



# **Biodiversity and ecosystem services**

Risk and opportunity analysis within the  
pharmaceutical sector

May 2011

A briefing prepared by KPMG Sustainability and the  
Natural Value Initiative, modified from a report that  
was prepared on behalf of Robeco Asset Management.



## About the Natural Value Initiative (NVI)

The NVI is a collaboration between Fauna & Flora International, the United Nations Environment Programme Finance Initiative (UNEP FI), Nyenrode Business University, the Dutch Association of Investors for Sustainable Development (VBDO) and the Brazilian Business School Fundação Getulio Vargas (FGV). The Natural Value Initiative has four broad objectives, to:

- Build awareness of corporate dependence on ecosystem services and impact on biodiversity and the links to corporate risk;
- Build expertise both in companies and investors on evaluating and managing biodiversity and ecosystem services (BES) risks and opportunities;
- Stimulate improved performance within the private sector and encourage greater reward of responsible behaviour;
- Mainstream biodiversity and ecosystem services into investment analysis.

<http://www.fauna-flora.org/initiatives/nvi>



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# 1. Executive summary

We are experiencing unprecedented rates of biodiversity loss. Sixty percent of the ecosystem services (such as freshwater, fisheries, pollination and climate regulation) which biodiversity underpins are either degraded or in decline<sup>1</sup>. Predictions are that this trend will worsen. It is clear that this has severe economic implications, not only for society but also for business as most industries depend on ecosystem services to function.

The pharmaceutical sector is both dependent on and impacts on biodiversity and ecosystem services, or BES. Approximately twenty five to fifty percent of the pharmaceutical market is derived from active ingredients from nature<sup>2</sup>.

The sector's dependence on BES stems from the use of active ingredients from nature in drug discovery and manufacture, the use of water and a reliance on inert raw materials such as fish oils, soya and palm oil in drug manufacture. Impacts include water pollution from drug manufacturing and use, overexploitation of active ingredients from nature that cannot be readily synthesised and the use of inert ingredients linked with environmental degradation.

**“ All companies reviewed have started to consider the business implications of declining biodiversity and ecosystem services (BES). However, none are managing BES in a comprehensive manner ”**

For the pharmaceutical sector, this may pose reputational, operational, regulatory and market risks as well as new opportunities linked to new drug discovery. Pharmaceutical industry investors may also face reputational and financial risks if the companies in which they invest do not adequately manage their own BES risks.

Robeco, the Dutch asset manager, undertakes a broad programme of engagement on environmental and social issues that are deemed to pose a risk to their investments. In 2010, Robeco identified BES management within the pharmaceutical industry as a potential area of risk and commissioned KPMG Sustainability and the Natural Value Initiative to examine how the pharmaceutical industry is addressing its BES risks. We evaluated ten companies using the Ecosystem Services Benchmark, which was developed by the Natural Value Initiative in conjunction with a range of BES experts and stakeholders and adapted for application to this sector.

**Pharmaceutical companies evaluated:**

- Astra Zeneca
- Bayer
- Bristol-Myers Squibb
- GlaxoSmithKline
- Johnson & Johnson
- Novartis
- Novo Nordisk
- Pfizer
- Roche
- Sanofi

All companies reviewed have started to consider the business implications of declining BES. However, none are managing BES in a comprehensive manner. The focus of corporate activity has been on understanding site-level impacts on biodiversity such as risks associated with potential impacts on protected areas or water consumption and on ensuring adequate controls over the sourcing of active ingredients from nature. Significant sourcing of active ingredients from nature is no longer commonplace in the industry; only two of the companies reviewed were undertaking bioprospecting in any substantial way. Less attention has been paid by the industry to impacts and dependence on BES throughout the supply chain related to inert materials.

The level of risk that this issue poses to the sector is not currently clear, particularly in relation to dependence on BES within the supply chain. A first step in better understanding this risk is for pharmaceutical companies to assess their dependencies and impacts on BES throughout their supply chains, and to disclose their impacts. The companies that are already doing this have identified a number of risks that they are now taking steps to manage.



Rebecca Foges, FFI

## 2. Trends in biodiversity and ecosystem services

### Defining biodiversity and ecosystem services<sup>3</sup>

**Biodiversity** is the variability among living organisms, including diversity within species, between species and of ecosystems.

**Ecosystem** services are the benefits that people receive from ecosystems and can be divided into three broad areas:

- **Provisioning services** - Goods or products obtained from ecosystems such as food, freshwater, timber and fibre;
- **Regulating services** - Benefits obtained from natural processes such as climate, disease, erosion, water flows and pollination, as well as protection from natural hazards;
- **Cultural services** - Non-material benefits obtained from ecosystems, such as recreation, spiritual values and aesthetic enjoyment.

Biodiversity is crucial for healthy ecosystem services.

The past 50 years have shown a significant shift in population, consumption patterns and natural resource extraction by human beings, resulting in the unprecedented decline in biodiversity and ecosystem services. The rate of species loss in recent decades is 100 - 1,000 times faster than the natural rate and sixty percent of the ecosystem services on which we as a society rely are degraded or in decline<sup>4</sup>. The Economics of Ecosystems and Biodiversity (TEEB) review estimated the economic implications of these trends to be in the region of US\$ 2 to US \$4.5 trillion in 2008 (3.3 – 7.5 percent of global gross domestic product or GDP)<sup>5</sup>. In addition, the World Economic Forum (WEF) placed biodiversity at the nexus of a wide range of global risks including food security, water management, poverty alleviation and climate change (see Figure 1).

**Figure 1: Links between BES and other sustainability issues<sup>6</sup>**

**Food security:** Climate change, land degradation, cropland losses, water scarcity and species infestations may cause projected yields to be 5 to 25 percent short of demand by 2050. BES – and in particular – genetic diversity can act as an insurance policy against disease and climate change which modern cultivars do not offer.

**Water management:** Biodiversity plays a role in ensuring that water is present in the right quantity or quality for business and society as a whole. The role that the Pantanal wetland system in Brazil, for example, plays in water purification and supply is estimated to have an economic value of US\$ 6.3 billion per year.

**Biodiversity**

**Poverty alleviation:** Loss of BES is expected to hamper efforts to meet the Millennium Development Goals – especially those related to poverty, hunger and health – by increasing the vulnerability of the poor. BES play a key role in ensuring sustainable livelihoods, such as forest products and provide roughly a fifth of poor rural families' 'income'.

