamic fashion.

A tool that helps address this aspect of risk - on the schedule as separate from the project as a whole - is applying Monte Carlo simulation, which utilizes algorithms to evaluate and quantify time and cost risks. By working through all project scenarios and analyzing various types of recorded risks, the simulation works out the potential impact of the combined schedule risks giving planners concrete information regarding the likelihood of meeting deadlines and the project end date. For example, a particular risk to the schedule could produce the outcome that the probability of reaching the project end date would be only 20% and take an extra five days to achieve the target probability of 80%.

As the simulation uses mathematical data, the quality of the results is dependent on the quality of the input data. The more accurate the timeline and information for expected completion times for tasks entered into the system, the more accurate the results will be. Often, this information is not on hand and needs to be requested from on-site experts, but the effort to obtain detailed information is worth making as the simulation then allows managers to link up work packages in a dynamic plan and assess how much the end date will shift according to different changes to the schedule. As a result, planners can adjust schedules on a continuous basis and are able to react to situations as they occur with a better understanding of the impact of their decisions on the project as a whole.

7 Risk management in practice

7.1 A case study applying tools in a turnaround project

Risk management tools such as those mentioned above were recently used during a turn-

around review at a chemical plant in France. The onsite team was aware of the need to address the potential risks to the project but did not have the internal resources available to properly address the issue. As such, a structured questionnaire was conducted with key personnel at the site using questions which are specifically designed to elicit the appropriate information concerning turnarounds.

Ranging from broad asset management strategy to how work permits would be managed during execution, approximately 90 questions were asked and answers rated from one to five, with five being the best. Although certain topics such as the language skills of contractor personnel, the state of plant documentation and the organizational set-up of the turnaround team have demonstrated a particularly high level of risk-sensitivity, the questions were structured in such a way that those topics did not disproportionately dominate the answers in order to gain as realistic a picture as possible.

In order to counteract the subjectivity of the assessment from both sides, model answers to the questionnaire had already been defined. For example, one answer read “80% of the work for the upcoming turnaround has already been carried out in the past by the same contractor” which would rate a 4 on the scale. This means that the process is weighted heavily towards a fact-based assessment and less prone to the interpretation of the interviewee.

Once all scores were gathered, they were then weighted with regard to how much time was remaining before execution in order to get an indication of prioritization. As a result, a clear list of the most risk-prone aspects of the project was produced which was then used along with the value of a day's worth of production to calculate the potential financial exposure created should a particular risk occur. Following this process, the management team was able to fully understand both the potential impact of risk on the project as well as the importance of addressing it as early as possible.

7.2 The most risk-prone aspects of turnarounds

In practice, one of the single most frequent topics that poses the greatest risk to turnarounds is the lateness of the availability of actionable information. Most companies carry out major projects on their sites continuously, which may concern civil engineering/construction (e.g. building or demolishing structures or roads, resurfacing roads), utilities (e.g. (re)laying or removing water or sewer conduits, power lines or working on electrical substations, wastewater treatment lines, sometimes even product supply lines), or engineering (e.g. intro-

ducing new technology, modifying or expanding the production environment). Most of this work is of no concern to the turnaround, but parts of it will have an impact, either in terms of actual interaction, i.e. the equipment affected by the turnaround changes, or as interference, i.e. by blocking roads, by interrupting power supplies or by putting a crane in the middle of the area where the turnaround is supposed to take place. Often, a small amount of vague information is provided regarding these other projects but the precise detail of what will happen and when is only communicated very late in the day (or not at all), leaving the turnaround team to suddenly realize that a lot of the assumptions they have worked with are not valid.

Another frequently-observed risk is the scope never reaching freezing point. The theory states that more than a year before the planned start of the turnaround, all possible items should have been selected, challenged and rejected or confirmed, in order to allow planning to move forward. A major part of the turnaround scope is inspection work that is mandated by the government and that cannot be done at any other time, for example, entering into a production vessel to check it for wear and tear. This is normally well-defined on a multi-year calendar. In theory, including all of this work in the scope should be feasible well before the start date, but in practice, it rarely is. Teams often find that even legal inspections can surface quite suddenly and late in the day.

Furthermore, cultural problems - whereby the senior management does not enforce the “scope freeze” practice and allows the late addition of major jobs - can create risks. Failing to restrict the amount of tasks to be included in the turnaround, is a risk in several aspects, e.g. regarding the identification of the resources needed both in terms of numbers and of trades, the selection and contracting of third parties to provide these resources, the definition of what needs to be procured in terms of materials and equipment (if a major vessel or piece of plant needs to be replaced it may take a year or more for it to be fabricated, quality checked and brought to the site), the reservation of cranes and special tools, and so on. As chemical plants are often clustered and they all conduct turnarounds, even getting the right people in sufficient numbers can be quite a challenge.

