

APG

The NHS:

New and Future Directions

A Paper from the American Pharmaceutical Group

July 2000

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Executive Summary – Key Conclusions and Recommendations

- The work of the Pharmaceutical Industry Competitiveness Task Force stresses the NHS' role in supporting the “international competitiveness of innovative medicines” produced by pharmaceutical companies in the UK. This is not just a question for PICTF. The APG urges the Government to make it part of the national plan for the NHS. Future reform must generate a pro-innovation culture where the NHS becomes an informed, sophisticated and effective user of medicines.
- Additional money for the NHS over the next three years will address the underfunding of health care in the UK compared to other European countries. The real comparisons that matter, however, are in health outcomes. For this reason, the APG believes that the Government should commit itself to making UK outcomes in coronary heart disease and cancer - which the Government has made its own priorities - among the best three in Europe by 2010.
- In a modern national health service “therapeutic conservatism” needs to be turned on its head. The Government should make clear that one of the purposes of increasing NHS funding is to ensure that it can fund innovative medical technology. It should ensure that the Service is managed at every level in a way that understands the potential of new medicines and is capable of using them effectively.
- The national plan should be accompanied by explicit criteria against which its impact can be measured. These should not focus on inputs, such as numbers of staff or new hospitals, but on outputs, and principally on improving key outcomes in health.
- National Service Frameworks should be rigorously implemented to ensure that the current variations in practice and outcomes are overcome and standards raised. The APG would like to see the Government place greater emphasis on keeping NSFs up to date, so that they lead the drive towards innovation. It would be counter-productive to establish national standards of care at yesterday's level of knowledge and experience.
- NICE, at least on the basis of its early appraisals, has shown as much preoccupation with cost as with promoting innovation. The national plan should be a clarion call for innovation in the NHS' use of medicine – and an opportunity for the Government to channel political will behind an objective that will deliver real benefits in improved health outcomes and better patient care.
- The Government should make NICE fully independent. The requirement on NICE to take account of “available resources” should be dropped: A body such as NICE should make its judgements solely on the basis of whether the technology involved provides genuine added-value for patients against alternative available means of treatment. This judgement should be objective, scientific and transparent and made without reference to affordability.

- The Government should consult upon and then publish a set of criteria against which the performance of NICE should be judged. These might include, for example, a requirement to promote innovation, and to make explicit NICE's role in improving health outcomes in key disease areas.
- The APG also believes that a standing committee of MPs and Members of the Welsh Assembly should be established with the powers to interrogate NICE about its work, and about specific decisions. The Annual Report of NICE should also be subject to a full debate, in government time, in both the House of Commons and the Welsh Assembly.
- The APG would like to see the concept of innovation-related financial incentives introduced into the NHS. These need to operate at the level of primary care organisations so that these organisations benefit in their budget where they use medicines, medical technology or other innovative practices effectively both to improve the quality of patient care and secure value for money. Such incentives might, for example, be linked to the implementation of key elements in national service frameworks.
- The future structure of the NHS should evolve on the basis of meeting the needs of informed patients. That people are becoming better-informed about their health and more knowledgeable about the treatment options available is to be welcomed. We recognise that this will create new pressures, both on clinicians and on the overall level of funding available. However, these considerations are outweighed by the fact that a modern health service should be able to provide for modern needs. The national plan should establish that the aim of Government policies towards the NHS should be to meet informed need rather than limit demand.
- The APG warmly welcomes the Government's commitment to examine the case for the progressive deregulation of pharmaceutical price and profit controls. The gradual deregulation of the PPRS is not only to the long-term benefit of the pharmaceutical industry in this country. It is consistent with the policy agenda that the Government has established and will be taking forward through the national plan. Reform in this area is, and should be seen as, an important part of the modernisation of the NHS.
- There is still no real sense that the pharmaceutical industry is seen as a partner in the modernisation of the NHS. There has been, for example, no formal consultation with the industry about, or close involvement with, the national plan. This is regrettable given the emphasis on partnership that the Government otherwise stresses. We hope that this will change. For our part, the APG is wholly committed to working constructively with the Government and the health service to promote innovation and change in the interests of patients.