**Climate change:** Global climate policy now makes provision for the reduction of emissions from deforestation and degradation (REDD), recognising the role that land use change plays in maintaining the climate. Ecological infrastructure such as forests, mangroves, river basins and wetlands offers significant potential to enable adaptation of both industry and vulnerable communities to climate change.

## What this means for business

The TEEB for Business report concluded that all businesses rely directly or indirectly on biodiversity and ecosystem services. In other words, the loss of BES has important implications for the long- – and in some cases – short-term viability of businesses dependent on them. Furthermore, the World Economic Forum in its global review of risk concluded that the consequences of the loss of BES will affect the growth objectives of most industry sectors in the developed and developing world. A recent survey of over 1,000 companies by McKinsey found that although climate change, pollution, and water scarcity remain top concerns, biodiversity loss is a major emerging issue for business, occupying a similar position in the public debate as did climate change in 2007<sup>7</sup>.

**“ The consequences of the loss of BES will affect the growth objectives of most industry sectors in the developed and developing world ”**



Nicky Jenner, FFI

### 3

## The relevance of BES for pharmaceutical companies

### Defining dependency and impact<sup>8</sup>

A company **depends** on an ecosystem service if that service is an input or if it enables, enhances, or influences environmental conditions required for successful corporate performance and if that input cannot be substituted.

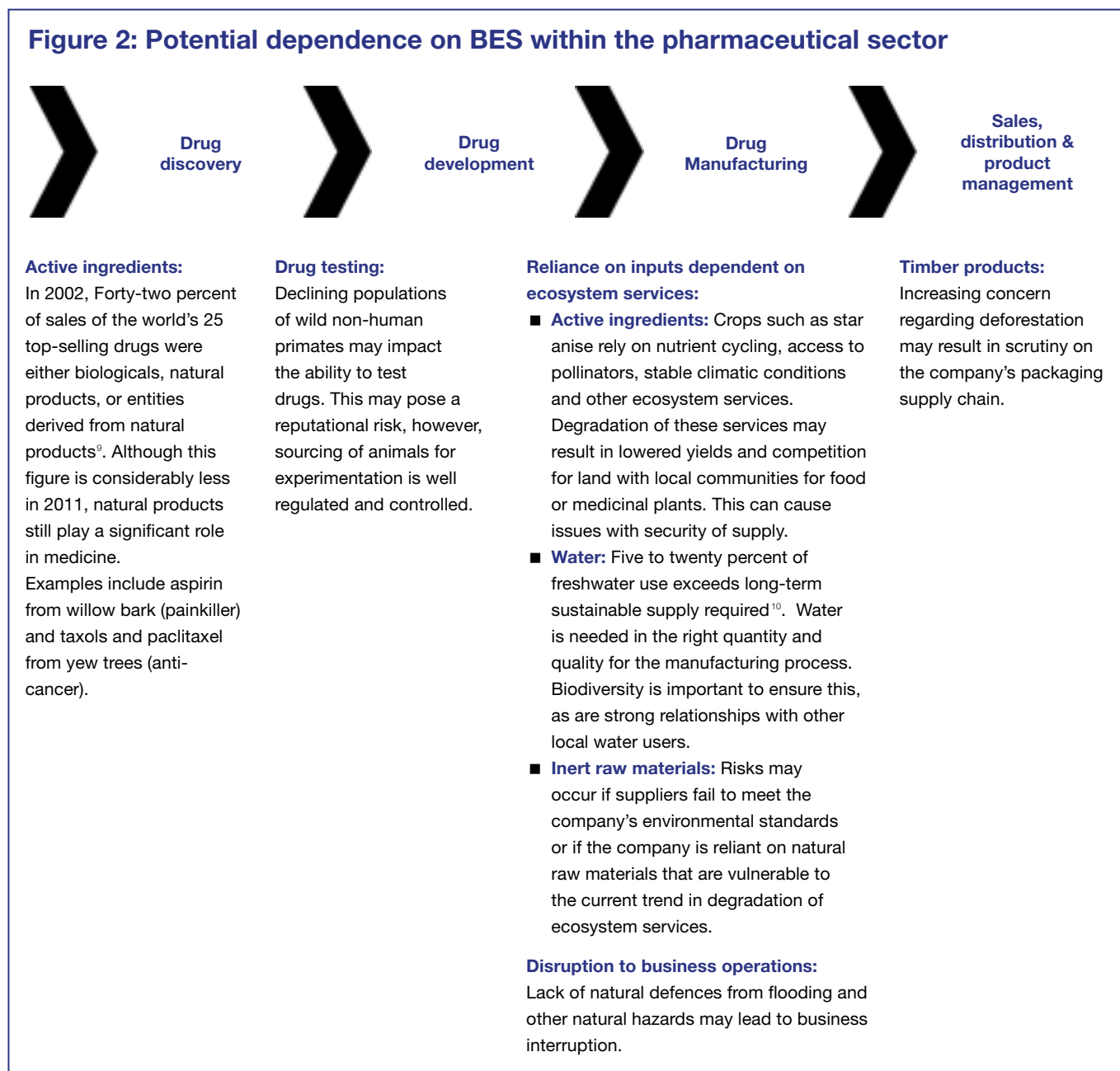
A company **impacts** an ecosystem service if the company affects the quantity or quality of the service.

Like all industries, the pharmaceutical sector both depends on and impacts biodiversity and ecosystem services. Though BES do not pose as significant a short-term risk in the same way as other business issues such as pharmaceutical counterfeiting or improving the access to medicines for use in developing countries, medium-term risks associated with BES are becoming more acute. Societal concern for BES decline is growing, which is likely to lead to stricter regulation of business, regarding biodiversity. In addition, investors are increasingly asking for clear reporting on how companies are addressing impacts and dependencies on BES before committing to investments.



### 3.1 How pharmaceutical companies depend on biodiversity

The potential dependence of the pharmaceutical sector on biodiversity and ecosystem services is outlined in Figure 2 below.



The sourcing of active ingredients from nature and the consumption of inert ingredients in manufacturing and distribution pose potential risks and opportunities to the sector. These are described in more detail below.

