

Corporate Responsibility



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Responsibility in business

An integral part of the way Shire works.

It comes as no surprise that Shire has always been committed to managing its business in a responsible way. Any pharmaceutical company—and especially one that aims to enable people with life-altering conditions to lead better lives—will always be aware of its wider social and ethical responsibilities. In this respect Shire is no different. Shire is different, though, in the depth and breadth of that commitment. The idea of ‘responsibility’ runs through everything Shire does, from its distinctive culture, to day-to-day decision-making, to its long-term strategic goals.

2009 was something of a landmark year for Corporate Responsibility (‘CR’) at Shire. The Company is proud of the way it’s grown and evolved its approach to CR over the last nine years, but it’s never been complacent. The aim has always been to make CR an integral part of the way Shire does business, and considerable progress had already been made. But when Tatjana May took over as head of the Shire Corporate Responsibility Committee in July 2008, one of the first and most important changes she made was to rename that team.

Informal discussions and feedback from employees had started to suggest that some staff felt that anything managed by a committee with the word ‘Corporate’ in the title was the preserve of management, rather than something directly relevant to their own jobs. As Jessica Mann, Senior Vice President of Global Corporate Communications, says, “This was despite the fact that the work many of them were doing was an excellent

example of Corporate Responsibility in practice every day, even if they weren’t thinking about it in that way.” So the change in emphasis and focus that’s now underway was initially prompted by the need to shift perceptions internally. Within Shire, ‘Corporate Responsibility’ has now become simply ‘Responsibility’, and the formal committee has been re-named the ‘Responsibility Co-ordination Team’.

The next stage of the change related to the Company’s 2015 ambition to be the most valuable specialty biopharmaceutical company in the world. As the diagram³ shows, making this happen in practice is going to depend not just on what Shire does, but how it does it. This insight has led to a major change in focus for Responsibility at Shire, and one that aligns these principles even more closely with the Company’s commercial goals and way of working.

A new focus

Shire is now organising its Responsibility efforts behind 13 focus areas, all of them directly related to the way Shire is run, the kind of business it is, and the way it manages its relationships with external and internal stakeholders.

Each member of the co-ordination team is now acting as sponsor for one of these areas. And it is very much ‘sponsorship’, rather than management or supervision. Each area has its own champions within the business, and the main role of the

OUR 2015 GOAL

We will be the most valuable specialty biopharmaceutical company in the world.

We'll attain the number one or number two position in each of our chosen therapeutic areas.

We'll grow sales by mid-teens year-on-year on average between 2009–2015.

And we'll have 50% of our sales coming from outside the US and 25% from outside the US, Germany, Italy, Spain, UK, France, and Canada.

We'll do this by

Nurturing and **strengthening our brave and collaborative culture**, which differentiates us from 'Big Pharma' and allows all our people to impact and shape our business.

Encouraging trust and openness in tackling business challenges.

Avoiding complacency and fostering innovation by taking measured risks and actively experimenting.

Learning from both success and failure, and moving opportunistically into areas that grow our business.

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RESPONSIBILITY FOCUS AREAS

BE RESPONSIBLE	PRODUCT SAFETY AND PHARMACOVIGILANCE	ETHICAL SALES AND MARKETING	PEOPLE ENGAGEMENT
STEWARDSHIP OF PARTNERS AND SUPPLIERS	OCCUPATIONAL HEALTH & SAFETY	CONDUCT AND TRANSPARENCY OF CLINICAL TRIALS	ENVIRONMENTAL IMPACT OF OPERATIONS AND ENVIRONMENTAL STEWARDSHIP
PUBLIC/PATIENT EDUCATION ON ADHD (ROW)	GEOGRAPHICAL EXPANSION	MANAGEMENT OF M&A	ACCESS TO MEDICINES
BIOETHICS AND ANIMAL TESTING	PUBLIC POLICY		

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- 1 Shire continued its support of Kids Company throughout 2009
- 2 Shire's Project Playground opens in the Feltonville neighborhood in Philadelphia
- 3 Our 2015 goal
- 4 Responsibility Focus Areas

co-ordination team member is to keep a watching brief on developments, and make sure that new ideas and success stories are shared more widely across the whole company. They can also offer advice and support if that's helpful, and provide a third-party sounding board on any new developments or emerging issues in that field.

As the diagram⁴ shows, some of Shire's 13 focus areas are now common CR priorities for any major business, like Health & Safety, People, and Environmental Stewardship; while others relate directly to the special challenges and responsibilities of a major drugs company, such as Product Safety, Bioethics, and Ethical Sales and Marketing. Some of the 13, however, are not necessarily what you'd expect to see in a more conventional list of CR objectives, but these cover key areas that will be instrumental in making Shire's long-term goals a reality.

The focus for 2010 and beyond will be on four of these areas in particular. That's not to say the others are less important, but the four that are being emphasized this year are either newer issues for Shire, or ones that are especially crucial to the 2015 goals. The first of these is geographical expansion.