1. Introduction

1.1 This is a time of intense debate about the future of the National Health Service. A “national plan” for the future development of the NHS is being set in place. At the same time the results of recent new policies, such as primary care groups, national service frameworks and the National Institute for Clinical Excellence have still to be evaluated. The people the NHS serves are different in outlook from when it was first created – better informed on the whole about health issues, more assertive and conditioned by higher expectations. The Secretary of State for Health, Alan Milburn, has argued that the NHS needs to prove itself to each successive generation. Most people continue to believe strongly in the NHS and what it stands for, and admire the staff who make it work. Yet disillusion with the ability of the NHS to deliver the highest quality of health care is growing.

1.2 This paper, presented by the American Pharmaceutical Group, is intended to contribute to the debate about the medium and long-term future of the NHS. It is written from the perspective of 12 multinational pharmaceutical companies, all of whom have a strong interest in the NHS. The NHS constitutes most of our market in the UK and, though this market is small in global terms, what happens here has a disproportionate impact upon the decisions taken in our companies. To take an obvious example, the judgements that NICE makes about our products will have an effect well beyond what they might mean for the use of those products in the NHS. “When NICE speaks, the world listens”, was apparently the view of one recent visitor to the Institute. This is our own experience too. This is why it is damaging to the UK when the messages crossing the globe from NICE are negative ones.

1.3 Less well-known to the public than the national plan, but no less important to our Group, is the work of the Pharmaceutical Industry Competitiveness Task Force (PICTF). This joint government-industry body, which is due to report to the Prime Minister by Spring 2001, is looking at a range of issues that make the United Kingdom a more or less attractive environment for the pharmaceutical industry to invest. Our companies have their roots in the United States. But we are all global businesses and operate and invest across the world. The UK has long been a favoured location – partly because of language, partly because of a strong scientific heritage, partly because of this

country's reputation for efficiency in licensing medicines. The APG companies have a very strong presence here, accounting for a third of the medicines provided to the NHS and over £500 million of spending on R&D every year. The purpose of the APG is to maintain and build upon this record.

1.4 PICTF will look at factors that are relevant to the competitiveness of the UK as a location for pharmaceutical investment. These include the clinical research infrastructure, intellectual property protection, the European medicines licensing regime and the role of the home market. There are many important issues here, such as the need to streamline and standardise the process for funding and organising clinical trials in NHS trusts. We suggest, for example, that trusts might wish to appoint managers whose specific task it is to liaise with pharmaceutical companies over trials. The danger otherwise is that the NHS, and therefore the UK, becomes a less favourable place for the industry to conduct trials at the later stages of medicine development. Patients will lose out from this.

1.5 The impact of the "home market" on industry competitiveness should be stressed in particular in the context of the NHS national plan. Most prescribing in this country takes place through the NHS and it therefore constitutes most of the home market. Those elements of the national plan that are relevant to the way in which the NHS approaches prescribing issues are also relevant to the work of PICTF. The inter-relationship between the two projects should be recognised.

The terms of reference of the Pharmaceutical Industry Competitiveness Task Force stress the role of the NHS in supporting the "international competitiveness of innovative medicines produced for the home and international market by the R&D industry in the UK". This is not just a question for PICTF. The APG urges the Government to make it part of the national plan for the NHS. Future reform must generate a pro-innovation culture where the NHS becomes an informed, sophisticated and effective user of medicines.

2. Funding Innovation in the Health Service

2.1 In his Budget in March 2000, and reaffirmed in the recent comprehensive spending review, the Chancellor of the Exchequer announced a substantial increase in funding for the NHS over the next four years. This will amount to an annual average increase in real terms of 6.1 per cent and represents a significantly larger annual increase in funding than the NHS has been used to over its 52 year history. It will take health care funding in this country, measured as a proportion of national income, well in the direction of the European average, in line with the Government's commitment.

