



Government Response to the Health Committee's Report on the Influence of the Pharmaceutical Industry

Presented to Parliament by
the Secretary of State for Health
by Command of Her Majesty
September 2005



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Government Response to the Health Committee's Report on the Influence of the Pharmaceutical Industry

Introduction

1. The House of Common's Health Committee published its report on the *Influence of the Pharmaceutical Industry* on 5 April 2005. This Command Paper sets out the Government's response to the recommendations in that report.
2. The pharmaceutical industry is an important sector for the UK. It has an outstanding record of innovation for the benefit of patients, and of investment in the economy. It has to be recognised that to carry out its business Government and its agencies will have dealings with the industry. It has long been the Government's policy that these dealings must be balanced and appropriate with an aim of securing beneficial outcomes for patients and the economy. We recognise that the sector is continually looking to improve the science of developing new medicines, and its business practices. This comprehensive investigation by the Committee has provided the opportunity for the Government to review its policies on how it relates to industry to ensure that they remain appropriate for today's environment.
3. The aim of this Government is to have a patient led NHS through empowering them with the information that allows participation in decisions about their healthcare. Patients rightly expect transparency in how their treatment is delivered, and the development and introduction of new medicines is no different. To have this transparency it is important to have a relationship with the industry. The establishment of the Pharmaceutical Industry Competitiveness Task Force (PICTF) in 1999 was the first step in this process as it brought the Government and industry together to discuss issues that related to the competitiveness of the industry in the UK. We are now building on this initial work, and this response sets out how all stakeholders are now being engaged so that the criticisms levelled at the industry in the past are being tackled head on.

4. As treatments have improved, patient's expectations have rightly increased. They expect innovative medicines to treat the diseases of today, and we have seen new medicines save the lives of thousands of people who have suffered from diseases such as cancer and coronary heart disease. Patients also want to be assured that these new medicines have gone through proper testing, and have met all of the regulatory requirements before they are brought to market. To achieve these aims the Government has been looking at how:
 - the conduct of clinical trials in the NHS can be improved to develop these new medicines
 - regulation by the Medicines and Healthcare products Regulatory Agency (MHRA) is made more transparent and now involve patients in the process.

Research and Development

5. The discovery of innovative medicines responds to people's expectations of better healthcare and can avoid or reduce hospitalisation. The NHS offers great potential for research and development (R&D). The NHS has high standards of clinical quality, a strong research heritage, links with first-class academic research institutions, and a largely unified structure, which means that clinical trials can span a number of hospitals, or cross primary and secondary care. It is these qualities that persuade the pharmaceutical industry to invest over £3 billion in R&D each year in the UK.
6. We realise that there is growing competition from other markets, and that the UK cannot afford to depend on these qualities alone. The relationship with industry will therefore benefit from the UK Clinical Research Collaboration (UKCRC), which is a wider partnership between Government, the voluntary sector, patients and industry. The UKCRC has a shared vision to establish the position of the UK as a world leader in clinical research by harnessing the power of the NHS. It is developing a major new clinical infrastructure in the NHS, comprising of enhanced Clinical Research Facilities as part of a "National Framework for Experimental Medicine", and a UK Clinical Research network. The latter will build on the success of the Cancer network cited in the Committee's report, and consist of a managed set of research networks. Initially these will also cover mental health, medicines for children, dementias and neurodegenerative diseases, stroke and diabetes, and over time, will enable research to be conducted across the full spectrum of disease and clinical need.
7. To build on this progress, the Government is consulting on a new strategy for the NHS contribution to health research in England. The consultation document *Best Research for Best Health: a New National Health Research Strategy* was issued in July 2005. It proposes lending greater coherence to government-funded actions by bringing them together in a virtual National Institute for Health Research. The aim of the Institute is to provide world-class support to researchers, and make the NHS a preferred host for multi-centre clinical and broader health research. Alongside the Institute, the Government proposes to implement changes in the funding schemes for health research; to reinforce and expand the research networks with capacity to provide reliable expert advice on regulatory processes; and to standardise and minimise the information needed for regulation, ethics and research governance.