Responsible international growth

Shire's international presence has increased substantially over the last few years and the next phase of growth will take this to a whole new level. The Company is going to have to find a way of doing this in a way that doesn't just make commercial sense, but respects both international best practice and local customs. As Caroline West, Responsibility Co-ordination Team member says, "It's about finding a balance between having our own global standards, and giving our local operations the flexibility to run their businesses in the best way for their own market, while of course, assuring that we are in compliance with local and internationally applicable laws. Our challenge is to provide the right framework to support our business goals."

Responsible expansion overseas is also about being aware of the possible pitfalls of entering a new market. Shire has an active and experienced New Market Development team, who ensure that a thorough due diligence process is completed for each prospective new market. This involves a co-ordinated effort by a whole range of internal teams, from Finance and Legal, to Commercial, Manufacturing and Distribution, Medical Affairs, Regulatory, and Pharmacovigilance. It's crucial to understand the risks and challenges the company might face in a new region, especially in emerging markets, where business practices can vary quite widely. Even in developed markets the regulatory framework can be very different, even in neighboring countries.

Corporate Responsibility



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Responsibility in business

Each will have its own anti-trade and anti-monopoly rules, its own anti-corruption regulations, its own employment laws and pricing controls. As Ann Brady, VP of New Market Development, says, “We could see a very real opportunity in a market but discover that there are too few protections of our intellectual property. We could hear from patients that we want to be able to treat, but find ourselves impeded by the current national infrastructure or cultural norms. Whatever steps we or our partners take on Shire’s behalf reflect on our reputation, and impact our company as a whole. We cannot be too careful.”

Understanding the issues around access to medicines

Media and public discussion of access to medicines tends to concentrate almost exclusively on the provision of low-cost drugs to people in developing countries, especially antiretrovirals for those suffering from AIDS in Africa. Shire played its part in sub-Saharan Africa by agreeing in 2009 to permit GlaxoSmithKline (‘GSK’) to enter into royalty-free voluntary sub-licenses in sub-Saharan Africa with generic manufacturers to make and sell AIDS antiretrovirals. However, more generally for a business like Shire operating in the specialty pharma and orphan diseases sector, there are broader issues involved.

The drugs developed by Shire’s HGT division are used to treat rare conditions, many of which affect small children, and most of which are life-threatening. In many cases there is no other treatment available, so even announcing the early-stage

development of a new therapy sets up expectations for patients and families who have no other hope. Some of these people will be able to participate in the clinical trials phase, but it’s never possible to involve all those who desperately want the chance to take part, so the challenge for a business like Shire is to ensure these trials are recruited and conducted in an ethical manner, in line with good industry practice, and with absolute integrity. And, of course, that access to treatment is carefully considered at the most appropriate moment along the pathway of development of new medicines.

A more sustainable supply chain

Some of the issues raised by Shire’s geographical expansion are directly relevant here as well. Shire is not a ‘fully integrated pharmaceutical company’ like some of the Big Pharma businesses. Its success has been built on a business model in which activities like distribution and manufacture are out-sourced, unless there is real value or competitive advantage from keeping them in-house. While this can bring distinct benefits, relationships with third-party contractors and suppliers need to be managed very carefully, so that Shire’s standards can be maintained. “As Shire expands, the number of these relationships is only going to grow,” says Susan Gavigan, Responsibility Co-ordination Team member, “and will cover everything from contractors carrying out drug testing and trials, to in-licensing partners, to small biotechs and academic departments working in collaboration with us on the development of new molecules.”



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- 1 Shire@Work global employee engagement survey administered by Gallup, in which 91% of employees participated in 2009.
- 2 Students from the University of Minnesota, Carlson School of Management, visit members of Shire's Responsibility Co-ordination Team to learn more about CR in the corporate environment, as part of their European fact finding tour.
- 3 Shire UK sponsored Action on Addiction, helping to provide their M-PACT counselors with a manual for their work with families.
- 4 Shire Massachusetts's employees helping Crittenton Women's Union.

Shire has already run a number of successful supplier conferences in the UK and US, and established a supplier audit program. 35 separate audits were carried out in 2009, but this will need to expand to keep pace with the Company's growth, and will also need to take into account specific risks relating to social, ethical, and environmental performance.

Promoting a better understanding of ADHD

ADHD is one of those conditions that is well-understood in some parts of the world, but poorly-diagnosed, and misunderstood, in others. After many years as the US leader in ADHD treatment, Shire has a detailed knowledge of this challenging and often traumatic condition, which affects not just the young person dealing with it, but their whole family. Likewise, it's only relatively recently become clear how many adults still suffer from symptoms that were traditionally assumed to disappear with adolescence.

More and more markets outside North America are becoming aware of the real prevalence of ADHD, and the various options available to manage it, and this is opening up a significant opportunity for Shire's range of ADHD therapies. But this opportunity needs to be managed in a sensitive and appropriate way, which is why Shire is investing so much time and resource into physician and patient education. A good example is the ADHD Awareness Week run in September 2009, which involved live web-chats with acknowledged experts in the condition.

Next steps

The way forward for Responsibility at Shire is now very clear; the challenge now is to find a robust way of setting milestones and measuring progress.

As Jessica Mann says, "Making Responsibility an even more integral part of the way we work is clearly the right approach, but it does make it slightly harder to define specific Responsibility goals. The co-ordination team is now working to establish short-term objectives for 2010–11, and longer-term aims out to 2015."