ABH

Reputation, Ethics & Human Rights in HealthTech

Discussion Document



The reputation of the HealthTech industry has been fundamental to ABHI's work since its inception in 1988. Progress on ethical compliance has been driven, at least in part, by media reports of inappropriate behaviour from both industry and healthcare professionals⁽¹⁾ and indeed legal action in several jurisdictions.

This was the catalyst for the introduction of our first formal Code of Business Practice (COBP) in 2008. Its primary aim was, and remains today, to supplement legislation and to provide a framework to support ethical interactions between industry and healthcare professionals.

Increasingly other ethical concerns such as human rights, environmental protection and community engagement have risen up the corporate agenda.

This discussion document outlines the current situation regarding human rights and the HealthTech sector. We seek to stimulate the debate, increase awareness of the issues and bring together like-minded organisations to help continually improve human rights standards.

ABHI

Association of British HealthTech Industries

ABHI is the UK's leading health technology trade association. With over 275 members, ABHI supports the health technology community to provide products and services that help people live healthier lives. Our work is focused on showing the value of HealthTech and encouraging a healthy environment for economic growth. We help companies understand HealthTech regulation and our work is underpinned by our Code of Business Practice, which all Members adhere to. .

HealthTech Interaction with Human Rights

Due to the diversity and complexity of its supply chain and presence in high risk locations, there is heightened potential for adverse human rights impacts in the HealthTech sector.

Reports in 2007 and 2016 ⁽²⁾ highlighted poor labour practices in the manufacturer of surgical instruments and medical gloves. These reports spurred action, driven by ethical procurement initiatives by UK and Swedish authorities, resulting in reported improvements in conditions.⁽³⁾

The issues previously reported have concerned direct manufacture of medical devices: further concerns could lie deeper in the supply chains with subcontractors and back to the extractive industries and conflict areas.

LIFE SCIENCES HUMAN RIGHTS CONCERNS⁽⁴⁾







Human Rights Principles & Programmes

There is increasing pressure worldwide on businesses to take steps to ascertain, manage and account for their human rights impacts and explain how they are doing this. Human rights are basic rights and freedoms that all human beings are entitled to without discrimination.

Modern human rights derive from the Universal Declaration of Human Rights (UDHR) and the subsequent covenants; the International Covenant on Civil and Political Rights and its two Optional Protocols and the International Covenant on Economic, Social and Cultural Rights, together known as the International Bill of Human Rights.

The UN calls on every 'organ of society' – including business – to play a part in promoting respect for the rights and freedoms set out in the UDHR, which include the right to life, liberty and security of person and the right to freedom from torture and slavery, to name a few. The basic principles of how businesses should respect human rights are set out in the UN Guiding Principles on Business and Human Rights (UNGPs)⁽⁵⁾.

Business and Human Rights Framework

- Human rights guidance for corporations is set out in the UNGPs on Business and Human Rights⁽⁵⁾ and subsequent instruments and guidelines
- The UNGPs were unanimously endorsed by the UN Human Rights Council in 2011 and enjoy widespread support from governments, businesses and civil society. They embody the obligation of all business enterprises, regardless of size, to respect human rights
- Companies are expected to respect internationally recognised human rights which, as a minimum, comprise the rights in the International Bill of Human Rights and the principles set out in the ILO's Declaration on Fundamental Principles and Rights at Work
- The UNGPs outline the process of human rights due diligence as a comprehensive human rights risk management system assessing the full spectrum of internationally recognised human rights

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Human Rights: A Public Concern

Adverse human rights impacts bring about legal obligations and risks of legal claims, commercial disruption and reputational damage.

UNGPs, initially a soft law instrument, are turning into hard law through reporting obligations, slavery and human trafficking regulations, industry standards, OECD guidance, investor requirements, procurement rules and legal action. Recent legislation demonstrates the rising trend in specific legal human rights-related obligations directed at companies.

Examples include the California Transparency in Supply Chains Act, the UK Modern Slavery Act 2015, the French corporate duty of vigilance law and EU Directive 2014/95 on the disclosure of non-financial and diversity information which has been transposed into national laws.

There is increasing activity from Non-Governmental Organisations (NGOs) who are actively targeting corporations, particularly in the extractives, apparel, agribusiness, retail and banking sectors. International NGOs, such as Amnesty International and Human Rights Watch, are involved in lobbying governments and raising public awareness through their educational work.

Realising that the essence of their support lies with general society, NGOs will often try to bring greater knowledge of human rights issues to the public.⁽⁶⁾





The Role of Industry Associations

An industry association exists to serve its members, provide strategic leadership for the industry and manage its reputation.

As a sector dedicated to improving the human condition, the issue of ethical trade and human rights has particular resonance for HealthTech companies.

Member organisations are at very different stages of development in understanding and acting upon their legal, regulatory and moral obligations, leading to an inconsistent approach across companies based on size, sector and geographical location.

Supporting Ethical Trade

Ethical trade aims to make international business work better for poor and disadvantaged people⁽⁷⁾. ABHI fully endorses this principle and is working to build awareness amongst its members and to develop systems with regulators, NGOs, the NHS and Government to help businesses implement improvement projects.

We recognise that value for money is a prime consideration in NHS procurement of medical supplies. We believe that ethical practices should also be a significant factor in decision-making with recognition of the supply chain impact of supporting high working standards.

Global Issue

The medical device sector is a global industry, from both a supply chain and trade point of view. Corporate policy in this area is generally decided at an international level. This requires the issue of human rights and particularly supply chain due diligence to be tackled globally.

To that end, ABHI is working with colleagues in Swedish Medtech, AdvaMed and HealthTech Europe with the common purpose of having our industry recognised as achieving the highest standards of ethical behaviour.

