Investor Consultation (UK)
UN Special Rapporteur on the Right to Health regarding the draft Huma Rights Guidelines for Pharma Companies in Relation to Access to Medicines

Henderson Global Investors – SRI feedback to consultation
March/April 2008

CONTACT

- The following are comments from the Henderson SRI team on the consultation, they do not necessarily reflect the views of Henderson Global Investors as a whole
- The feedback is intended to help input into the second draft of the guidelines
- Form of feedback is informal (which was indicated as an appropriate approach) given the short deadline
- Please do not hesitate to contact the individual below for any clarification or additional questions

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GENERAL COMMENTS/FEEDBACK

- Strongly welcome Paul Hunt's involvement on this issue, and efforts to move the agenda forward
- Believe it is appropriate that there are efforts at the UN level to tackle this issue, and to focus on encouraging the drug industry to recognise their roles and responsibilities and take more strategic action. Aware that Paul Hunt has only decided to focus on companies having already been active (and continuing to be active) on encouraging States (who have primary responsibility for this issue) to play their role, and recognising the importance of the industry in enabling/facilitating governments to fulfil their duties
- Believe a rights-based approach to tackling this issue is an interesting one, and coming from the UN, an appropriate approach. Access to health is a basic human right. However execution of this approach needs to be balanced with pragmatism - the resulting guidelines should have inspirational elements but also be workable. Human rights is an issue of relevance to investors, as how companies manage this can potentially have a positive or negative impact on shareholder value. For instance, the risk of poor human rights management of this issue, could lead government and society at large to introduce/tighten regulation which may make it more difficult for the company to conduct its business. Conversely, strong management of this issue can result in a company benefiting from the opportunities (positive reputation enabling it to enter new growing markets, ability to attract and retain skilled staff etc.), an argument often overlooked
- Although the guidelines would not be legally binding, the attempt to promote best practice on this issue is welcomed

SPECIFIC COMMENTS/FEEDBACK

Approach

- Current guidelines are too detailed and prescriptive, and would not be appropriate at the level. It may be more helpful for the guidelines to be at a strategic level, based on principles. Companies would then either be invited to sign up to the principles (and in time, required to demonstrate their compliance against these) or be required to 'comply or explain' their position with regards the principles
- The 'principles based' and 'comply or explain' approaches have previously been used to great success e.g. in the UK, the Combined Code on Corporate Governance works on such an approach. The UN Global Compact is a principles based approach. Another example of a principles-based approach, combined with more detailed guidelines that may be useful to consider relates to that for nanotechnology (draft principles for this attached)

Focus

- Initiative needs to be more explicit about the rationale for the focus taken (could be addressed in background/supporting doc?). Seems that initiative is focused on access to medicines within developing and emerging markets, rather than more generally. More specifically the focus appears to be implicitly on communicable diseases, however, chronic conditions are increasingly becoming an issue in emerging markets

Scope

- Initiative needs to be more explicit about the rationale for the scope taken (could be addressed in background/supporting doc?). Seems that initiative is centred on access to medicines for global innovative/branded drug companies. This may appear to be unfairly selective. If intended focus is on access to medicines within the broader area of access to health, it would be more appropriate to broaden scope to include all (or all global) drug companies (innovative, branded, biotech etc.) and/or all disease categories (communicable, chronic)
- Overall, there are a number of different options possible:
    - Expand focus to access to health (not just medicines) and include any healthcare company (product and service providers). Could focus on global picture, or narrow in on developing and/or emerging markets, and include companies which have a presence in these markets, or there these will be important future growth markets. Could include any health conditions, or focus on those with particular relevance for developing and/or emerging countries
    - Expand focus to access to healthcare products – medicines and medical devices. Could focus on global picture, or narrow in on developing and/or emerging markets, and include companies which have a presence in these markets, or there these will be important future growth markets. Could include any health conditions, or focus on those with particular relevance for developing and/or emerging countries
    - Expand focus on access to health (not just medicines) and include drug companies, but also include other key stakeholders e.g. NGO, governments. Could include any health conditions, or focus on those with particular relevance for developing and/or emerging countries
    - Keep focus on access to medicines, including drug companies, but also include guidelines for other key stakeholders e.g. NGOs, governments etc. Could include any health conditions, or focus on those with particular relevance for developing and/or emerging countries
    - Etc.

Positioning

- Although the basis of the guidelines is rights-based, it may be useful to outline clearly what the business risks and opportunities are for the drug companies on this issue – can refer to those already outlines by others e.g. PSG, only need to list these, (in the background/supporting doc?). Although this is a rights-based approach, clearly if companies do not address the concerns, the issue could evolve and escalate into being business critical, so it would be value

Content

- The current guidelines broadly address the right topics/issues

Length

- Too long and detailed as they are
- Guidelines doc itself should not be more than 2-3 pages

Language/style/presentation

- Should not be presented in too formal a style, like a UN doc if want to be accessible for as many different stakeholders as possible
- Possibly consider bulletin form – may help reduce the quantity of pages needed