8. The Government recognised that research ethics and governance may not be working consistently throughout the country. In October 2004, the Government announced a review of the operation of NHS Research Ethics Committees. The report was published on 6 June 2005. It builds on recent investments that have already given ethics committees a managed operating system. The recommendations are intended to give ethics committees stronger support and organisation with a view to improving the efficiency, quality and consistency of their work. The National Patient Safety Agency will consult on an implementation plan.

Regulation

9. Quite rightly the Committee focussed in some detail on the regulatory system, looking at both the regulatory history of specific cases and more general regulatory issues. The medicines regulator plays an important role in ensuring that the medicines we use are of sufficient quality, safety and efficacy.
10. The amended European legislation which underpins the regulatory system will come fully into effect in October 2005 and will bring significant benefits to public health. Key are the new requirements on pharmaceutical companies to provide any new information relevant to the risk:benefit profile of a particular medicine, and the capacity of the regulator to monitor risk:benefit throughout the life cycle of the product. The legislation addresses a number of other issues, including user involvement in the development of Patient Information Leaflets (legislation which was implemented early in the UK and which gives legal force to work already being carried out by the MHRA).
11. On its creation in April 2003 the MHRA inherited strong scientific and regulatory values from both of its predecessor organisations. However, at the same time, Ministers called for the MHRA to ensure its public health role and messages were understood by the public and health care professionals. The development of a Communication Division in the MHRA, to carry out a range of functions from handling press and public information queries to raising awareness of risk and benefit in medicines and devices, is a major step forward in addressing wider medicines related issues.
12. Safety is at the heart of the MHRA's agenda. The new pharmacovigilance requirements will enable a more proactive approach to be adopted. Implementation of the recommendations in the Report of the Review of Access to the Yellow Card Scheme also offers important opportunities for strengthening medicines safety surveillance. The Report made a comprehensive range of far reaching recommendations impacting on the scheme and their implementation will ensure that it continues to be a world leader. Implementation of the recommendations will address a number of issues raised in the course of the Committee's inquiry. Of particular note is the development of the patient voice in regulation, through the involvement of patients and lay people in the advisory process and direct patient reporting of suspected adverse drug reactions.

13. The regulatory environment has been subject to a series of changes from internal and external stimuli. The creation of the MHRA and its new openness, the raft of new legislation with the increased power to act to protect public health and, last but not least, the increasing patient voice, are part of a programme of planned change. The Government will, however, review the progress made in due course and make the findings of that review publicly available.

Moving Forward

14. The Committee recognised the need for the Government to have a forum to be able to communicate with the pharmaceutical industry on the disease areas that will be a priority in the future. As it can take on average 10–12 years for a new medicine to be brought to market it is important that there is a forum that allows Government and industry to share information on future priorities.
15. One of the areas considered by the Committee was how the Government could inform the industry the disease areas where more research was needed. This is an issue for more than just the UK, and the WHO published a report on this area in November 2004 entitled *Priority Medicines for Europe and the World*. We have been looking at how Government and industry can take forward these discussions within the UK. The UKCRC has agreed to hold a *Futures Forum* that will bring the key stakeholders together to advise Ministers on priority areas for innovation in healthcare intervention. This will help all stakeholders foster a better-shared understanding of the key health challenges ahead and how to tackle them.
16. Legislation brought forward by the EU, competition from markets such as the USA or China, and changes within the UK environment can all impact on the pharmaceutical industry based here. The Ministerial Industry Strategy Group (a body which came out of PICTF to continue dialogue between Government and industry) has decided to develop a Long Term Leadership Strategy for medicines. This is designed to: secure the provision of safe and effective medicines for patients; maintain and strengthen the UK pharmaceuticals industry within Europe; and to advance healthcare innovation with the NHS.
17. MISG will initially develop strategies in three areas:
 - NHS and Industry Working Together:** will look at how increased dialogue and partnership between the NHS and industry would deliver significant benefits for patients, Government, industry and research.
 - European Environment:** the European Commission has announced a new pharmaceutical strategy to help member states take forward the Lisbon objectives. This worksteam will provide the UK with a forum that can help shape and progress this agenda. It can also feed in the lessons learnt from this long-term strategy work, particularly those on regulatory issues.