## Drug discovery

The most obvious link between the pharmaceutical industry and BES is with the sourcing of active ingredients from nature<sup>11</sup>. It is estimated that only a fraction of the 53,000 species used medicinally worldwide have been used by the pharmaceutical industry in drug discovery<sup>12</sup>. Given current species extinction rates, the pharmaceutical industry may well be missing out on new drugs. One estimate suggests the Earth is potentially losing one major drug every two years<sup>13</sup>.

However, trends in sourcing of active ingredients from nature have changed over time, suggesting that the reliance of the industry may be less than it was historically. Though initially pharmaceutical companies ran extensive natural product discovery, or “bioprospecting” programmes, many have shut them down in recent years. This move away from natural product-based research and development is due to concerns about long discovery times compared to synthetic molecules, as well as challenging sourcing logistics.

Nonetheless, Pharmaceutical Insight recently identified the search for medically active compounds either by using indigenous knowledge of species or by screening compounds as a key industry trend<sup>14</sup>. Indications are that bioprospecting is expected to grow to a US\$ 500 million industry by 2050<sup>15</sup>. Active ingredients from natural products cannot always be replicated by modern chemistry. They can also act as pathfinders to new modes of clinical action. For example, the compound paclitaxel (found in *Taxus* spp. and source of the anti-cancer drug, Taxol) was described as the kind of molecule that no chemist would ever sit down and think of making.

## Access and benefit sharing (ABS)

The Convention on Biological Diversity (CBD) recently drafted the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. Over twenty countries have already signed up and it is expected to enter into force before the eleventh CBD Conference of the Parties in autumn 2012. Signatories are then legally bound to ensure that pharmaceutical companies and other users of genetic materials are adhering to the rules, such as free and prior informed consent of local communities, mutually agreed terms for resource use and monetary benefits arising from the commercialisation of products based on genetic resources.

This presents a potential risk to pharmaceutical companies – particularly smaller players in the industry – if they do not have the appropriate systems in place for compliance. This risk will increase if the agreement is applied retrospectively to active ingredients sourced prior to the ratification of the CBD. The Protocol will provide a more clearly defined operating environment for companies using genetic resources, with countries assigning focal points to deal with company negotiations and to ensure that the appropriate stakeholders are consulted and included in access and benefit sharing arrangements.

Investors should take heed of these developments as companies that do not comply may lose their access to key active ingredients and so jeopardise part of their drug discovery and development programmes.

## Drug manufacturing

### Active ingredients: Use of wild grown species

A company may face reputational issues if it is sourcing active ingredients from a species that is overexploited or if the harvesting leads to conflict with local communities who use the species for traditional medicine. Overexploitation may lead to species extinction, which could draw further negative attention to the company and prevent future harvesting for local communities and the pharmaceutical company. Security of supply is another risk if the species is threatened by declining ecosystem health. However, many companies readily deal with these risks by shifting to the creation of synthetic alternatives.

## Ensuring security of supply

Drug approval systems such as those administered by the US Federal Drugs Agency require consideration of the sustainability of harvesting practices in the drug approval application process. Companies are required to demonstrate sustainability and put in place mitigation actions for impacts identified. Reliance on wild caught species is considered to be a risk by the industry that is managed through the creation of synthetic alternatives. Although this may be more costly, it offers the opportunity for ensuring uninterrupted supply.

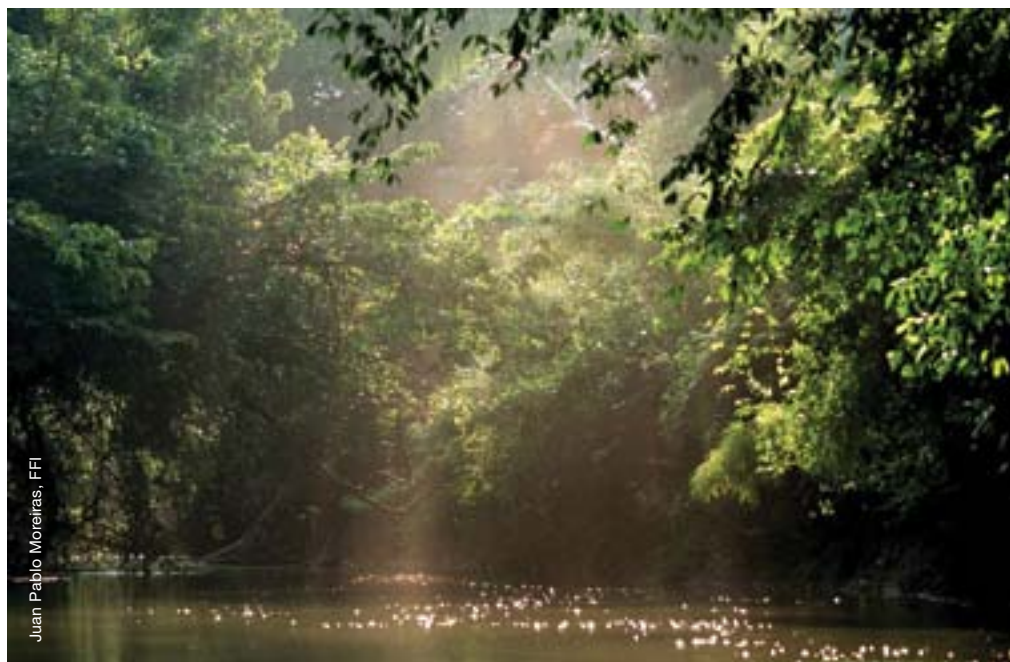
Several of the active ingredients in Sanofi's major drugs are derived from natural plant or animal extracts. For example, Taxotere® is an oncology drug extracted from the needles of yew trees. Artesunate® is an antimalarial drug derived from wormwood. All of these are either cultivated or synthesised, following a longstanding trend within the industry to synthesise active ingredients rather than rely on natural sources for drug manufacture, which may present security of supply issues.

## Water

Beyond the active ingredients derived from nature outlined above, water is the sector's key ecosystem service dependence. Every company we reviewed in our survey had identified water quality and sourcing as a priority issue. Extraction of water without due consideration of the needs of local communities and the environment may give rise to inequitable distribution of access to this vital resource, leading to potential community unrest, non-governmental organisation campaigns and reputational risks.

Careful management of ecosystems, through protection of riparian zones, soil cover and wetland areas, can play a key role in continued water security.

