14/15 Belgrave Square London SW1X 8PS Telephone: +44 020 7565 7190 Facsimile: +44 020 7565 7191
E-mail: admin@bioindustry.org Web: http://www.bioindustry.org

Draft BIA Response to Draft paper for Consultation dated 19 September 2007

"Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines"

The Bioindustry Association ("BIA") is the trade association for innovative enterprises in the UK's bioscience sector. The BIA represents over 300 members, the majority of whom are actively involved in research and development of products designed to improve human health. The BIA is active in representing this industry sector in communications a wide range of audiences. It is responding to the draft guidelines (the "Guidelines") identified above as, whilst it supports the objective of the Guidelines, it is concerned that as providers and potential providers of medicines, biotechnology companies will be covered by the Guidelines and the interests of its members would be prejudiced by adoption of the Guidelines in their current form.

Three broad themes emerge from the Guidelines:

- they are discriminatory against the pharmaceutical and biotechnology industry;
- they would place undue burdens, for example, in terms of corporate governance on SMEs which are the majority of the membership of the BIA; and
- they do not reflect commercial reality.

The BIA agrees with the Special Rappoteur's view that the primary responsibility for enhancing access to medicines must be placed on individual states themselves. The BIA encourages the Special Rapporteur to identify more precisely the positive and negative impacts that individual States have said pharmaceutical companies have on the ability of governments to realise "the highest attainable standard of health for individuals within their jurisdictions" and also to broaden the types of companies in respect of which this question is asked of governments to avoid any perceived discrimination against the pharmaceutical industry.

Also, the BIA encourages the Special Rapporteur to engage more with representatives of the biotechnology industry, both directly with companies and through trade associations to assist in the production of the next draft Guidelines. The BIA would be happy to work with the Special Rapporteur to this end.

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Turning to the substance of the draft guidelines and the general points made above:

The Guidelines are discriminatory

BIA acknowledges that access to medicines is an important issue. In order to encourage economic and political development of poor nations, BIA recognises that improving the overall health of citizens in such nations is crucial and that new improved pharmaceuticals is one way in which to achieve this. BIA further acknowledges that access to new, improved pharmaceuticals creates tension between on the one hand the need to encourage innovation by allowing innovators to earn a return on the significant investments made to develop such new products and on the other hand those countries where citizens are not able to afford a fair market price for the new pharmaceutical.

However, focussing on the pharmaceutical industry is not, in the BIA's view, productive and is discriminatory in itself. Many industry sectors contribute to proper access to medicines (for example, from sectors making and selling treatments through the distribution sector to companies building infrastructure to allow delivery of treatments). The Guidelines should apply to any industry sector whose activities affect access to medicines.

Therefore, to the extent that the Guidelines were to be approved, the BIA sees no reason why they should not apply broadly to **all** companies operating in "low and middle income countries" and whose activities impinge upon access to medicines.

The makeup of the "pharmaceutical industry" sector

A high proportion of the membership of the BIA are SMEs. The BIA is concerned that the Special Rapporteur does not acknowledge the diverse makeup of the pharmaceutical/biotechnology sector and may be proceeding on the basis that the Guidelines would apply only to large multi-national companies with substantial resources. This is not the case; many of the companies that operate in the biotechnology sector will not possess the resources to carry out many of the material proposals in the Guidelines. For example:

- The recommendation that all companies engage in the UN Global Compact is not realistic.

- The management guidelines again are unrealistic for the majority of the BIA's members. To implement such an additional tier of policy within the management of an SMEs is a significant burden.

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- The provisions relating to lobbying and financial support are too broad in scope and again place unreasonable burdens on SME companies. Further, certain arrangements will be commercially sensitive and their disclosure may be prejudicial to compliance with rules regulating the manner in which listed companies can operate in relation to price sensitive information.

- The requirement for all companies to become involved in the support of research into neglected diseases again makes unrealistic assumptions as to the resources of SMEs operating in this industry sector.

Intellectual property and drug pricing/reimbursement

The BIA believes that certain of the Special Rappoteur's points are rightly made and considers that, on the whole, its members would not have problems in abstaining from lobbying for TRIPS-plus standards in States or in supporting countries seeking to validly utilise the provisions found in Article 31. However, the Special Rappoteur may not recognise the balance being struck in the TRIPS agreement between fair protection for the research investments made by innovative companies and the rights of a State to promote access to medicines and public health. In particular, we consider that, in relation to compulsory licensing, it is reasonable for industry to insist upon, and lobby for, measures to be taken by States issuing such licences that are adequate to prevent cheaply made medicines finding their way back into the market in developed countries.

The question of not enforcing either data exclusivity or patent rights is one that should be taken on a case by case basis and further policies of not filing patents in certain countries neglects to recognise that a patent term is twenty years and much can happen to the status of a State within this time period. The concept of companies entering into non-exclusive voluntary licences is also one that should be applied on a case-by-case basis. There is no rationale, nor any justification for a widespread program of non-exclusive licensing across all companies' portfolios of products. The same comments apply to technology transfer agreements with companies within low-income and middle-income countries.

Further, any voluntary system of not filing patents or extending patent duration in states currently defined as low-income and middle-income needs to precisely identify those countries included in such a scheme, make provision for regular reviews of any list of countries so produced and also indicate the sanctions for companies found not to be adhering to the policy.

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The BIA agrees that differential pricing policies can be effective in addressing certain specific needs but again, no justification can exist to apply such policies across all products. Such a policy is open to serious abuse and could/would lead to the creation of an international "black" parallel import trade.

The Special Rapporteur gives no credit to the patent system for the encouragement of innovation and also the disclosure of useful R&D information. There should be recognition that part of the quid pro quo for the grant of a patent monopoly right is that the inventor discloses valuable information within the patent document. Patent documents have become an increasingly important source of primary research information.

Over and above the points made above, any of these schemes would need careful assessment as to:

- the ability (in terms of infrastructure and resources) of the State in question to take advantage of any concessions being offered;

- the need for any of the particular schemes/products within the State in question; and

- the potential for the transfer of products out of the country into which the rights and/or products are being transferred.

Regulatory issues/counterfeiting

In general terms the BIA agrees with the Guidelines as they refer to promotion and marketing, public private partnerships conduct of clinical trials, combating corruption and counterfeiting. However, there should be recognition that primary responsibility for a number of these areas, e.g. in setting up adequate regulatory and law enforcement systems rests with States themselves.

Associations of pharmaceutical companies

Guidelines relating to disclosures of lobbying efforts and/or corporate governance insofar as they relate to associations pharmaceutical companies should be restricted to those activities that are clearly associated with access to medicines within low and middle income countries. It should not be a responsibility of each member company to continually police the activities of its association.

The BIA has no doubt that member companies would comply with independent monitoring organisations where appropriate and justifiable but it cannot be incumbent upon pharmaceutical companies to have to set up such organisations.

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Further considerations/commercial realities

The BIA urges the Special Rapporteur to engage with the pharmaceutical and biotechnological industry in order better to recognise the commercial realities faced by companies operating within the pharmaceutical sector. In particular, such considerations would include:

- The public pressure to develop new treatments;
- Utilisation of the capital to be invested wisely and most efficiently;
- Protection of investment in new treatments of which filing patents on innovative treatments and medicines is one aspect; and
- The need to recover funds spent developing new treatments from sales of treatments that are approved for marketing in order to encourage further innovation.

Contact:
Joseph Wildy
EU Public Affairs Manager
jwildy@bioindustry.org