Accountability of the pharmaceutical industry

M N Graham Dukes

The pharmaceutical industry is accountable on the one hand to its shareholders and on the other to the community at large. These two obligations can, in principle, be met. However, the industry has developed practices that do not consider society, including excessive or inappropriate pricing of drugs, an indifference to the needs and limitations of the developing world, an imbalance between true innovation and promotional activity, interference with clinical investigations, and efforts to mould medical thinking and priorities as a means to enlarge the market. In such respects, the pharmaceutical industry must now be called to order. The industry has shown itself to be sufficiently resilient to adapt to change if society insists on it. However, to influence multinational corporations effectively, the efforts of governments will have to be complemented by others, notably the many voluntary organisations that have shown they can effectively represent society’s public-health interests.

Previous articles in this series have considered the broad role that the pharmaceutical industry has in society. This industry is not merely a provider of drugs, but is now a substantial purveyor of information and persuasion. The cost of the drugs it supplies (and indirectly the cost of its ancillary activities) weighs greatly on public and private purses. In some countries, pharmaceutical companies are major employers, innovators, science financiers, taxpayers, and earners of foreign exchange. In these respects, the commercial interests of a pharmaceutical company could run parallel to those of the community at large. Yet, these interests on occasion diverge, and when they do a solution has to be found.

To whom does the pharmaceutical industry owe a duty?
Accountability of one party to another is not mainly a matter of statute law, though law and regulation can reflect and formalise the relationship. More usually, accountability arises because a particular party has voluntarily taken upon itself—or agreed to do—certain duties, or has simply undertaken these duties over a long period, so that others have come to rely on them.

Two definitions of industry accountability predominate: commercial duty to shareholders; and duty to the community.

In the commercial sense, a pharmaceutical company is obliged to deliver a sound return on investment for shareholders. That return must be adequate to reward investors but also be sufficient to attract new capital when needed. From this point of view, the pharmaceutical industry has done very well. Throughout periods of economic stagnation and even recession over the past 30 years, it has remained highly and increasingly profitable. Mergers have hardly ever taken place because of economic stagnation and even recession over the past 30 years, it has remained highly and increasingly profitable. Mergers have hardly ever taken place because of failing companies; the strong have simply linked up with the even stronger (see article by Henry and Lexchin, published in The Lancet on Nov 16, p 1590).

From the broad social point of view, the pharmaceutical industry has a duty to supply communities with good drugs at an affordable price, and to provide reliable information on them. Accountability of a corporation is argued to be founded in human rights principles. In a narrower interpretation, the industry has legal duties to agencies, such as drug regulatory bodies established by government, to ensure that the public interest is served (see article by Collier and Iheanacho, published in The Lancet on Nov 2, p 1405). In this respect, the pharmaceutical industry is, despite all its achievements, presently under fire. Quality has been maintained and the innovative process has most certainly continued, but critical questions have been raised, notably about priorities set in research, the level of drug prices, and the manner in which information is provided.

Priorities in research
Publicly funded programmes are underway to develop drugs for disorders that affect the world’s poorest people. These programmes show the extent to which industrial science has neglected this unprofitable area, instead companies have developed drugs for affluent societies that can pay for them. It is hard to see that the worldwide pharmaceutical industry—if is to be judged accountable to society—can be said to be discharging its duties adequately as long as it continues to neglect the desperate needs of the world’s poorest populations.

Drug prices
Drug pricing has become a contested issue in poor and affluent countries. In developed countries, a new drug is generally sold at the ex-factory price, which is 30 times or more of basic manufacturing cost. However, cost of drugs has become one of the substantial elements in costing of public health care, to the point at which it is increasingly difficult to sustain adequate services. However, the issue is of much greater importance in the developing world, where lifesaving products are, as a rule, financially out of reach of most people who need them. The solution to this problem is less likely to lie in donations, most of which have little overall effect and do no lasting good (see article by Henry and Lexchin, published in The Lancet on Nov 16, p 1590), than in a general readjustment of the manner in which drugs are priced and sold across the world. Major corporations that negotiate with international agencies for bulk contracts in the developing world have found it possible to reduce their prices to 5% or less of those maintained elsewhere, which has been shown with vaccines and oral contraceptives.
and there is no reason to believe that at these vastly reduced prices corporations are selling their products at a loss. What is more, when prices of drugs for poor populations are cut, the volume of use has not been shown to greatly increase.

The much-repeated argument from pharmaceutical companies, that high drug prices are mainly attributable to research costs, merits cautious scrutiny. With publicly available data, we can ascertain that costs of advertising and promotion generally much exceed research expenditure. Furthermore, industrial research usually benefits from public support, either in the form of tax breaks or as direct scientific input. For example, development of the anticancer drug paclitaxel, marketed by Bristol-Meyers Squibb, was actually funded by the American taxpayer through the National Cancer Institute.

**Drug information and promotion**

The self-evident duty to tell the truth about medicines has again arisen as a result of the pharmaceutical industry having assumed, in the course of the 20th century, such a dominant role in providing drug information that the community has become heavily dependent on it. This role of the industry has been discussed in the first article in this series by Collier and Iheanacho (Nov 2, p 1405).

**The need for a balance**

Ideals about public health and welfare coexist with an increasingly vigorous commercial and competitive creed, and can be overshadowed by it. A fair proportion of people in any western country today have an interest in the financial well-being of the drug industry, either as workers, investors, or as pensioners indirectly dependent on the industry’s performance on the stock market. The difficulty arises when financial performance is at all dependent on practices that might seem to betray the industry’s broader duty to contribute positively to health care. The constant flow of new drugs, including many which contribute little or nothing new to health care, promotional pressure on doctors to prescribe new drugs (generally more costly than the previous product), and the setting of prices at the highest level which a market will bear can all be criticised from society’s point of view, but are they healthy in a commercial sense? In business, after all, a truly solid future is one based on supply of necessary goods at fair prices. No one would benefit if the pharmaceutical-industrial edifice as a whole ever collapsed; but it is surely high time to consider how a new and better balance between health and commerce can be found.