“ The Earth is potentially losing one major drug every two years ”



## Inert ingredients

The industry uses agriculturally-based inert ingredients in drug manufacturing, including sugar, fish oils, vegetable oils from soya, canola, palm oil and sunflower seeds and timber in packaging. Although potentially only sourced in small amounts, some of these ingredients depend on ecosystem services such as pollinators, healthy soils and sufficient water for irrigation.

## 3.2 How pharmaceutical companies impact on biodiversity

The potential dependence of the pharmaceutical sector on biodiversity and ecosystem services is outlined in Figure 3 below.


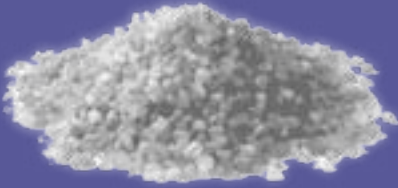
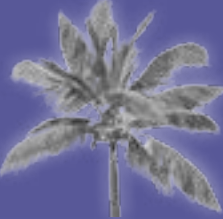



A number of these issues are described in more detail below.

## Drug manufacturing

### Cultivation of active and inert ingredients

Agriculture uses seventy percent of available freshwater, and unsustainable farming practices can result in issues such as the depletion of soil nutrients, soil erosion, the introduction of invasive species, and desertification. Although the pharmaceutical sector may use relatively small quantities of agricultural products, it may still face reputational and operational risk if it uses unsustainably produced commodities. There are a number of multi-stakeholder initiatives underway to develop principles to improve the social and environmental impacts of the higher profile crops.

<p><b>Soya</b></p> 	<p><b>Sugar</b></p> 
<p><b>Impacts:</b> Habitat loss (especially in the Amazon), human rights <b>Initiative:</b> Roundtable for Responsible Soya</p>	<p><b>Impacts:</b> Habitat conversion, labour rights <b>Initiative:</b> The Better Sugarcane Initiative</p>
<p><b>Palm oil</b></p> 	<p><b>Fish oil</b></p> 
<p><b>Impacts:</b> Habitat loss (especially in Indonesia) <b>Initiative:</b> Roundtable on Sustainable Palm Oil</p>	<p><b>Impacts:</b> Overfishing, loss of access to protein by communities <b>Initiative:</b> Marine Stewardship Council</p>

### Other environmental impacts

The mining of titanium dioxide and talc has various environmental impacts, both direct, such as water pollution, and indirect, such as increased consumption of bush meat by migrant workers at mine sites. There is a small potential reputational risk if the company is shown to be sourcing from mines that have caused damage to natural habitats and had associated negative impacts on local communities.

## Sales, distribution and product management

### Water

Most primary pollution from pharmaceuticals in water arises from the fact that medicines are released into the environment without being properly metabolised by patients; sometimes as much as eighty percent of the drug is excreted<sup>16</sup>. This phenomenon is already disrupting ecosystems and wildlife — and potentially humans. For example, increased oestrogen (from the pill and hormone replacement therapy) in water can lead to feminisation of fish, declines in fertility, developmental effects and impacts on the sustainability of wild fish populations<sup>17</sup>. Concentrations of pharmaceuticals in the water supply are likely to rise with increased water scarcity and increasing human populations in the future.

### 3.3 Business implications of BES for the pharmaceutical sector

Indications are that BES is emerging as a systemic risk for some industry sectors in the same way as climate change. It is not yet clear how significant an issue this is for the pharmaceutical sector. The trend towards producing synthetic drugs rather than harvesting from the wild reduces the sector's direct dependency and impacts on BES. However, our research indicates that there may be issues associated with other dependencies (such as water) and supply chain risks, which could also pose a risk for the sector. The extent of this risk is as yet unknown given that the dependency on natural resources and impacts through the supply chain are poorly analysed and understood. See Table 1 below for more details of the *potential* risks and opportunities pharmaceutical companies might face.



**Table 1: Summary of risks<sup>18</sup>**

Risks/opportunities	Example
<p><b>Operational</b></p> <p><b>Security of supply and maintenance of operating margins:</b> Despite a trend in outsourcing and downscaling of bioprospecting, sourcing of pharmaceutical ingredients from natural products remains important to some companies. Biodiversity loss places access to new active ingredients under threat. Increasing scarcity of raw materials – both wild and cultivated – as a result of ecosystem services failure or overexploitation may lead to a narrowing of profit margins or disruption to operations through security of supply issues. Failure to ensure ethical labour practices for cultivated goods may also impact on security of supply. This may lead to higher input costs.</p>	<p>Snake root, the active ingredient of Reserpentine used to control hypertension, has historically been overexploited in many of the countries in which it grows.</p>
<p><b>Regulatory and compliance</b></p> <p><b>Restrictions over access to land or raw materials:</b> Failure to understand and implement the requirements of emerging legislation can lead to loss of revenues, lack of access to product and reputational risk. Relevant legislation includes: the Convention on Biological Diversity (see box on page 8), the Cartagena Protocol on Biosafety and the Convention on International Trade in Endangered Species (CITES). Greater clarity over access and benefit sharing rules may result in greater ease of accessing active ingredients from nature but also greater scrutiny on the issue of intellectual property rights relating to compounds derived from natural products.</p> <p><b>Growth of compensation regimes:</b> Development of market-based instruments and compensation regimes may require more stringent controls over pollution.</p>	<p>A major pharmaceutical company had its patent application for its phytopharmaceutical Umckaloabo, which is extracted from the root of South Africa's Pelargonium sidoides plant, challenged because the compound had been used for many years as a traditional remedy in South Africa and therefore failed to meet the requirements set out in the CBD for access and benefit sharing.</p> <p>The European Union Liability directive sets a framework for attributing blame and securing compensation for corporate impacts on biodiversity.</p>
<p><b>Market</b></p> <p>Many drugs are reaching the end of their patents, leading to increasing pressure to discover new drugs. Companies that fail to adequately manage stakeholder relations, observe the rights of local communities or abide by national regulations and best practice guidance on access and benefit sharing may risk losing access to patents. This has implications for future revenues and for brand value.</p>	<p>In 1995 a US-filed patent for turmeric to be used to heal wounds was overturned when challenged by the Indian Council for Scientific and Industrial Research on the grounds that turmeric has been used for thousands of years for healing wounds and rashes.</p>
<p><b>Reputational</b></p> <p>Association with adverse impacts on biodiversity and ecosystems and people, such as use of endangered species, can damage a company's brand and restrict its 'social licence to operate'. Where ingredients used are cultivated, failure to abide by good agriculture practice, for example, use of personal protective equipment for application of pesticides, may give rise to reputational damage.</p>	<p>Squalene from sharks' livers is used in swine flu vaccines. Although a by-product of commercial fisheries, it could be sourced from species listed as vulnerable to extinction by the IUCN Red List. This usage could pose a reputational risk. Synthetic versions are not currently available but alternative sources are being researched.</p>
<p><b>Financing</b></p> <p>As investors and lenders put in place more stringent environmental and social requirements, securing access to finance will require more rigorous environmental performance on these issues.</p>	<p>A survey by United Nations Environment Program Financial Initiative asked its members how BES is currently incorporated in financial products and services and on an organisational level. Of the 27 institutions surveyed, 59 percent stated that they integrated consideration of BES into their products and services<sup>19</sup>.</p>

## Emerging opportunities

The industry's dependence and impact on BES can also build value depending how pharmaceutical companies deal with BES in their business operations and in reporting.

