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EDITORIAL

Implications of pharmaceutical cost controls for medical research

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Changing Environment

Major changes are taking place, both globally and nationally. We are suffering recession in the developed world, which has also significant impact on third world countries trying to survive and improve their standing in the world. New, important economies are emerging in South East Asia. These issues must be faced in the context of pressures on governments of the Western World. One symptom of these changes is that health care is being reviewed in terms of expenditure, patient demands, expectation and shifting demographics. There is a growing elderly population in the developed countries with the associated demands on resources contributed to by a decreasing workforce.

In the USA, particularly, health care costs as a percentage of GDP are running out of control. They are currently at 14% but will reach 20% by the end of the millennium, if some action is not taken. The Clinton government is currently reviewing its health care system and has appointed a task force under Hilary Clinton. Its proposals are likely to have far reaching consequences if approved by Congress. This has already contributed to the depression in pharmaceutical company share prices in the USA. Health maintenance organisations (HMO's) are an increasingly powerful source, influencing the delivery of health care to its members. They are able to purchase health care from providers, negotiate prices directly and determine treatment protocols based on cost effectiveness.

In Europe, recession is also forcing governments to examine health costs and in particular, drug expenditure as an easily identifiable factor in containing costs. In the UK the NHS is subject to the same pressures and the changes initiated by the Conservative government are having a substantial impact. The decentralisation of control to the provider is a device intended to contain costs. This has been effected by introducing the purchser-provider concept, to much consternation in the medical profession. We now have trust status hospitals and GP Fund Holders. They are responsible for getting the best value for money for their patients. Again, drug costs are an easy target for scrutiny.

Changes in Society

As ever, patient expectation continues to increase. The emergence of new diagnostic and operating techniques are often, though not invariably, more expensive. Changing demographics means that more elderly patients have more degenerative diseases, requiring more care and treatment. Their consumption of drugs will also increase as a consequence. As new therapies emerge, patients can be expected to demand access to them. Unfortunately, patients do not necessarily understand the need for rationing. Emergence of new illnesses such as AIDS and immune deficiency from other sources such as transplantation surgery will increase drug consumption, one example being the increase in tuberculosis as a consequence of immune deficiency.

Government Attitudes

Health care must be controlled otherwise it could consume every penny in the exchequer. This is not new and rationing has been practised ever since the NHS was introduced. However, the pace of change has increased and significant initiatives must be taken to meet cost containment targets. There is more public scrutiny of government proposals but as always, governments are subject to public opinion. Drug costs are a reasonable target, as measures to control drug prices will be generally well received by the medical profession and patients alike. Acceptable measures are generic substitution and control of industry profits. Unpopular actions are the restriction of, or access to, certain expensive new treatments. There is however, ambivalence in government between controlling drug prices and the benefits accruing from R&D investment by pharmaceutical companies. A successful R&D industry, delivers benefits for the country in terms of employment and revenues from exports. Companies need a satisfactory return on investment and if the environment is hostile to enterprise, investment in R&D will be curtailed.

In "The Health of the Nation" *(1)* white paper, it was stated that "the aim of the Department of Health is to improve the health and wellbeing of the nation and secure

high quality health care for those who need it". It recognises that research is a powerful tool in delivering this objective. Professor Michael Peckham was appointed as director of Research and Development in 1991, to determine a new strategy for R&D. He will advise the Secretary of State for Health on NHS R&D, the health research by non-departmental public bodies the concordat between the MRC and health department and other research bodies (including industry).

Universities

The academic institutes are also suffering financial constraints. This impacts on their ability to develop techniques, perform research and train students. Research costs have been frozen and traditional tenured posts have disappeared. Morale in universities is low, with the negative impact on recruitment of new blood into research and teaching. This weakens these institutions and will have substantial long term impact.

In addition in the UK, there has been a shift in emphasis towards treatment in the community. This will influence the type of patient referred to university institutions for treatment ie, they will be less than representative of the total patient population. In addition, because of the need to pay overheads, university based research will be much more expensive than community based research. The quality and type of patient has always been an issue for deciding on placement of studies in university settings. However, with the considerable improvements in standards within the community, the attractiveness of clinical research in academic establishments is diminishing.

Regulatory Environment

This also is changing. There will be an announcement by the European Community about a central agency for reviewing and approving regulatory dossiers, for new products. The location of which, is still to be decided. There will be a multi-state procedure for approving dossiers and this will be binding on member states.

The regulatory environment over the years has become more demanding, under principally, the influence of the US Food & Drug Administration. These increased demands make the costs of performing clinical research much more expensive than in the past. Furthermore, the provision of safety and efficacy data may no longer be sufficient. The real economic impact of new medicines may have to be assessed. Also, the true measure of clinical superiority over a comparative agent must be discussed. Statistical superiority alone, is not sufficient. There has to be evidence that this translates into a longer term benefit, such as effects on mortality or morbidity.