Regulatory environment: this workstream will carry out “blue skies” thinking to consider whether there might be better controls at the time of release of new medicines into clinical use, and better ways of proactively gathering safety data to avoid sudden scares. A range of options from changes in EC and UK law, through to enhancements to the Yellow Card Scheme, will need to be considered. This was an issue the Committee referred to on a number of occasions.

18. One essential element of this work is that it will involve the relevant stakeholders, including patients, prescribers, NHS managers, researchers, regulators, as well as Government and industry. It will also be taken forward in a transparent way, and once up and running updates will be placed on the Department of Health website at www.dh.gov.uk

Relations with Government

19. The Committee considered which Department would be best placed to represent the interests of the pharmaceutical industry. As the Committee's inquiry demonstrated, and is further highlighted through this response, the relationship between patients, Government, the NHS, industry, and the other stakeholders is an intricate one. However, they also clearly demonstrate that the interests of patients and the industry are not mutually exclusive. Having one department lead helps to balance these interests, while separation could bring an unhelpful tension between health priorities, and economic drivers. Having reflected carefully on this, and considering how national and European policies in this area largely impact on both patients and industry, the Government believe that the responsibility for co-ordinating the relationship with industry should remain with the Department of Health. We will also put in place arrangements for closer co-operation between the Department of health and DTI to ensure that the interests of patients, the NHS and industry are fully represented across Government.

Conclusion

20. The current practices that govern how the Government relates to the pharmaceutical industry, and the commitments given in response to the Committee's recommendations can reassure patients that this Government is working to provide the innovative and safe medicines that they have the right to expect. It is in the interest of patients, the Government, the NHS, and the industry to work constructively to ensure that this remains the case in future.

Editorial Note

For ease of reference, and to assist in cross referencing in this document, we have numbered the Committee's recommendations to reflect the sequence in which they appeared in the *Conclusion and Recommendation* section of the Committee's report. The paragraph numbers from the *Conclusion and Recommendation* section are given in brackets.

Where different recommendations addressed overlapping issues we have grouped them and provided a single overarching response.

The Government's response to the Health Committee's Recommendations:

Recommendation 1 (paragraph 3): However it occurs, the presence of many 'me-too' drugs on the market creates difficulties for prescribers and the NHS. Although this is a considerable problem, we were given no obvious solution. We expect that there will continue to be a large number of me-too drugs. The National Prescribing Centre and others should particularly consider issuing independent advice in areas where many 'me-toos' exist.

We recognise that having a high number of medicines in the same class (so-called "me-too" drugs) might be confusing for prescribers in deciding between products with essentially the same characteristics, but differences in their respective marketing authorisations. It would be very difficult for the Department of Health, or any organisation acting at its behest, to provide central advice on the choice of product when so much depends on the patient's clinical circumstances. The responsibility for prescribing rests with the doctor who has clinical responsibility for that particular aspect of a patient's care and we would expect clinicians to use their clinical judgement in each case. However, the National Prescribing Centre (NPC), when it prepares a bulletin on a particular therapeutic area, does already include advice on the principles that should underpin the prescriber's choice of treatment. We will consider whether there is scope for the NPC to undertake additional work as part of their established Medicines Management programme.

Recommendation 2 (paragraph 18): We recommend that the clinical trials register be maintained by an independent body and the results of clinical trials data, containing full trials information, be put on the register as a condition of the launch of the Marketing licence.

The Government shares the Committee's commitment to transparency and accountability relating to registration of clinical trials and publication of their results. However, to add the registration of clinical trials and publication of their results to the conditions of a Marketing Authorisation (licence) would require a change to the European legislation that regulates those placing a medicine on the European market.

New European legislation (Directive 2004/726/EC), which comes into force October 2005, already provides for information on medicines on the European market to be made available to all European citizens. The information will be publicly accessible from the EuroPharm database, which will be maintained by the European Medicines Agency (EMA). The information available will include details of clinical trials on medicines on the European market conducted in the Community and will be sourced from the European Clinical Trials database – EudraCT.