2.2 The APG welcomes the additional money being provided for the NHS. It has long appeared an anomaly that one of the richest countries in the world funds a significantly lower level of spending on health care than comparable European countries such as France, Germany or the Netherlands. Narrowing the funding gap represents an important step towards improving the UK's performance in key measures of health.

Additional money for the NHS over the next three years will address the underfunding of health care in the UK compared to other European countries. The real comparisons that matter, however, are in health outcomes. For this reason the APG believes that the Government should commit itself to making UK outcomes in coronary heart disease and cancer - which the Government has made its own priorities - among the best three in Europe by 2010.

2.3 The Secretary of State for Health has indicated that he sees the main spending priorities going forward as recruiting more staff and improving the fabric of the NHS. Extra money will also be needed to correct the financial deficits that the NHS is facing. It is certainly true that some of the constraints that the NHS faces is due to a shortage of properly-trained staff. Investment is required in NHS infrastructure particularly, we believe, in information technology. It is also true that if the NHS is to be the high quality and modern health service to which the Government and the public aspire, additional investment will need to be made in medical technology, including new medicines.

2.4 The recent announcement that the first draft of the human genome sequence has been completed has focussed attention on the potential of new medicine. Genomic knowledge is already greatly assisting the process of drug discovery and the pace of development will accelerate in coming years. The discoveries and the medicines that will result will have a profound impact on human health. Diseases currently with no known cure such as Alzheimers or multiple sclerosis can be overcome. Medicines can be developed that are effective in particular patients or which have fewer or no side effects. Scientific advance will make this a reality. The question is whether the NHS is in a position to harness the benefits for the people it serves.

2.5 The impact – and potential cost – of new technology is too often seen as a threat, or at best a “challenge” to the NHS. The prevailing philosophy of health service planners is one of “managed entry”: when a new medicine arrives the first instinct is to find ways of managing or controlling its impact on budgets. It sometimes seems as if the NHS budget is there to be protected against incursions made against it by the cost of medicines. This is, to put it mildly, a curious attitude when those medicines in fact represent one of the most important tools that the NHS has to fulfil its role.

2.6 The Secretary of State argues that the extra funding for the NHS presents a “once in a lifetime” opportunity for reform. That reform needs to embrace a far more positive attitude at all levels of the NHS towards the potential of new and innovative medicine. The health service is notoriously slow at responding to new innovation in medical technology. This may, in part, reflect a natural “therapeutic conservatism” on the part of British doctors. It is also reinforced by a system of spending constraint and tight budgetary control that sees new medicines as a threat rather than an opportunity.

In a modern national health service “therapeutic conservatism” needs to be turned on its head. The Government should make clear that one of the purposes of increasing the budget of the NHS is to ensure that it can fund innovative medical technology. It should ensure that the Service is managed at every level in a way that understands the potential of new medicines as is capable of using them effectively. The first question should not be “what does this cost”, but what is its value to our patients and how can we use it in a way that maximises that value as well as value for money.

3. From a Sickness Service to a Health Service

3.1 As a national *health* service, the NHS leaves much to be desired. In terms of outcomes such as cancer survival rates or mortality from coronary heart disease, the UK lags well behind other countries in Europe. The NHS is not the only factor involved, but it is undoubtedly an important one. The success of the national plan should be judged ultimately on whether it enables the NHS to make a difference in these key areas of public health.

The national plan should be accompanied by explicit criteria against which its impact can be measured. These should not focus on inputs, such as numbers of staff or new hospitals, but on outputs, and principally on improving key outcomes in health.