Industry Pressure

There is a clear potential for diminishing commercial return, associated with spiralling R&D costs. These adverse circumstances, together with the diminishing commercial potential for non-novel compounds (so called me-too's), make the research environment particularly problematic. By its very nature, drug discovery is speculative with only 5 in 4000 compounds screened in pre-clinical testing entering clinical trials *(2)*. There is only a 20-1 chance of success, when a compound is first tested in man ie, a 5% chance that this product will survive throughout the clinical development phase till market approval *(3)*.

R&D costs are funded usually from existing profits, anything that harms profits will impact on R&D. In 1990, Merck and Glaxo, the industry's two most profitable firms, were also its biggest. Yet in recent months, both of these companies (as with others) have witnessed a massive reduction in profits or share prices.

Governments are pressing for generic substitution, even worse, therapeutic substitution is being promoted by some health advisors.

Adaption to Change

In order to continue to do business as profitably as possible, strategic alliances between companies and mergers/takeovers are becoming more frequent. New treatments are becoming more elusive and costly to develop. This will demand collaboration between companies. With new technologies being so expensive, such as biotechnology or new diagnostic techniques, companies will have to develop an expertise in this area or merge/link with companies experienced in these fields.

Improvements in efficiency in both R&D and marketing are needed for companies to survive. This, in turn will mean more focused programmes more clearly targeted to the evaluation of treatments. There will be decreasing opportunities for funding the less focused research that may be of more interest to academic investigators.

Other means of decreasing R&D costs will be the shift toward community based research. This, in the short term, will help avoid such expenses as university levies, which are charged to cover overheads.

Psychiatric Research

In the "Health of the Nation", mental illness was identified as a priority area for research. The following projects have already been commissioned:- (3)

- COMMUNITY CARE OF THE SEVERLY MENTALLY ILL
- ASSESSING MENTAL HEALTH NEEDS OF THE POPULATION
- MENTAL HEALTH OF NHS WORKFORCE
- TRAINING PACKAGES FOR USE IN PRIMARY CARE AND THE COMMUNITY

Whilst all of these are praiseworthy none of them tackles the major therapeutic issues of efficacy, safety or the economic benefits of treatment. It will no doubt be left to industry to introduce and evaluate new medicines. It is notable that industry sponsored trials have contributed to huge amounts of data on standard comparative agents. This has given prescribers of the older agents greater knowledge and confidence of their actions.

Also, within the industry, it is clear that there is a move towards cost containment by either decreasing or minimising price increases and aiming for increased profits through volume increases. Difficult decisions are having to be made, such as rationalisation of research programmes and the shedding of personnel. Glaxo and Merck, whilst still profitable, have already begun this process.

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In 1992/93 in England, the estimated annual R&D expenditure was around £2 billion, of which industry contributed around 60%. This percentage may well decrease, with significant impact on existing research bodies.

The Future

Pharmaceutical Research and Development will survive. However, some companies will not. The question is; "is size important in determining the probability of survival"? Obviously not, though the big companies will be better able to fund the enormously costly research programmes. In order for companies to survive they must respect the needs of the health care providers, who in turn, must understand the dynamics of the pharmaceutical R&D environment.

New drug discoveries will ultimately improve both the quality and quantity of life. Governments must recognise this and allow the pharmaceutical industry sufficient return on investment, to continue to identify new and useful products. It is in everyone's interest to have a vigorous and successful pharmaceutical industry. The aim is to produce new treatments for the benefit of mankind. Therefore, a reasonable return on investment must be allowed. The industry will adapt, as will government. The days of high profits for modest clinical gains are over. The profits will become more modest as the prices are curtailed, unless substantial economic data can support premium prices.

The UK government is closely addressing its pharmaceutical pricing policy. This will have a substantial impact on the profits from such medications. In turn, this has led to a market decrease in research. It has been suggested that a similar proposal be adopted for antidepressants. A recent government sponsored publication in the British Medical Journal by Song *et al (4),* suggested that the tricyclic antidepressants were drug of first choice and the new specific serotonin uptake inhibitors had no real advantages despite high costs. It is possible, therefore, that this will have an impact on reimbursement terms. Undoubtedly, industry will shirk from conducting more research into depression if the commercial return is sufficient. The medical profession has been slow to react to such initiatives. Perhaps, it does not understand, or even supports these government plans. Either way, the source of funding psychiatric research will be adversely affected.

References

1. The health of the nation: a strategy for health in England. London: HMSO, 1986.
2. PMA, In development AIDS Medicines, Drugs and Vaccines Survey Report 1991.
3. Research for health: a progress report on the NHS R&D strategy. Journal of the Foundation for Science & Technology 1992; Autumn.
4. Song F, Freemantle N, Sheldon TA, *et al.* Selective serotonive reuptake inhibitors: meta-analysis of efficacy and acceptability. BMJ 1993; 306: 683-7.

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