

groups working on the 123 rare and intractable diseases, each consisting of leading clinicians and researchers in Japan. Patients' samples obtained with informed consent are shared among members of the research groups for investigations including biochemical and genetic testing.

Third, although principal investigators and collaborating experts of each research group have changed over the 35 years, knowledge and expertise have been passed on to successive groups for continued research and development.

The government established the Japan Intractable Diseases Information Centre in 1997. This website, frequently visited by medical professionals, patients, and the public, provides general information on the 123 rare and intractable diseases, a list of experts in the research groups, research achievements, and contact addresses of patients' support organisations.

Because there has been pressing demand to include more diseases in the programme, the Expert Advisory Board recently added seven more diseases to the list, totalling 130 specified diseases (as of June 23, 2008).

We declare that we have no conflict of interest.

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## Rare diseases: a role for primary care

We were pleased to see *The Lancet* highlighting the issue of rare diseases (June 14, p 1978).<sup>1</sup> We also believe that rare diseases as a group are an important medical and social issue<sup>2</sup> and that patients' support groups will continue to have a major role

in moving this agenda forward.<sup>3</sup> We were surprised, therefore, to see no mention of the role that primary care can or does have in the care of patients with rare diseases and their families.

We know that general practitioners see a lot of people with rare diseases.<sup>4</sup> General practitioners are well placed to provide patient-centred, holistic care that could mitigate some of the common problems experienced by those with a rare disease. We published an outline version of what good-quality primary care for rare diseases might look like.<sup>5</sup>

Primary-care services would not be neglected in planning strategies for chronic diseases, and nor should they be for rare diseases. Patients, families, and health systems have a lot to gain from their inclusion.

We declare that we have no conflict of interest.

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## The new Access to Medicine Index

The Access to Medicine Foundation's new index set out to improve access to medicines through a transparent, quantifiable comparison of corporate social responsibility for 20 pharmaceutical companies. It has turned out as an attractive new business tool for big pharma. The index has taken a strictly business approach to measuring access to essential medicines, presenting data collected

from the giant pharmaceutical companies while overlooking crucial information from end-users and local consumers (patients) in developing countries.

The core approach of the index, published by a foundation led by a former industry marketing consultant, assesses the pharmaceutical companies on a five-point scale according to criteria developed by a Dutch investment research consultancy. The weakness of the study lies in its "on-paper" approach to measuring the effectiveness of corporate social responsibility programmes. Moreover, the method leaves the results vulnerable to attack. The index is based on information made available by pharmaceutical companies and a few non-governmental organisations, with the largest input coming from surveys of the pharmaceutical industry itself.

Five multinational pharmaceutical companies take the top spots in the index, whereas generic manufacturers languish nearer the bottom of the list, despite doing more to improve access to essential medicines for the world's poor through lowering drug prices. This index might give a financial boost to the big brands and their socially conscious investors, but it cannot achieve its objective of real improvements in access to essential medicine in developing countries.

The aspiration to produce a quantifiable study of corporate social responsibility standards that promotes access to medicines is laudable. However, measuring access to essential medicines is best achieved by looking at both pharmaceutical policy and the view from the ground. Without accompanying data on the effectiveness of pharmaceutical corporate social responsibility policy, the value of the index is, at best, debatable. Having the rules is not the same as playing by the rules. What we need is a comprehensive analysis of industry performance on access to essential medicines that rewards

For the Japan Intractable Diseases Information Center, see <http://www.nanbyou.or.jp/>

The printed journal includes an image merely for illustration

For the Access to Medicine Index see <http://www.atmindex.org/>

impact rather than rhetoric and promotes health outcomes rather than investment incentives.

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In the same week that Pfizer won its legal right to ward off market entry for Ranbaxy's generic version of Lipitor (atorvastatin),<sup>1</sup> the Access to Medicine Index also received media interest.<sup>2</sup> This innovative index incorporates hitherto neglected criteria to rank pharmaceutical companies according to their efforts to improve global access to medicines. These criteria include the affordability and availability of a drug in low-income and middle-income countries; accessibility of generic medication; research and development of vaccines and drugs targeting illnesses found mainly in low-income and middle-income countries; and philanthropic donations. The transparency of the Access to Medicine Index holds promise in creating a public image incentive to promote corporate social responsibility.

Less developed countries have long faced difficulties of accessing essential pharmaceuticals.<sup>3</sup> Yet, issues of equity and access have evaded the public eye in high-income countries. However, with the escalating costs of market-driven health care and domestic disparities in access and delivery, wealthier nations are increasingly attending to corporate ethics.

The Human Development Index conceptually exemplifies how ranking indices might stimulate global consciousness. The Access to Medicine Index could motivate more effective and sustainable commitment because active pharmaceutical-sector involvement was sought, and because there are underlying monetary incentives at stake for an industry dependent

on progressively better informed consumers.

The ramifications of legal proceedings akin to the Pfizer-Ranbaxy case affect availability of life-saving medication in low-income and middle-income countries, but also cost-containment strategies and quality of care in high-income countries. The Access to Medicine Index invokes parallels between efficiency and equity, wider implementation of proven treatments, and innovation to produce cheaper or more user-friendly (eg, combination) therapies. The burgeoning need for these therapies in populous developing countries should be viewed as consumer markets where low-cost, high-volume sales could be profitable.<sup>4</sup>

Incorporating novel strategies such as "out-licensing" can overcome patent barriers to treatment access in low-income and middle-income countries and ensure drug delivery to disadvantaged people that the medication is intended for, while protecting corporate profits in high-income countries where most large pharmaceutical company profits are made.<sup>5</sup>

In a globalising world, traditional static models of health care might need to give way to innovative, dynamic mergers between the values of profit-driven business and doing public good. Tools such as the Access to Medicine Index might be one way to stimulate cooperation between sectors that should not have mutually exclusive aims, edging health care back towards the social good that was intended.

We thank Reshma Roshania for her critical review and comments. We declare that we have no conflict of interest.

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## Registries and RCTs for new interventional procedures

Georgios Lyrtzopoulos and colleagues from the Interventional Procedures Programme (May 24, p 1734)<sup>1</sup> highlight that lack of evidence creates challenges to the introduction of new interventional technologies. Registries have real benefits, but downplaying the role of randomised controlled trials is unacceptable. Registries are about audit of data as submitted, whereas trials are a response to uncertainty over best practice, with complete data being collected.

Registries provide pilot data for the size of randomised trials and document learning curves for new technologies, as in the Endovascular Aneurysm Repair (EVAR) trials in patients with abdominal aortic aneurysm.<sup>2,3</sup> Funding for these trials was conditional on randomisation and careful documentation, which enabled a protocol of fitness and anatomical suitability for the procedure to be followed. In EVAR 1, across the 41 centres, operative mortality was remarkable at 1.7% for EVAR and 4.7% for open repair.<sup>3</sup> A later trial in the Netherlands and Belgium, DREAM,<sup>4</sup> adopted a similar protocol with similar results. Auditing in a registry would not