3.2 The Government has established a target-based approach with the aim of reducing death from cancer, coronary heart disease and stroke, mental illness and accidents. As the APG pointed out in its briefing paper in 1998 *Hitting the Targets*, medicines can play a major part in achieving this strategy. The national plan should pave the way for a more active approach towards prevention in these areas, fully utilising medicines wherever appropriate.

3.3 In the case of coronary heart disease, for example, a wide range of medical therapies are available that attack the causes of this disease. The management of CHD is a complex issue: intervention through the use of medicines is possible at different stages, all of which can significantly contribute towards reducing death from this disease, as well as improving morbidity. There are currently huge differences in performance. The Prime Minister himself, for example, has pointed out the variations in patients at risk from heart disease who receive medicines to control their blood pressure and cholesterol. The national service framework for CHD is designed to tackle this problem. It is comprehensive and contains much that the APG welcomes.

The National Service Framework for coronary heart disease, like other NSFs, should be properly implemented to ensure that the current variations in practice and outcomes are overcome and standards raised. The APG would like to see the Government place greater emphasis on keeping NSFs up to date, so that they lead the drive towards innovation. It would be counter-productive to establish national standards of care at yesterday's level of knowledge and experience.

3.4 The same observations about poor outcomes are also true of cancer and mental illness. Britain has a higher death rate from cancer than either France, Germany or the USA, but a lower spend per head on cytotoxic medicines – important agents that destroy cancer cells. Working through NICE, the Government has recently moved to increase the use of taxanes in England and Wales, for the treatment of breast and cervical cancer. This is welcome, but it starts from a very low baseline. Even if the NICE guidance in respect of these medicines were fully implemented, the NHS would still be some way behind other countries, notably the USA, in its use of cytotoxic agents.

3.5 Mental illness is a further area where there is evidence of access to modern and effective medicines being hampered on grounds of cost. This is particularly true in the case of schizophrenia where access to more modern atypical antipsychotics – a class of drug that has fewer debilitating side effects than older (and cheaper) medicines – is extremely patchy. As a result many patients are being treated with medicines that leave the state of their illness far worse than it needs to be. Although the Government has promised money for the newer medicines, the situation is changing only slowly. The national plan should inject new urgency into tackling this problem.

Initiatives such as NICE and the national service frameworks have been advanced as a way of improving the quality of treatment and care. So far, however, their impact has been limited and NICE, at least on the basis of its early appraisals, has shown as much preoccupation with cost as with promoting innovation. The national plan should be a clarion call for innovation in the NHS' use of medicine – and an opportunity for the Government to channel political will behind an objective that will deliver real benefits in improved health outcomes and better patient care.

3.6 Governments at the centre have long been preoccupied with the size of the drugs bill, seeing it as an area where growth needs to be strictly controlled. The targets for growth that have resulted, and the policies which have flowed from them, have been set in relation to wider budgetary targets and have had nothing to do with the value that can be extracted from spending on medicines. The current Secretary of State for Health has indicated a break with that policy. Mr Milburn has described it as a “naive assumption” that bearing down on the size of the drugs bill is necessarily a good thing. As he told the House of Commons:

“If drugs mean easier, better and quicker treatment for the patient, instead of going to hospital, that is a good thing and if it means growth in the NHS drugs bill, we should welcome it” (*Hansard*, 28 July 1998, col. 158).

3.7 The APG strongly supports the Government’s objective of securing value for money in the drugs bill. There is still too much waste, with some medicines being prescribed inappropriately, or where patients do not complete the full course of their medicine with the result that its impact on their condition is lessened or even negated. We also recognise the important role of generic prescribing in securing overall value for money and creating so-called “headroom for innovation” – in other words freeing up funds from the overall budget for spending on new medicines. Mr Milburn’s statement above raises the issue of both the value and the cost-effectiveness of medicines. This is where NICE enters the equation.