Furthermore, the new legislation requires Member States' Competent Authorities (MHRA in the UK) to publish summaries of the findings of clinical trials submitted as part of an application for a Marketing Authorisation – Public Assessment Reports. These summaries will be prepared independently by expert assessors in the Member States Medicines Agencies and be made available to the public via their websites. These will complement the European Public Assessment Reports (EPARs) which summarise trials conducted to support a medicine licensed via the European procedure.

The Department of Health is also actively engaged in supporting the World Health Organisation initiative to create a single portal from which anyone can access information about clinical trials conducted worldwide. We welcome the public commitment from the global pharmaceutical industry to support this initiative by voluntarily registering their clinical trials of medicines on public registers and making summary findings publicly available within one year of the grant of a marketing authorisation in any country.

Together, these initiatives will soon make comprehensive information about the safety and effectiveness of medicines much more easily accessible.

Recommendation 3 (paragraph 19): Clinical trials have significant limitations. We recommend:

- a. that the MHRA work with the pharmaceutical industry and outside experts to design clinical trials that establish the real therapeutic value of new medicines using measures that are relevant to patients and public health. Trials should be designed to more accurately predict the performance of drugs in routine clinical settings.**
 - b. that research ethics committees encourage where appropriate the inclusion of comparator drugs and non-drug approaches in the evaluation of proposed clinical trials. Ethics committees should also require applicants to prove that the trial does not duplicate previous research and that results will be published in full.**
- a. The Government believes that well conducted randomised clinical trials are the best and most appropriate way to evaluate the efficacy and safety of medicinal products. However, it does recognise that there may be occasional deficiencies in the design and conduct of individual clinical trials.

When inadequate and inappropriate trials are presented, part of the MHRA's remit is to critically evaluate the information and take appropriate action, often resulting in the refusal of the marketing authorisation. Part of the assessment process includes consideration of the relevance of the clinical trials to the proposed clinical practice situation.

The MHRA is already working to minimise the number of inadequate trials that are conducted by the pharmaceutical industry. To this end, the MHRA offers a service whereby companies can seek scientific advice on the design and analysis of the clinical trials included in their clinical development plan. Some 117 such meetings were held in 2004. At these meetings, companies are encouraged to run trials where the test treatment is compared to a relevant comparator and advice is given on the most appropriate endpoints to use to quantify the clinical relevance of the intervention.

The MHRA and EMEA have also produced many guidelines to assist applicants outlining clinical trial requirements necessary in order to obtain a market authorisation in many therapeutic areas.

- b. The Department of Health's governance framework for ethics committees states the principle that research which duplicates other work unnecessarily or which is not of sufficient quality to contribute something useful to existing knowledge is unethical. Protocols submitted for review should already have passed scientific critique from experts who are expected to comment on the originality of the research. The ethics committee is not constituted to undertake additional scientific review but it is expected to satisfy itself that the review already undertaken is adequate .

The Medicines for Human Use (Clinical Trials) Regulations 2004 specify the considerations ethics committees are required to take into account when reviewing pharmaceutical clinical trials. Regulation 15 requires committees to consider the relevance of a trial and its design. Schedule 3 requires the applicant to provide a summary including justification, relevance and methodology; and an assessment of the ethical issues, including the importance of the trial and the new knowledge to be gained.

The Clinical Trials Regulations provide the legal basis for ethics committees to consider the issues covered by the recommendation. Ethics committees are required to give an independent opinion. It would be inappropriate for the Government to interfere with the committees' evaluation of particular studies, but the National Patient Safety Agency, which is now responsible for the Central Office of NHS Research Ethics Committees, will continue the development of mechanisms to help ethics committees work consistently to the standards required by the Regulations.

Recommendation 4 (paragraph 20): We recommend that the NHS take further steps to facilitate the conduct of clinical trials, with each Trust having a single point of contact for the pharmaceutical industry to approach when considering a trial.