...the pressure to produce materials at the lowest cost can put vulnerable workers at risk of labour rights

abuses.

British Medical Association⁽⁷⁾

OUR GOALS

To ensure our industry's supply chain is managed to high ethical standards so every worker is valued and safeguarded

- To establish a regulated selfassurance⁽⁸⁾ approach to human rights incorporating reporting requirements on a 'no-blame basis'
- 2. Establish a coalition of HealthTech associations and relevant supporting organisations to promote and build on global best practice
 - **3.** Create a support network for members with particular focus on a collaborative approach and joint remedial actions

Supporting N	<i>lembers</i>
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Awareness	Build companies' knowledge of relevant legislation, schemes, risks and opportunities
Support	Provide tools, knowledge and infrastructure
Best Practice	Bring all members, and wider industry, up to standard of the best in sector, utilising CoBP and other mechanisms

External Engagement

Government - Health System - NGOs



At the 2017 conference "Human Rights & the Role of Corporations", hosted by ABHI and Norton Rose Fulbright, it was suggested that there remain a number of undiscovered issues. These present potential operational, reputational and legal risks.

The conference outlined the following key points that would support the practical implementation of Human Rights programs:

- Addressing human rights is the right thing to do from an economic and ethical point of view
- 2. Human Rights Due Diligence, as a holistic risk management programme, is essential to identify, address and avoid potential adverse human rights impacts
- Innovation and sourcing are increasingly complex international issues this requires a global response to potential human rights impacts
- 4. Need to recognise the increasing activism by consumer, investors, NGOs & unions
- 5. There needs to be increased transparency. The debate over bribery and corruption provides a lead on how an open dialogue on difficult issues can be achieved
- 6. Multinational businesses need to provide social stewardship and take a lead in contributing to legislative processes and the development of best practice
- 7. There is a need promote the human rights debate widely within the sector and collaborate with governmental, health organisations and, critically, with NGOs
- 8. No-blame culture and processes are needed



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UK Legal and Contractual Obligations

Companies in the UK HealthTech sector are increasingly being made aware of the requirements to respect human rights.

The two main instruments are the <u>Modern Slavery Act 2015</u> and the <u>Labour Standards</u> <u>Assurance Scheme</u> (LSAS).

The Sustainable Development Unit, jointly funded by, and accountable to NHS England and Public Health England, has also published <u>Ethical Procurement for Health</u>.

Modern Slavery Act

Consolidates the offences of slavery and human trafficking, ensures that perpetrators can receive suitably severe punishments and enhances support and protection for victims.

It also contains provisions to require that businesses which operate at least a part of their business in the UK and have an annual global turnover of at least £36m to disclose what action they have taken each year to eradicate modern slavery in their own business or their supply chains.

Most of the HealthTech sector is exempt from these reporting requirements as over 90% of HealthTech companies are designated SMEs.

LSAS

LSAS is a labour standards management system developed by NHS Supply Chain (NHSSC), in conjunction with the Department of Health and industry bodies.

Companies supplying particular categories of products to the NHS through public procurement tenders have to comply with standards of Human Rights.

Initially piloted by NHSSC for surgical instruments, the application of LSAS has now been extended to other product categories, with further scope increases anticipated.

By actively requiring suppliers to continually improve their labour standards management system, the scheme reduces the potential for abuses to go undetected.

Key Human Rights Organisations

British Medical Association (BMA)

The BMA Fair & Ethical Medical Trade Group was established in 2007 to investigate, promote and facilitate fair and ethical trade in the production and supply of commodities to the healthcare industry. It promotes transparency, open dialogue and continual improvement in setting ethical standards.

Ethical Trade Initiative (ETI)

ETI is an alliance of companies, trades unions and NGOs that promotes respect for workers' rights globally. Its members work in partnership to improve the working lives of vulnerable people in supply chains covering a wide spectrum of activities from sewing uniforms and assembling equipment, to providing cleaning or catering services.

Organisation for Economic Cooperation and Development (OECD)

The <u>OECD</u> issues <u>guidelines for</u> <u>multinational enterprises</u> that are nonbinding principles and standards for responsible business conduct, consistent with applicable laws and internationally recognised standards. The guidelines are the only multilaterally agreed and comprehensive code of responsible business conduct that governments have committed to promoting. International Labour Organisation (ILO)

The ILO offers expertise and knowledge about the world of work. It develops policies and programmes to promote basic human rights, improve working & living conditions. To support this it creates labour standards backed by a system to supervise their application. This is backed by an extensive programme of international cooperation to help countries put these policies into practice in an effective manner



- 1. <u>http://www.pmlive.com/pharma_news/the_impact_of_th</u> e_us_sunshine_act_617570
- 2. <u>In good hands Tackling labour rights concerns in the</u> <u>manufacture of medical gloves</u>. BMA Medical Fair & Ethical Trade Group, March 2016
- Healthier Procurement, Improvements to working conditions for surgical instruments manufacture in Pakistan, SwedWatch, BMA, Medical Fair & Ethical Trade Group 19 March 2015
- 4. <u>Exploring human rights due diligence. Good practices</u> and challenges for business enterprises. Norton Rose Fulbright 2017
- 5. <u>Guiding Principles on Business and Human Rights</u>, United Nations 2011
- 6. <u>http://www.coe.int/en/web/compass/human-rights-activism-and-the-role-of-ngos</u>
- 7. https://www.bma.org.uk/features/isthisethicaltrade/
- 8. <u>Regulatory Futures Review</u>, Cabinet Office, January 2017
- 9. https://www.bma.org.uk/features/isthisethicaltrade/



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