3.8 NICE has been given several objectives. One is to promote “faster access to treatment”. Another is to tackle “postcode prescribing” – the availability of a particular medicine in one health authority area but not another. A third objective is to provide a single authoritative source of guidance for clinicians, whether in respect of a particular technology or more generally through the guidelines programme in the management of a particular condition, amid the welter of (sometimes contradictory) professional guidance.

3.9 All of these objectives are important. From the APG’s point of view, the key role for an organisation such as NICE should be to promote faster access to new medicines, against a background, as we have outlined above, of considerable resistance to innovation within the NHS. The very last thing that NICE should do is make that

position worse, by introducing new hurdles or new delays for patients receiving treatment. A major concern that the APG has is that of “blight”, where health authorities adopt the policy of not using medicines that are being appraised by NICE, pending the outcome of the review. Since this review can take up to or over a year, this means, in effect, slower patient access to treatment – the exact opposite of what NICE is supposed to achieve.

3.10 There is an important job to be done in identifying where medicines are being used inappropriately in the NHS, for example because they have been overtaken by better alternatives, and providing guidance that supports clinicians in moving to more effective means of treatment. Unfortunately, however, the role of NICE has been focused on attempting to demonstrate the cost-effectiveness of new medicines either at the time of, or shortly after, their launch. These are products that have already proved their safety, quality and efficacy through a rigorous licensing process. Economic evaluation of the type with which NICE has been charged can only be meaningful after a product has been in widespread use for several years, unencumbered by the sort of therapeutic caution that pervades the NHS.

3.11 NICE is trying to do the wrong job the wrong way round. The danger is of a pernicious catch-22 that will harm the interests of both patients and innovative pharmaceutical companies: access to treatment is delayed by NICE; yet by delaying access it becomes even harder to build up the sort of evidence about the wider value of a medicine that NICE is trying to measure.

3.12 These fears are being borne out in practice. The evidence from the early appraisals seems to suggest two things. Firstly, that NICE is as much concerned with cost as cost-effectiveness and secondly that its tendency may be to favour well-established technologies, which have more evidence from use in practice to support them, rather than newer innovations.

3.13 The root of many of these problems, we believe, lies in the uneasy relationship between NICE and the Department of Health. NICE is not independent of the Government. Ministers (and the National Assembly for Wales) decide what technologies it should appraise – in contrast to the equivalent Health Technology Board in Scotland.

NICE has been given the role of judging the “cost-effectiveness” of medicines and must make its recommendations in light of “available resources” – thus further blurring the boundary between cost-effectiveness and affordability. While this awkward relationship persists, so too will scepticism that, far from having the aim of promoting new technology, NICE is in fact a further instrument of cost-control.

3.14 If there are constraints of affordability, then this should be for Ministers to decide. Within the larger budget for the NHS promised for the years ahead, the onus should shift even more heavily onto ministers to justify denying patients access to a truly effective medicine on the grounds of its cost. This is why it is important that progress with the national plan is measured against improving health outcomes, in order to provide a context in which those judgements should be made and for those making them held to account. It should also be up to Ministers to ensure that NICE guidance is implemented, especially where health authorities may be concerned that their budgets are insufficient. We welcome the Secretary of State’s decision to earmark funds specifically for the implementation of NICE recommendations.

The Government should make NICE fully independent. The fact, for example, that the Government selects what technologies NICE looks at establishes from the outset an unfortunate conflict of interests. The requirement on NICE to take account of “available resources” should be dropped: NICE should make its judgements solely on the basis of whether the technology involved provides genuine added-value for patients against alternative available means of treatment. This judgement should be objective, scientific and transparent and made without reference to affordability.

In order to underpin the independence and credibility of NICE, more thought should be given to how it is held to account. The Government should consult upon, and then publish, a set of criteria against which the performance of NICE should be judged. These might include, for example, a requirement to promote innovation, and to make explicit NICE’s role in improving health outcomes in key disease areas.

The APG also believes that a standing committee of MPs and Members of the Welsh Assembly should be established with the powers to interrogate NICE about its work, and about specific decisions. The Annual Report of NICE should also be subject to a full debate, in government time, in both the House of Commons and the Welsh Assembly.