Together with its partners in the UK Clinical Research Collaboration(UKCRC), the Government is committed to taking forward a range of measures that will strengthen the ability of the NHS to facilitate the conduct of clinical and public health research. These include the co-ordination of major investments in clinical trial networks and facilities for experimental medicine; building up incentives for organisations and individuals to engage in clinical research, building up the research workforce, and streamlining regulatory and governance processes.

Following the implementation of research governance, each health care organisation is expected to identify someone authorised to give permission, on behalf of the organisation, for research to take place. Health care organisations usually have a research office, or work with one, that can act as a single point of contact for industry. Trusts and pharmaceutical companies expect to seek agreement around a national model clinical trial agreement. It is no longer normal practice for companies to approach individual clinicians, without the involvement of the host organisation.

Recommendation 5 (paragraph 21): We recommend that limits be set as to the quantity of material prescribers receive, particularly in the first six months after launch. Less experienced and non-specialist doctors are ill-equipped to cope effectively with the promotional material. The pressure on nurses and pharmacists is likely to intensify as their prescribing powers are further extended. Stricter controls are needed in respect of drug company representatives' promotion of their products to junior doctors and to nurses or pharmacists with new prescribing powers.

Recommendation 6 (paragraph 33): The intensive marketing which encourages inappropriate prescribing of drugs must be curbed. Present methods of supplying independent information, as described by Lord Warner, are inadequate. We recommend that all the promotional material for a new product be pre-vetted by the MHRA prior to publication, and that consideration be given to limiting those who can prescribe a new drug in the two years following launch. Drug and Therapeutics Committees would be well-placed to implement this. Wider prescribing rights would be permitted once comparative studies, and trials investigating the potential adverse effects of the medicine in large populations, had been undertaken and after formal evaluation of the value of the product in clinical practice had been confirmed by the Licensing Authority and/or NICE.

The Government agrees that there must be proper controls in place to ensure that marketing carried out by pharmaceutical companies is acceptable, and does not adversely impact on prescribers clinical judgement. It is important to remember that clinicians are responsible people who have undergone years of training and make critical decisions about the health of their patients each day.

There is no indication that the measures currently in place are not effective. The fact that generic prescribing has risen to nearly 78% (in 2003) clearly indicates that clinicians are writing prescriptions generically and not by individual company product.

The current measures in place are:

- **Medicines (Advertising) Regulations 1994** (regulation 21 'inducements and hospitality') govern the promotion of medicines by a pharmaceutical company to anyone who is qualified to prescribe.
- The Departmental guidance **Standards of Business Conduct for NHS Staff, and Commercial Sponsorship – Ethical Standards for the NHS** (November 2000) give clear guidance to NHS employers and staff in maintaining strict ethical standards in the conduct of NHS business, including on receiving sponsorship. The Department has again reminded the NHS of the need to adhere to the guidance. NHS Employers will highlight the need for NHS staff to adhere to these guidelines through their communication channels.
- All NHS staff have to follow a **Code of Conduct**. A model code is attached to the guidance and makes it quite clear that staff are expected to declare gifts, benefits or sponsorship of any kind and refuse gifts which may be seen to compromise their personal judgement or integrity.
- **Health professionals are subject to their own codes of conduct** which are maintained by their professional colleges and councils such as the GMC guidance *Good Medical Practice*.

- **Self Regulation.** The ABPI established the Prescription Medicines Code of Practice Authority (PMCPA) in 1993 to operate its code of practice on promoting medicines to health care staff of prescription only medicines. Where NHS staff (or anyone else) believe that the code of practice has not been adhered to they can make a formal complaint to the PMCPA.

The Government recognises that concerns have been raised about the controls on marketing after launch and on promotion by representatives from pharmaceutical companies during this period. It has therefore asked the PMCPA to consider proposals to strengthen their code to reflect these concerns. This might include limits on the spend, amount or rate of issue of material for newly licensed products or those with new indications, new patient populations, etc.

The Government accepts the Committee's recommendation that promotional material for new products be pre-vetted. The MHRA already undertakes pre-vetting according to published criteria, which has included some new chemical entities. This will now be extended to all such products. This amounts to around 20 products in a year in total. In context, the MHRA pre-vetted the advertising of 30 products according to its published criteria in the last financial year. Pre-vetting for new products can be planned into the licensing timetable, need not delay launch of a product and is normally considered by the MHRA in a matter of days. The MHRA will reprioritise its existing activities to achieve the change within existing staff resource and will continue to focus its activities primarily according to its published criteria.