- **New product development:** innovative alliances can lead to access to new products, and natural products can offer the opportunity for creating drugs with new modes of action that are highly unlikely to be created through synthetic means.
- **Ensuring access to resources through strong stakeholder relations:** strong access and benefit sharing agreements can build strong local relationships which are vital to gaining access to active ingredients from nature for new drugs.
- **Ensuring security of supply:** proactive management of raw materials suppliers can pre-empt supply issues and reduce costs whilst building relationships with local stakeholders.

Those companies that capitalise on opportunities in line with their core business may develop a competitive advantage over those that do not.



## 3.4 What it means for investors

BES impacts and dependencies in the pharmaceutical industry could translate into potential risks and opportunities for investors in the medium term.

- **Reputation and brand:** Investors in pharmaceutical companies failing to abide by best practice standards on access and benefits sharing, or those shown to be sourcing ingredients from unsustainable sources, may face increased reputational risk.
- **Regulatory and compliance:** The value of an investment in a pharmaceutical company may decrease if the company loses access to patents and associated revenue by failing to comply with national regulations and international guidance on use of active ingredients from nature.
- **Investment return:** Loss of investment returns may be caused by many BES-linked trends, for example, the narrowing of profit margins due to increased costs of sourcing sustainable inert ingredients.

These risks are likely to increase with the growing trend to shift corporate valuation and consider the true economic value of BES in policy making and corporate decision-making.

## 4 The current state of business responses to BES



Juan Pablo Moreiras, FFI

## 4.1 Our approach

We based our methodology on the Ecosystem Services Benchmark, a tool developed by the Natural Value Initiative in conjunction with external stakeholders and investors to evaluate corporate management of impacts and dependence on BES. This methodology was adapted for application to the pharmaceutical sector. Our analysis looked at ten major pharmaceutical companies and was divided into five broad areas of performance: competitive advantage, governance, policy and strategy, management and implementation and reporting.

**The companies we evaluated are:**

Astra Zeneca  
Bayer  
Bristol-Myers Squibb  
GlaxoSmithKline  
Johnson & Johnson  
Novartis  
Novo Nordisk  
Pfizer  
Roche  
Sanofi

*See appendix 1 for details of methodology.*

## 4.2 Overview of our findings

**Companies were generally open to engagement on the issue.** This is despite the companies' stakeholder engagement processes not having identified BES impacts and dependencies as an issue, apart from water. Eighty percent of the companies that were reviewed responded to a request for interview.

**Companies are starting to consider the implications of ecosystem services for the business.** However, the focus of current activity in all companies is still on impacts rather than dependencies. Despite an initial recognition of BES as an issue, risk assessments rarely included consideration of BES dependence and impacts within the supply chain.

**Companies have different risk profiles depending on various factors.** These include whether or not they are conducting bioprospecting activities, producing drugs dependent on cultivated materials, operating in locations near biologically sensitive sites (such as IUCN protected areas) and using raw materials known to impact on biodiversity and ecosystem services or on natural resource-dependent communities.

**It was challenging based on public disclosures to determine potential risk exposure of companies on this issue.** Company disclosures on BES were often distributed in a number of different areas of the website. Often companies would make position statements with no publicly available framework for ensuring their enforcement throughout the company operations. For example, although companies indicated that they made no significant use of raw materials dependent on or impacting BES and that unsustainable supply could be substituted, the lack of detail available on risk assessments made it difficult for us to verify these claims.

The case studies highlighted in the following sections are examples of companies addressing particular risks stemming from their dependencies and impacts on BES. Among their peers, these companies have shown leadership.



Berry Mulligan, FFI

## 4.3 Company responses to dependencies

**Companies' bioprospecting policies were in proportion to their programmes.** Fifty percent of the companies reviewed were actively bioprospecting. Companies with substantial bioprospecting programmes often had mechanisms to ensure compliance with policy statements. Companies tended to disclose their position on bioprospecting even if not undertaking any. This creates potential confusion for stakeholders. However, policy disclosures were often high level; the language used was frequently rather vague and lacked concrete commitments. There is therefore a risk that policies might not act as a strong framework to drive performance improvement. Access and benefit sharing (ABS) is a key issue regarding bioprospecting policies and practices. Our analysis found that two of the five actively bioprospecting companies did not have clear ABS policies.

### Case Study 1:

#### Novartis and bioprospecting - innovation, competitive advantage and managing risk

The use of natural products is relatively small within Novartis' drug discovery and development programme and thus not critical from a business perspective. However, the company considers natural products to be an important enrichment for innovation or catalysing innovation alongside combinatorial chemistry and molecular modelling and synthesis. Natural products provide the company with a competitive advantage over peers not active in that field by providing access to novel active ingredients that simply would not be constructed in a lab. Examples for natural products applied in medicine include eg cyclosporine (immunosuppression), cone snail peptides (neuropathic pain), penicillin (bacterial infections) and the taxol family of cancer drugs derived from the yew tree.

Ensuring strong positive relationships with local users and institutions, as well as compliance with national and international regulations, is crucial for continued access to the plants, animals and other species that may contain new active ingredients. Novartis uses a contract-based system to trace active ingredients from source to end point. This process controls compliance of bioprospecting activities with the company's stated position, helps to build trust with collaborators by being highly transparent and ensures compliance with the Convention on Biological Diversity, including its ABS requirements.