4. From Consensus to Change

4.1 The APG believes strongly that medicines should be judged by their value to patients and the NHS rather than their cost. This too, on the basis of statements made by the Secretary of State, one of which we have quoted above, is also the Government's position. An issue for the national plan therefore is how to translate this consensus view into action at the level where patients are treated.

4.2 The creation of primary care groups, evolving over time into primary care trusts, is significantly changing the environment within which treatment and care is provided. The new primary care organisations have been given control of unified budgets, out of which the costs of prescribing medicines must be met, alongside other needs. When this move was first announced, the APG welcomed what was, in effect, the cash-limiting of prescribing, within the total budget. We believe that this provides the basis for moving from central controls over the drugs bill to local decision-making, based upon PCG experience on the ground.

4.3 A recent survey of primary care groups and trusts has been carried out jointly by the National Primary Care Research and Development Centre in Manchester and the King's Fund. Overall, the survey was optimistic about progress at PCG level. It found that, not surprisingly, managing the budgets they have available for spending on medicines is a major concern of PCGs. Most have been proactive in terms of developing policies, such as prescribing incentive schemes and dedicated pharmaceutical advisers, designed to manage prescribing costs.

4.4. The survey also pointed out that many more PCGs were concerned with the cost-control in prescribing than with seeking how they can improve the quality of care they provide to their patients through better management of the medicines they use. The survey authors concluded that this balance should change in the future, with greater emphasis given to quality rather than cost. The APG agrees with this conclusion.

4.5 PCGs have finite budgets and of course it is right that they should be concerned about managing costs, as is any well-run organisation. Equally, it is important to recognise that medicines provide benefits to patients as well as costing money. The challenge for PCGs is how they can maximise the gain for their patients in terms of improved health outcomes from the budget they have available. Often this will involve spending more on medicines where the opportunity exists both to improve outcomes and secure savings elsewhere in their budgets. A problem exists that there is at PCG level no clear incentive mechanism for the group to invest in medicines on the basis that it represents better overall value for money in their budgets.

4.6 The Chancellor of the Exchequer and the Health Secretary have both spoken of “incentives” to reward better-performing parts of the NHS. So far a small “performance fund”, has been established, although this represents only £60 million out of the additional £2 billion being provided for the NHS in the coming year. The performance fund and the idea of incentives should be extended in the national plan. It is not sufficient to point out at the centre that investing in medicines can represent a better overall use of resources. A mechanism for turning words into action is badly needed.

The APG would like to see the concept of innovation-related financial incentives introduced into the NHS. These need to operate at the level of primary care organisations so that these organisations benefit in their budget where they use medicines, medical technology or other innovative practices effectively both to improve the quality of patient care and secure value for money. Such incentives might, for example, be linked to the implementation of key elements in national service frameworks.

5. Less Centralisation, More Deregulation

5.1 Studies of the early development of primary care groups, such as the Audit Commission report *The PCG Agenda: Early Progress of Primary Care Groups in the New NHS* (February 2000) or the more recent survey conducted by NHS Alliance, have shown that some groups are having difficulty in resolving potential conflicts between local and central direction. This does not strike us as altogether surprising: indeed, it is a symptom of what we see as potentially a fundamental tension that goes to the heart of this Government's health policies. Nor is the problem new: the issue was raised, but never satisfactorily resolved, under the previous Conservative Government's health reforms.

5.2 The balance between central control and local autonomy in the "new NHS" is not at all clear. Policies such as national service frameworks suggest a clear centralising agenda. On the other hand, the autonomy granted to primary care groups, and even more so to primary care trusts, will create a dynamic that pulls in the opposite direction. The Health Secretary has responded by talking about "earned autonomy" being granted to NHS organisations, though the implications of this policy need, in our view, to be much more thoroughly explored.