Format/Output

- There should be two documents as a result of the current initiative:
  1) The set of guidelines themselves: should not need to be updated that frequently as if they are the rights ones, should continue to be relevant for some time
     - Layout: principle x; rationale for principle x; possible approaches/KPIs

  2) The background/supporting document: will need to be updated as appropriate
     - The significance of the issue
     - The context for the development of the guidelines
     - The rationale for why the guidelines have the approach, focus, scope etc. that they have
     - An outline of how the guidelines fit within the broader context/what next e.g. whether there will be other guidelines be developed for other healthcare (non-drug) companies by the UN; whether non-healthcare companies will also be includes in new guidelines on access to medicines/health; whether guidelines on access to medicines will be developed for other stakeholders e.g. NGOs, invest whether there will be other UN initiatives on other issues such as access to water; whether the focus will be expanded in future for all markets beyond developing and/or emerging economies
     - Contact details of those to contact for more information
     - Useful resources

Company engagement

- When engaging with companies, wherever possible, contact should be made with the board management, the Chief Executive Executive for example, as well as the individuals with responsibility for such issues. This ensures the CEO is aware of the enquiry, and may help to ensure the dialogue gets the attention and resources appropriate
- We have been enormously disappointed to hear of the broadly negative response to the initiative to date from the industry. It appears to broadly reflect the scepticism faced by the Access to Medicines Index Project. It is most likely the reasons for this response are varied: the perception that the initiative is not neutral, but positioned with an NGO agenda; the concern about taking a rights-based approach to the issue; the inclusion of focus on emerging countries as well as developing countries (which represent viable markets in short/medium term) and the sense from the industry that they are being singled-out as being the key barrier to what is a complex issue involving being players. Such concerns can be corrected and overcome, although it will be difficult to do, and maybe there is a role of us as investors to help facilitate this. We believe companies and the industry should be more open minded to the initiative, and play their play in making it as useful and effective as possible, and will seek to convey this with the companies
- There is value in conducting a pilot of the guidelines on a few companies, as this can help identify any unforeseen issues, and help improve on the guidelines. The pilot does not need to be formalised, in terms of being a publicly announced exercise. It would be good to get as many companies to participate as possible, and involve not just those that are broadly supportive e.g. Novo Nordisk, but those who are sceptical e.g. GSK. There may be some scope for some of us investors to help encourage the sceptics to consider participation

Possible set of principles?

No particular order ….

.. not comprehensively completed for each principle, but wanted to given an indication of where I am coming from…

Draft UN Human Rights Guidelines for Drug Companies in Relation to Access to Medicines in Developing and Emerging Countries

This set of principles is intended to apply to all drug companies with product portfolios of relevance to developing and/or emerging economies.

Companies are encouraged to consider and adopt the following set of principles with regards to developing and/or emerging countries as these are considered best practice with regards the issue of access to medicines.

Companies should be transparent about the extent to which they are in compliance with the principles, taking a 'comply or explain' approach, being clear about whether this is in relation to 1) developing and or 2) emerging countries

Principle 1: Recognise and uphold the human right to access to health, and so more specifically, access to medicines, whilst ensuring ability to maximise shareholder value

> **Rationale**: it is important for companies to acknowledge they are aware of the UNDHR which is a legally binding document which many States have signed up to, which explicitly states that access to health is a basic human right. This is the foundation upon which companies should act, and must take into account, when conducting their business. However at the same time, the inclusion of the statement about the need to maximise shareholder value recognises that most companies have a primary duty to do this for their investors, and that often it can be difficult to balance the two needs.
>
> **Possible actions to demonstrate compliance with principle** (max 3-5?):
> = Explicit reference to this in a formal company policy, including reference to UNDHR
> = Establishment of a corporate strategy which seeks to facilitate access to medicines, in a sustainable manner
> = Membership and/or participation in external HR related initiatives e.g. UN Global Compact
> = Explanations provided in instances where the company has not felt it possible to implement an access to medicines policy whilst maximising shareholder value

Principle 2: Allocate responsibility and accountability for delivering of efforts to facilitate access to medicines

> Rationale: it is critical that there is clear and direct responsibility assigned to individuals within the company for the development, implementation and delivery of the AtM strategy, otherwise, there is a danger the strategy will not succeed.
>
> Possible actions to demonstrate compliance with principle (max 3-5?):
> = Clear organisational/individual accountability for development, implementation and delivery of corporate AtM strategy, ideally including board level accountability
> = Establishment of KPIs for specific aspects of the AtM strategy
> = Linking of remuneration with achievement of specific KPIs

Principle 3: Working in partnership with other stakeholders to facilitate access to medicines

Rationale: this principle recognises that the AtM issue requires the involvement and co-operation of all stakeholders, not just companies; but that companies do have a critical role to play given the nature of their business. To work, collaborative needs to be in partnership, with all stakeholders entering with an open mind and willing to respect and consider other viewpoints, and other possible solutions.

Possible actions to demonstrate compliance with principle (max 3-5?):
= Company has entered into multi-stakeholder initiatives, PPPs, aimed at facilitating access to medicines
= Company has entered into initiatives working with other stakeholders to prevent product divergence

Principle 4: Develop and produce safe high quality drugs, manufactured to the highest standards, according to best practice, marketed responsibly

Rationale: this states upfront the critical need for companies to ensure they are developing safe medicines to the highest quality. It is a universal principle for any drug company. It also covered the need for companies to ensure they are marketing their drugs in a responsible way.