**Problems with surveillance**

To make the pharmaceutical industry accountable to communities is becoming ever more difficult. One reason for this difficulty is industry’s ability to disarm criticism. Alongside direct corporate and industry-wide publicity, influence on professionals and opinion makers has been exerted through associated bodies, which project an image of neutrality and are not immediately recognisable as being associated with industry. The Tufts University Center for Drug Development (http://csdd.tufts.edu/), a powerful lobby for acceleration and simplification of drug approval procedures in the USA, is one such example. The Office of Health Economics (http://www.ohe.org) in the UK has done much to defend drug prices, and sometimes other organisations have propagated drug use in particular areas, such as use of oestrogens in the menopause: the Wilson Foundation, financed by the Ayerst Company, was active in the USA from 1960 onwards; the International Health Foundation, financed mainly by the Organon Company in Europe, was active from about 1969 onwards. The overall effect of such efforts of public relations has clearly been to divide and disarm opposition in the community.

A second element now complicating defence of the public interest is the sheer size of companies, which endows them with a remarkable ability to influence even western governments (see article by Abraham, published in *The Lancet* on Nov 9, p 1498).

A third complication is the multinational character of corporations that now dominate the pharmaceutical market. A purely national company is subject to the dictates and sanctions of national law; by contrast, a multinational corporation may operate under 50–100 systems of law. In the health sector, in which public money is in short supply, a national government faced with such extraterritorial complications is likely to find itself unable to assess pricing issues or take corrective action.

**Governments and intergovernmental organisations**

In the past, when the commercial interests of the pharmaceutical industry—or of a particular company—have conflicted with those of the community, it has generally been national governments that have called companies to account. Regulation, designed to ensure that drugs are only marketed if they are efficacious, safe, well-made, and honestly promoted, has proved very necessary in the 40 years since the thalidomide disaster. The issue of drug regulation has been discussed in this series by Collier and Iheanacho, published in *The Lancet* on Nov 2, p 1405.

Domestic drug regulation initiatives have not been united across the globe, have not served as the world community’s counterpart to the multinational companies, have not been able to deal with these large firms on an equal footing, and have not set demands or called the industry to account when necessary. Regionalisation of drug policies, most advanced in the European Union, is undoubtedly a step in the right direction, yet it still has far to go. Even in Europe, standards and policies still vary, whereas at the international level, disagreements and criticisms are encountered with respect to issues such as the high-proportion of me-too drugs presently being accepted, the growing emphasis on speed of approval, and the high proportion of hastily approved drugs that subsequently show serious safety problems.

WHO, in theory, is the spearhead of choice when dealing with global health issues. The organisation has always undertaken excellent technical work in the area of drug policy and regulation, but the world community has never endowed it with the means to take effective regulatory or legal action, and even within its limits it has not always done its best. Former Director General of WHO, Haldan Mahler, provided firm leadership with respect to drug issues for a time, but his term was followed by a period of neutrality. More recently, WHO has been burdened with the notion of partnership with the pharmaceutical industry, a synonym for a relationship in which the flow of industrial money into an impoverished organisation could at any time come to weigh more heavily than courage and high public principles.

**Approaches for today, and tomorrow**

Whatever the structural drawbacks in formalising of industry’s accountability to world society, there are hopeful signs. The one most important development in
this area during the past 12 months has been the sudden growth in public awareness of the issues entailed. For example, a great, worldwide public outcry put an end to the attempt, by a group of multinational companies, to block the South African government’s attempt to provide low-cost generic drugs for people with AIDS.\(^\text{17}\) The notion has taken root that industrial power is sometimes being abused and that alertness is called for.

The potential worldwide market for drugs is large enough to lend support to a healthy and creative industry without need for commercial abuse. What is more, the pharmaceutical industry has shown in the past that it is resilient enough to adapt to change when the community demands it. It has learnt to live with a level of regulation that would have been unthinkable 50 years ago. Bowing to revelations and public pressure, since 1970 the industry has all but abandoned the practice of undertaking unethical clinical research in prisoners or people living in developing countries. Companies have begun, albeit somewhat grudgingly, to move towards more strongly differentiated pricing designed to serve the world’s poor.

A major challenge that remains is to reduce the imbalance between promotional and research expenditure, perhaps moving progressively towards a system in which health systems themselves provide the bulk of new drug information rather than indirectly funding, as they presently do, an army of company salesmen. To judge from figures currently available, a modest reduction in advertising would make available funding sufficient to strikingly increase research expenditure.\(^\text{17}\)

Critical reaction to recent events has been engendered less by governments or intergovernmental agencies than by activists working together in voluntary but influential organisations that seek to serve the public interest. Médecins Sans Frontières has committed itself strongly to action in this area, especially with respect to failure of the multinational industry to serve the needs of the developing world, either in terms of product development or pricing.\(^\text{15}\) Another organisation, Health Action International (http://www.haiweb.org), has for a decade provided firm but thoughtful pressure on industry and governments and formulated well-deserved and constructive criticism of drug policy and practice. A small group known as Healthy Skepticism (http://www.healthy skepticism.org; formerly the Medical Lobby for Appropriate Marketing) has consistently and insistently drawn the attention of producers to promotional malpractice, calling for (and often securing) correction. These organisations are small, but they are capable; they bear malice towards no one, and they are incrustably honest. If industry is indeed persuaded to face up to its social responsibilities in the coming years it may well be because of these associations and others like them.

Conflict of interest statement
None declared.

References
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