5.3 The APG's view is that policies should move in the direction of more autonomy – less centralisation and more deregulation. We recognise that, in a national health service, there is a desire to reproduce service standards at an equal level across the whole country. The danger in this process is that it leads to a process of levelling down rather than levelling up. At the very least, the onus is upon the Government to show that central direction can lead to levelling up. The evidence so far is not encouraging.

5.4 As we argued above, primary care organisations are, in our view, the right level about which decisions about how to treat patients should be taken. Of course this should be informed by national guidance and this is where the centre has a potentially useful role. It is legitimate to tackle variations in practice since these may reveal inappropriate or inefficient practice. If within a primary care organisation, for example, evidence showed a significant variation among the constituent GPs in their prescribing of antibiotics, this would be an appropriate issue to address at this level. At the same time, the organisation should have the freedom to innovate in how it provides services,

even if the results of that innovation were not simultaneously available to all the patients of all other PCOs. The challenge becomes one of spreading good practice throughout the NHS.

5.5 A further consideration is that patients are themselves becoming more demanding and informed. The Government wishes to respond to this: the Secretary of State has talked about making the NHS a “consumer-centred service sector industry”. It is highly doubtful, if not impossible to conceive, that this could be simultaneously achieved alongside making the NHS more beholden to central direction. If the NHS is to be centred on the needs of its “consumers”, then it is only at the interface with those consumers that those needs can be resolved.

The APG believes that the future structure of the NHS should evolve on the basis of meeting the needs of informed patients. That people are becoming better-informed about their health and more knowledgeable about the treatment options available is to be welcomed. We recognise that this will create new pressures, both on clinicians and on the overall level of funding available. However, these considerations are outweighed by the fact that a modern health service should be able to provide for modern needs. The national plan should establish that the aim of Government policies towards the NHS should be to meet informed need rather than limit demand.

5.6 Our belief in less centralisation in the NHS is consistent with our view that there should be less central regulation of pharmaceutical prices and profits. The APG has long argued for the progressive deregulation of the Pharmaceutical Price Regulation Scheme and is pleased that the Department of Health has now agreed to work with the industry to examine the case for such a move.

5.7 The APG does not advocate an unfettered free market in pharmaceuticals. Governments and health care systems will always have a legitimate interest in what is spent on medicines. However, the focus of regulation should change from cost, which is

the principal concern of the PPRS, to value. We believe that there are in fact changes moving into place that make such an approach a realistic prospect. These are:

- **Competition within the supply of medicines.** This is already an established fact for which ample evidence exists. In the UK, as in other markets, we see:
 - An increasing number of corporations competing and increasing numbers of competitors in the main therapy classes.
 - Faster entry of new products – creating earlier competition.
 - Second, third and subsequent entrants into a therapy area are, on average, pricing below the market leader.
 - The real price of breakthrough therapies has fallen.
 - Competition from generics is extensive and effective – especially in the UK where the level of generic prescribing is exceedingly high by European standards.
- **Informed Demand.** Government policy should make the NHS at local level better informed about the value of medical technologies, so that it can make purchasing and treatment decisions on this basis. At the same time, patients themselves, as we argued above, are becoming better informed about medicines.
- **Integrated Budgets.** The Government has moved towards integrated budgets by introducing unified health budgets at PCG level. This is a significant advance over the old compartmentalised budget structure where there was no incentive to invest in particular medical technologies because the savings would only become apparent in other budgets. With the unified budget, a holistic approach towards rational decision-making should become possible.
- **Incentives to Best Practice.** The supply side in pharmaceuticals is highly competitive, but the liberalisation approach will only be effective if there is also a competitive element on the demand side. The Government has acknowledged the importance of spreading best practice. However, as noted above, policies need to go further by applying incentives at the level of primary care organisations in order to promote good practice.