Possible actions to demonstrate compliance with principle (max 3-5?):
= Company has adopted the highest quality standards with regards its manufacturing processes, attaining external certifications
= Company has adopted the highest safety and quality standards and practices with regards its R&D, clinical practices, and post-market pharmacovigilance
= Company has efforts to prevent counterfeiting of its medicines
= Company has had few incidents of product recall due to poor drug safety and quality, or due to irresponsible marketing practices

Principle 5: Ethical and responsible public policy business practices

Rationale: this principle stresses the need for companies to be consistent in their public and private policy interactions with other stakeholders on AtM issues (although clearly it is a universal principle for companies). The concern here is that publicly companies may be open to policy efforts to facilitate AtM, but in private, they may be engaged in efforts which obstruct such efforts. This principles aims to foster trust between companies and other stakeholders

Possible actions to demonstrate compliance with principle (max 3-5?):
= Company is transparent on its position on key AtM issues, and can demonstrate how this is aligned with public policy activities either directly or via trade associations
= Company can explain the reasons for apparent inconsistencies in its private and public policy positions on specific AtM issues should these arise

Principle 6: Facilitate access to existing drugs/medicines

Rationale: this principle focuses on a company's existing marketed products, and aims to encourage companies to consider ways to facilitate physical access to these, either through creative approaches to granting access to the production of the drugs and/or through sustainable pricing mechanisms that make them more affordable. Included here is also the recognition that approaches centred around discounts and donations may in some instances, be useful, although it is critical these are managed to be sustainable.

Possible actions to demonstrate compliance with principle (max 3-5?):

= Approaches taken by the company to facilitate physical and affordable access to their existing drugs e.g. voluntary licensing, non-enforcement of patents, preferential pricing & discounts, donations etc.
= Involvement in innovative, creative pilot initiatives exploring different business models/ways to facilitate access e.g. bottom of the pyramid approach

Principle 7: Facilitate access to new drugs/medicines – research & development that takes into global disease burdens as a way of prioritising efforts

Rationale: this aims to encourage companies to consider their drug portfolio within the broaden context of global health needs. Not only will the companies be helping to address health issues of greatest need, as their products are truly deemed to add value, they should also find themselves to be in a beneficial position business wise

Possible actions to demonstrate compliance with principle (max 3-5?):
= Has R&D efforts and/or marketed products which are targeted at the top global disease diseases
= Has R&D efforts and/or marketed products which are targeted at disadvantaged, underserved communities e.g. those living in poverty, childhood and maternal health, genetic diseases etc.
= Has adapted and reformulated medicines to take into account local situations, so as to maximise their usage and effectiveness

Principle 8: Facilitate access to new drugs/medicines - IPR

Rationale: this principle acknowledges the importance of IP for the drug industry in terms of simulating R&D, and the role this regime can play in influencing access to medicines. It does not take a view on the relative role of IP in facilitating in access, rather it just acknowledges it may play a role, however large or small that may be. It seeks to encourages companies to explore innovative and creative ways of ensuring it is rewarded for its efforts whilst not acting as a significant access barrier

Possible actions to demonstrate compliance with principle (max 3-5?):
= Company is involved in pilot initiatives which explore innovative, creative ways of ensuring reward for R&D efforts whilst facilitating access to its new medicines
= Company has adopted practices which take a more flexible approach to IP and facilitate access to its new medicines

Principle 9: Facilitate access to new drugs/medicines – appropriate and sustainable pricing, discounts and donations

Rationale: this principle acknowledges the importance of pricing in ensuring AtM strategies are sustainable in the long run for the company and society. As new medicines are likely to be more effective than the existing ones, or make new treatment options, ensuring they are affordable is particularly critical. As the medicines are new, yet to be marketed, it encourages companies to explore new business models with regards to pricing. Included here is also the recognition that approaches centred around discounts and donations may in some instances, be useful, although it is critical these are managed to be sustainable

Possible actions to demonstrate compliance with principle (max 3-5?):
= Company is involved in pilot initiatives which explore innovative, creative ways of ensuring affordable access to new medicines whilst being rewarded for its efforts e.g. high volume/low price
= etc.

Principle 10: Commitment to being transparent and open about approaches to facilitating access to medicines and how effective they have been

Rationale: this principle is a universal one, but is particular critical for this issue. Companies should be transparent about the extent to which this issue is relevant to them, and the approach they are taking to managing it. It seeks to encourage companies to approach reporting in a strategic, systematic way, providing quality disclosure which is useful and meaningful.

Possible actions to demonstrate compliance with principle (max 3-5?):
= Company explicitly reports on its position and approach to this issue#
= Company's reporting is clear, systematic, useful, providing meaningful insight
= Balanced and fair reporting in terms of policies and systems, and performance (using appropriate quantitative and qualitative measures, input/process/output/outcome KPIs, trend reporting etc.)