The company has developed provisions regarding prior informed consent, ABS and capacity building. Novartis undertakes technical capacity building linked to natural product development, and the need to build local capacity is a theme in the company's activities. For example, collaborating scientists are given training opportunities at Novartis' facilities in Basel. The newly acquired skills make the collaboration partners more attractive for further collaborations in their home countries.

**Product substitution and ingredient synthesis reduces the risks of BES dependence.** We identified a number of examples of potential dependence on BES which had been addressed through synthesising the active ingredient. Though many of the companies are dependent on raw materials that rely on BES, such as palm oil, soya, sugar or wild caught species (e.g. fish or squalene from sharks), our analysis suggests that thirty percent of the companies that we examined potentially face operational risk from these dependencies, although the extent of this risk was not clear.

**Some companies are beginning to examine BES issues within the supply chain.** Water quality and consumption have been identified as an issue within all companies. Forty percent identified operational sites in water stressed areas and twenty percent had signed up to the UN Global Compact's CEO Water Mandate, which commits them to good water stewardship practices. However, disclosures on raw materials consumption were uniformly limited. Only two companies referred to the need to ensure sustainable sourcing of active ingredients in policy commitments, although it was not clear whether the motivation was to manage impacts, dependencies or both. None of the companies outlined steps taken to ensure sustainability of supply of ecosystem services or ecosystem service dependent commodities other than water, although a number were embarking on this process.

## Case Study 2:

### GlaxoSmithKline investigates its inert ingredient sourcing risks

GlaxoSmithKline has taken the initiative to understand how it impacts on BES through sourcing of raw materials. The company has reviewed its raw materials use and amongst others has identified the use of palm oil, fish oil and the use of paper as areas for potential concern, even though the typical quantities used by the company are a very small fraction of the total usage of these materials globally. The company intends to only use palm oil from sustainable sources and an inventory is currently underway to determine the ingredient's use. In addition, a target to source paper packaging from sustainable sources has been included as part of the new environmental sustainability strategy. There are supplier standards in place, which are distributed to suppliers and which are part of the supplier audit process. Actions are in place for follow up of these audits, depending on the outcome of the audit.



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## 4.4 Company responses to impacts

**All companies evaluated are actively managing the issue of pharmaceuticals in the environment, as shown by policies to evaluate product and manufacturing environmental impacts.** Strategies include minimising contamination of manufacturing site wastewater, reviewing products to evaluate potential environmental risks, engaging in research programmes and development of product information databases and patient take-back schemes such as SMARxT Disposal (see appendix 2).

### Case Study 3:

#### AstraZeneca addresses its site-level biodiversity impacts

Pharmaceutical operations close to areas of high biodiversity can potentially negatively impact on wildlife and ecosystem services. AstraZeneca has recognised this risk and taken a leading stance within the sector on site-level biodiversity risk management.

In 2003 the company surveyed manufacturing sites, carrying out risk assessments based on the operations' location, size and proximity to protected sensitive sites or designated nature reserves. Some Biodiversity action plans (BAPs) are in place for sites deemed high risk and others are under development. Measures are in place to minimise pharmaceutical contamination of water at a site level and the company is engaged in collaborations to address the issue more broadly. Site-level training has occurred and there is a dedicated intranet site to raise awareness of the BAP work amongst employees.

**A significant number of companies were undertaking eco-efficiency or 'green chemistry' programmes.** Having historically come under fire from pressure groups for its use of significant quantities of raw materials to generate a relatively small amount of drug, the industry is engaging in 'green chemistry' programmes. These aim to reduce natural resource usage and minimise impacts on the environment.

**Direct impacts to biodiversity were more likely to be addressed than indirect impacts.** Over fifty percent of the companies reviewed had conducted a review of the proximity of their manufacturing sites to protected areas. The three that did have operations in or near biologically sensitive sites are all actively managing their biodiversity impacts. However, only two companies had evaluated their supply chains with regards to impacts on biodiversity. Given that companies use a number of ingredients that are linked to sustainable sourcing concerns, such as palm oil, soya, and fish oil, this poses a potential reputational risk for all companies. Our analysis identified that fifty percent of the companies could face potential risks to their brands due to impacts of products in their supply chain. The extent of this risk is not yet clear.

## 5 Recommendations for BES risk and opportunity management

The pharmaceutical sector has a central role in producing and delivering accessible drugs. As such it is faced with a wide range of significant issues, from medical counterfeiting to improving the affordability of medicines for use in developing countries. Mismanagement of biodiversity and ecosystem services can pose a potential risk or be an opportunity for differentiation. It is not yet clear how big the risks associated with this issue are for the sector. The advent of synthetic manufacturing of molecules has reduced the reliance of the industry on active ingredients from nature and therefore reduced the associated risks. Nonetheless, our study showed that companies have different risk profiles on this issue. Similarly, the maturity of management systems varies from company to company.

We suggest the following actions to enable companies to understand and manage the risks and opportunities around this issue:

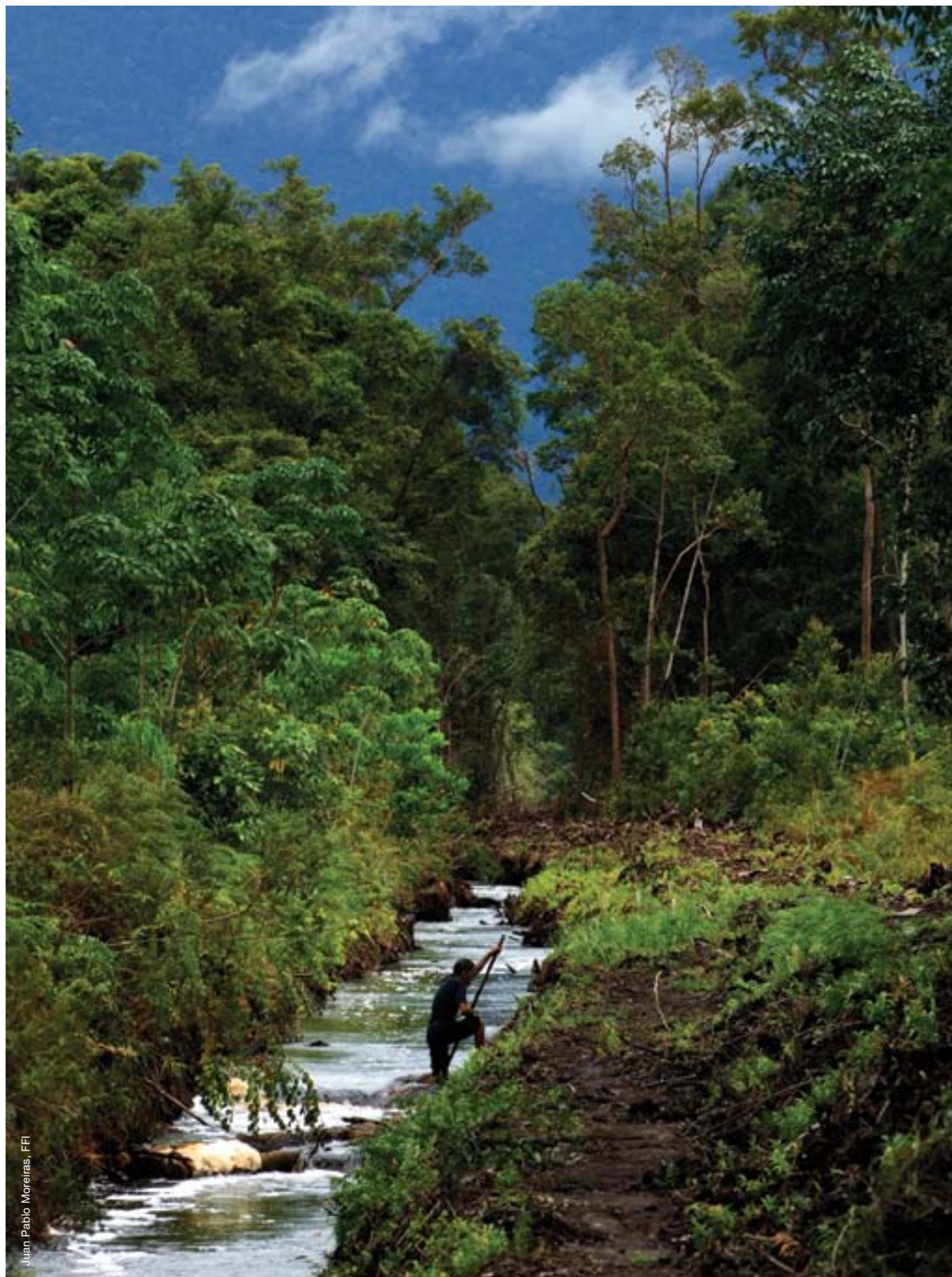
**Governance:** Companies should carry out a comprehensive risk assessment of BES issues, addressing use of active ingredients from nature in drug discovery and development, direct operational footprint of manufacturing sites and sourcing of inert and active ingredients.

**Policy and strategy:** Companies should make clear their impacts and dependencies on BES and their commitment to managing them via position or policy statements. This provides a more robust framework for managing an emerging business issue and allows more effective communication with stakeholders on the subject. Alternatively companies should clearly demonstrate that BES is not a material issue for them through disclosures on risk assessment processes.

**Management and implementation:** Greater disclosures on implementation of position statements and policy commitments, in particular on the management of BES dependence and impacts in raw materials sourcing, would provide greater assurance to stakeholders that risks associated with BES are being effectively managed. Companies should recognise and take into account business externalities, which can lead to disruption of supply chains, higher input costs and increased regulation.

**Reporting:** Based on current disclosures it is not possible to determine company risk exposure in relation to BES. Lack of information on how companies are managing their risks and opportunities leads to decreased investor confidence. Companies should be encouraged to disclose more information on the volume, nature and provenance of raw materials sourced, the outcomes of product and issue risk assessments and the activities underway to address them (if that assessment shows them to be material).

*Appendix 2 offers a number of initiatives that can assist companies in addressing this issue.*



Juan Pablo Moreira, FFI

## Appendix 1: Detailed methodology

The Ecosystem Services Benchmarking (ESB) tool was developed by the Natural Value Initiative in collaboration with investors from around the world: three UK-based asset managers (Aviva Investors, F&C Investments and Insight Investment); a US-based asset manager (Pax World); a Brazilian-based bank (Grupo Santander Brasil) and a leading Australian pension fund, VicSuper. This methodology was adapted for application to the pharmaceutical sector.

The ESB evaluates company performance against specific criteria, which represent the different categories of a strong management system for the issue of BES. For each criterion, companies are evaluated against four performance levels reflecting the range of current practice, from apparent inactivity in managing the issue (Level 1) to perceived best practice (level 4).

Some elements of the benchmark play a greater role in risk management and realising opportunities than others. We therefore adjusted the relative scores of each section as shown by the percentages in the parentheses below to calculate the final score and level of performance.

### Criteria

- 1** Competitive advantage (15%): Extent to which value is created or protected through company activity to ensure sustainable use of biodiversity and ecosystem services.
- 2** Governance (20%): Extent to which processes and resources are in place to undertake a formal risk and opportunity evaluation of impact and dependence on BES.
- 3** Policy and strategy (20%): Extent to which there is a consistent policy and strategic framework for managing risk and opportunity and supporting guidance/standards.
- 4** Management and implementation (25%): Extent to which tools, training and assurance processes are in place to drive improvement through the company and its suppliers.
- 5** Reporting (20%): Extent to which internal and external reporting processes, targets and indicators are in place for BES.

Where companies were known not to undertake certain activities e.g. bioprospecting, these questions were removed from the analysis and the overall potential score for that company adjusted accordingly.

### Limitations:

We recognise that this methodology has the following limitations:

- **Objectivity:** the ESB offers a rigorous framework for analysis, however, an element of subjectivity is inevitable.
- **Performance versus process:** the lack of quantitative metrics for BES meant that we had to rely on management process as a proxy for performance on the ground.
- **Evidence-based analysis:** site visits were outside the scope of the analysis, hence we relied on company statements and public disclosures combined with a press review.
- **Integration:** the analysis pulls out a single issue when in reality business operation requires a trade off between multiple issues.

**For more information on the Ecosystem Services Benchmark, please visit the Natural Value Initiative website:**

**[www.naturalvalueinitiative.org](http://www.naturalvalueinitiative.org)**

## Appendix 2: Relevant industry initiatives or guidance

The table below has been modified from UNEP (2010) Are you a green leader? Business and biodiversity: making the case for a lasting solution.