A final example of a “typical” risk is the organization and management of the actual turnaround execution. An unusually large number of people, many of whom may never have been on site, need to get work permits and access the equipment for the specific job they are scheduled to carry out at a particular time. They are also required to deliver quality work (“first time right”), be able to get onto

and off the site, and need a place to eat and wash. As the client organization is ultimately responsible for this, steps need to be taken to manage the extra workforce and its needs. This requires preparation months in advance as well as a high level of qualified personnel which is often underestimated and may have adverse consequences. Firstly, in view of the limited amount of time of the turnaround window, any delay has knock-on effects. Secondly, when things turn out to have been done substandard on start-up, it may mean the whole plant has to be taken down again and start again from scratch.

8 Conclusion

The use of risk management tools to evaluate risk is in no way a new concept, but the way in which they are used often restricts their impact. As turnarounds and large capital projects involve so many variables and are constantly changing, it is vital that managers overcome the idea of risk as a static obstacle and understand that in order to address it properly in this context, a dynamic approach must be used. This means that the tools created to aid risk identification and mitigation must be used on a continuous basis and applied to planning and scheduling processes as the event continues.

Part of the problem with risk management as a whole is that many people have great difficulty understanding the very concept of probability and tend to rate the risk of something spectacular occurring far higher than of something mundane. As a result, risk evaluation processes tend to focus on extreme risks and preventive measures and ignore the risk of rather more “standard” risks occurring. This can give managers a false sense of security during execution and expose the project and the team to very real dangers. As a result, really understanding the probability of risks occurring and being able to evaluate both their severity and criticality requires a good degree of experience and judgement.

Within the industry, more must be done to improve the understanding of and definition of risk. Companies should be prepared to commit both time and money to in-depth risk evaluation and to ensuring that managers are fully aware of what risk actually means in practice. When such large numbers of workers are involved and the volume of product and money at stake are vast, getting risk management right is not beneficial, but an absolute necessity.

Instructions to authors

In the following we want to present important instructions to authors.

More information can be found on the internet at www.businesschemistry.org. If you should have any further questions, please do not hesitate to contact us at info@businesschemistry.org.

The Journal of Business Chemistry publishes original, refereed material on all aspects of business chemistry. It is devoted to presenting theories and practices of management and leadership in the chemical industry and is designed to appeal to practicing managers and academics.

Manuscripts may be submitted for consideration as research papers, papers for the practitioner's section or as commentaries. All submitted research manuscripts have to contain original research not previously published and not under consideration for publication elsewhere. As it is an international journal, all papers must be written in English.

Authors are required to submit manuscripts via e-mail (submit@businesschemistry.org).

The text needs to be sent in MS Word or rich text-format and needs to include the following:

- contact information of the submitting author (to whom all correspondence regarding the manuscript, including proofs, will be sent)
- information about the other authors (addresses, current positions etc.).

Organization of the manuscript

- Abbreviations should be defined.
- Although the guidelines are flexible, especially for case studies, the manuscript should be arranged in the following order:
 - a) Title, author(s), and complete name(s) of institution(s)
 - b) Abstract
 - c) Introduction
 - d) Methods
 - e) Results
 - f) Discussion
 - g) References

Title page

- List the names of all authors and their complete mailing addresses
- Identify author to whom all correspondence should be sent

References and footnotes

- Citations in the text contain only author's name and date of publication; e.g. (Leker, 2001).
- Full references have to be included at the end of the paper in alphabetical order using the style presented on the internet at www.businesschemistry.org.
- Footnotes should not be used for citation, but can be used for additional notes and explanations.

Authors are fully responsible for the accuracy of their references.

Tables and figures

Tables should be numbered consecutively, have titles and sufficient empirical detail in a legend immediately following the title. Each column in a table is required to have a heading; abbreviations should be defined in the legend.

Figures should have titles and explanatory legends containing sufficient details to make the figure easily understandable. Numbers, letters and symbols used have to be sized appropriately. The abscissa and ordinate should be labelled clearly.

Figures and tables should be sent as separate jpg.-files and MS Excel files respectively.

All tables and figures should be placed at the end, not included within the text, but have their intended position clearly indicated, e.g.: (figure 1 here).

Comments

If you have any comments on articles of the previous issue you are welcome to send them to us as a separate submission. The comments are revised only by an Executive Editor and might be published in the next issue if they suit the academic discussion.

Thank you for your contribution!