5.8. The revised PPRS, which came into force last October, contains an explicit commitment that the factors which influence the dynamics of medicine supply and use in the NHS will be “systematically evaluated and formally reported on from time to time in the Reports to Parliament and will inform the PPRS mid term review”. Moreover, “the potential for further deregulation of profit and price controls through the PPRS will be assessed at that time”. A joint study, conducted by the ABPI and the Department of Health, has been established and this will look at the following main areas:

- Key indicators to measure competitive performance.
- Competition in the in-patient sector.
- Demand-side effectiveness.
- The experience of less regulation overseas.

The APG warmly welcomes the Government’s commitment to examine the case for the progressive deregulation of pharmaceutical price and profit controls. This establishes a direction of travel for which the Group has long been arguing. We believe that the gradual deregulation of the PPRS is not only to the long-term benefit of the pharmaceutical industry in this country. It is consistent with the policy agenda that the Government itself has established and will be taking forward through the national plan. Reform in this area is and should be seen as an important part of the modernisation of the NHS.

5.9 Deregulation in pharmaceutical pricing is not an issue confined to the UK alone. It should be welcomed and pursued more generally and is, in our view, central to the need to complete the single market in pharmaceuticals across the EU. Like other pharmaceutical companies, members of the APG are concerned about the continuing problem of parallel trade, which undermines the industry in this country and is a significant barrier to competitiveness. This problem arises to the extent that it does in pharmaceuticals because the continuation of national price controls in different EU countries is incompatible with the free movement of goods across borders in the single market. The APG believes that the long-term solution to this problem lies in the deregulation of price controls and the liberalisation of markets.

6. Conclusions

6.1 The success or otherwise of the national plan will be judged by whether it can improve health outcomes, especially in key areas such as cancer, CHD and mental health, where the UK lags well behind comparable countries. The national plan will also only succeed if it is capable of providing for the modern health needs of people in this country, bearing in mind that those needs are now better informed than ever before. The impact of the plan should be measured explicitly on this basis.

6.3 We believe that the informed need of modern patients can best be met by giving as much power as possible to clinicians and managers on the ground to take decisions in the interests of their patients. The new primary care organisations provide a forum for doing this. While there is an important role for central guidance, this should not be at the expense of local innovation. The dangers of “levelling down” are, in our view, very real.

6.4 The NHS has a poor record for responding to and taking up medical innovation. The Secretary of State Alan Milburn has recognised the value of medicines in improving health, quality of life, as well as being a more cost-effective use of resources. This should mean, in part, recognising the added-value that new medicines can provide rather than sticking doggedly to time-honoured practice. One of the most important challenges of the national plan is to translate that view into reality on the ground. The Government has begun to talk in terms of increased use of financial incentives to promote performance. We welcome this approach and would like to see it developed.

6.5 The APG does not believe that the Government should become a wholly disinterested observer in what the NHS spends on pharmaceuticals. Its duty is to demand value for money in all public expenditure, of which expenditure on medicines is a significant part. That Ministers have begun to recognise the importance of value rather than cost should lead to entirely different basis for the relationship between the pharmaceutical industry and the NHS. This should be based upon the deregulation of price and profit controls and a much more competitive environment among informed, effective and incentivised purchasers. This, we believe, is a natural part of the modernisation that the Government demands.

The changes that we are seeing in the NHS do indeed provide a framework for such a more positive relationship between the pharmaceutical industry and the NHS to be realised. In that respect the new NHS presents the pharmaceutical industry with an important opportunity. This is important not just to patients but also to the standing of the industry in the UK, and to inward pharmaceutical investment.

As yet, however, there is still no real sense that the pharmaceutical industry is seen as a partner in the modernisation of the NHS. There has been, for example, no formal consultation with the industry about, or close involvement with, the national plan. This is regrettable given the emphasis on partnership that the Government otherwise stresses. We hope that this will change. For our part, the APG is wholly committed to working constructively with the Government and the health service to promote innovation and change and innovation in the interests of patients.



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