Name	Description
The American Chemical Society's Green Chemistry Institute <a href="http://www.acs.org">www.acs.org</a>	Provides a set of principles on green chemistry and green engineering which aim to minimise the impacts of chemical products and processes on the environment and human health from the process and product design stage.
Biotechnology Industry Organization (BIO) "Guidelines for BIO Members Engaging in Bioprospecting" <a href="http://bio.org/intl/ip/international/200507guide.asp">http://bio.org/intl/ip/international/200507guide.asp</a>	Provides non-mandatory guidelines related to bioprospecting which includes both access and benefit sharing (prior informed consent, development of appropriate agreements, respect of tradition, culture and values) and sustainable use.
Convention on Biological Diversity (CBD) Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits <a href="http://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf">www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf</a>	Voluntary guidelines on genetic resources and associated traditional knowledge, innovations and practices covered by the CBD and benefits arising from the commercial and other utilisation of such resources.
World Business Council for Sustainable Development (WBCSD) Guide to Corporate Ecosystem Valuation <a href="http://www.wbcsd.org">www.wbcsd.org</a>	A framework for improving corporate decision-making through valuing ecosystem services, helping companies to navigate through related jargon and techniques. It was road tested by 14 multinational companies and launched in April 2011.
International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) guidelines "Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization" <a href="http://www.efpia.org">www.efpia.org</a>	Sets out the elements of "industry best practice" including obtaining prior informed consent, reaching mutually agreed terms incorporated into a "formal contractual benefit-sharing agreement", and avoiding negative impacts on traditional use when commercialising genetic resources.
International Standards for the Sustainable Wild Collection of Medicinal and Aromatic Plants (ISSC-MAP) <a href="http://www.floraweb.de/map-pro">www.floraweb.de/map-pro</a>	Provides specific guidance on sustainable sourcing practices for medicinal and aromatic plants, and a set of principles and criteria that address conservation, sustainable use, access and benefit sharing and good environmental practice.
Pharmaceutical Supply Chain Initiative (PSCI) <a href="http://www.pharmaceuticalsupplychain.org">www.pharmaceuticalsupplychain.org</a>	A group of major pharmaceutical companies that have produced a set of principles for responsible supply chain management. Although the environment is included in the initiative, the focus is on energy, waste, environmental consents and emissions. Dependence or impact on BES is not mentioned, in particular water.
SMARxT Disposal <a href="http://www.smarxtdisposal.net">www.smarxtdisposal.net</a>	The U.S. Fish and Wildlife Service, the American Pharmacists Association, and the Pharmaceutical Research and Manufacturers of America have created the SMARxT DISPOSAL campaign to educate consumers about how to dispose of medicines in a safe and environmentally protective manner.
Union for Ethical BioTrade (UEBT) Verification framework <a href="http://www.uebt.ch">www.uebt.ch</a>	A verification system for companies that operates at an international level on the issues of biodiversity conservation, sustainable use of biodiversity, and fair and equitable sharing of benefits derived from the use of biodiversity.
WHO/IUCN/WWF Guidelines on the conservation of Medicinal plants <a href="http://apps.who.int/medicinedocs/en/d/Js7150e">http://apps.who.int/medicinedocs/en/d/Js7150e</a> <a href="http://www.who.int">www.who.int</a>	Provides a framework for the conservation and sustainable use of plants in medicine.

## Acronyms

ABS	Access and benefit sharing
BAP	Biodiversity Action Plan
BES	Biodiversity and ecosystem services
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species
ESB	Ecosystem Services Benchmark
IUCN	World Conservation Union
MA	Millennium Ecosystem Assessment
NVI	Natural Value Initiative
TEEB	The Economics of Ecosystems and Biodiversity
UNEP FI	United Nations Environment Programme Finance Initiative
UNEP WCMC	United Nations Environment Programme World Conservation Monitoring Centre
WEF	World Economic Forum
WRI	World Resources Institute

Glossary	
<b>Access and benefit-sharing (ABS)<sup>20</sup></b>	Refers to the way in which genetic resources may be accessed, and how the benefits that result from their use are shared between the people or countries using the resources (users) and the people or countries that provide them (providers).
<b>Active ingredients</b>	The substance in a drug that is pharmaceutically active. Some medications may contain more than one active ingredient. Some active ingredients may be dependent on BES because they cannot be commercially synthesised. Alternatively they may be derived from BES.
<b>BES dependent raw materials</b>	Materials used in the production of drugs that are reliant in some way on biodiversity or ecosystem services. We use this to refer only to inert ingredients rather than active ingredients.
<b>Bioactive substances<sup>21</sup></b>	Substances which have an effect upon a living organism, tissue, or cell.
<b>Biodiversity</b>	'Biological diversity' means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems (Article 2, Convention on Biological Diversity).
<b>Bioprospecting or natural product discovery</b>	The process of looking for potentially valuable genetic resources and biochemical compounds in nature. A natural product is a chemical compound or substance produced by a living organism found in nature that usually has a pharmacological or biological activity for use in pharmaceutical drug design and discovery.
<b>Ecosystem<sup>22</sup></b>	A dynamic complex of plant, animal, and micro-organism communities and their non-living environment interacting as a functional unit. Examples of ecosystems include deserts, coral reefs, wetlands, rainforests, boreal forests, grasslands, urban parks and cultivated farmlands. Ecosystems can be relatively undisturbed by people, such as virgin rainforests, or can be modified by human activity, such as farmlands.
<b>Ecosystem services<sup>23</sup></b>	The benefits that people obtain from ecosystems. Examples include freshwater, timber, climate regulation, protection from natural hazards, erosion control, and recreation.
<b>Endocrine disruptors<sup>24</sup></b>	Substances that interfere with the synthesis, secretion, transport, binding, action, or elimination of natural hormones in the body.
<b>Genetic resources or natural products</b>	Refers to the genetic material from plants, animals or microbes that has actual or potential value to be used. These uses can range from basic research that seeks a better understanding of the world's natural resources to development for commercial products.
<b>Inert ingredients</b>	Ingredients within the drug that are not pharmaceutically active e.g. gelatin, water, sugar, titanium dioxide or talc. These may be based on a natural product.
<b>Prior informed consent</b>	Permission given by the Competent National Authority (CNA) of a country to an individual or institution seeking to obtain access to genetic resources, in line with an appropriate legal and institutional framework.
<b>Raw materials</b>	Materials used by the company in the manufacturing of drugs. These could be inert or active ingredients and could be genetic resources or other raw materials.

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