The Government agrees that clinicians should receive independent advice on medicines. Guidance and advice is offered at national and local level already from local Drugs and Therapeutics Committees and from NICE respectively. In addition, the Department of Health purchases the Drug and Therapeutics Bulletin (DTB) for all NHS doctors in England. The DTB is an independent eight-page bulletin, published monthly by the Consumers' Association. It provides critical impartial reviews of treatments.

There are a range of measures that regulate marketing of products by companies, and prescribers receive independent advice from a number of sources. We believe by enhancing the current arrangements in the ways described above, we will continue to ensure that prescribers make decisions based on the clinical need of the patient. However, we do recognise the importance of monitoring these measures to make sure that they remain adequate, and we will therefore continue to keep these under review.

The Government agrees that there is a need to look at whether there is a safer way of introducing new drugs. The Ministerial Industry Strategy Group is beginning three strands of work looking at developing long-term strategies for the UK based industry. One of these strands is looking at regulatory issues and this will bring all stakeholders, including patient groups and prescribers, together to do some "blue skies" thinking to consider whether there might be better controls at the time of release of new medicines into clinical use, and better ways of proactively gathering safety data to avoid sudden scares. A range of options from changes in EC and UK law, through to enhancements to the Yellow Card Scheme, will need to be considered.

Recommendation 7 (paragraph 22): Marketing practices that appear to be illegal should be reported by the pharmaceutical industry and others to the MHRA.

Recommendation 8 (paragraph 23): We recommend a major review of the investigation of complaints (of marketing and advertising practices) to ensure the process is far quicker and effective sanctions are enforced.

Recommendation 9 (paragraph 34): We recommend that the MHRA and the PMCPA better co-ordinate their work relating to the promotion of medicines to avoid duplication. Complaints should be investigated swiftly, particularly when claims for new drugs are involved. When the PMCPA has evidence that a company has breached the regulations it should inform the MHRA of its findings. When companies are found to be in breach of advertising or marketing regulations by the MHRA, we recommend that corrective statements always be required and that such statements are given as much prominence as the original promotional piece. The publication of misleading promotional material is a criminal offence and the punishment should befit such a status.

A major review of the processes underpinning the investigation of complaints about medicines advertising has been undertaken resulting in more transparent and open published procedures with audit built in, quicker determinations and a greater reliance on the available sanctions. This includes the use of corrective statements, publication of the outcomes of all complaints and consideration to prosecution where appropriate. This has, for example, resulted in a reduction in the average time for completion of external complaints from 16 to 6 weeks. The outcome of the review was published in a peer reviewed journal (*Int J Pharm Med* 2003; 17: 5-6). The MHRA has committed to further public consultation on the regulation of medicines advertising through the review of its Blue Guide and, subject to the outcome of that process, will further consider the need for a wider review of the area.

The Government agrees that better co-ordination between the work of the PMCPA and the MHRA in their complementary but different roles would strengthen regulation as a whole. With that aim, the MHRA is consulting with PMCPA to develop and publish a memorandum of understanding on how the MHRA and the Authority work in the future. Separately, the ABPI are also consulting on a review of the industry's self-regulatory code. The Government has asked the PMCPA to consider whether limits on promotion following product launch could be achieved through self regulation.

The Government agrees that corrective action when companies have been found to be in breach of the legislation serves an important purpose in correcting any potential misunderstanding. Corrective action can also be a form of sanction but to require such statements on every occasion, regardless of the nature of the breach, would not be proportionate and would run the risk of trivialising the impact of corrective statements compared to use in a targeted way. The MHRA will, however, be consulting on the extent to which it should publish all correspondence with pharmaceutical companies relating to the advertising and promotion of medicines.

In order to achieve yet greater transparency the MHRA will publish each year an outcome report, detailing the MHRA's actions in regulating medicines advertising, including a breakdown of performance against published indicators and identifying any new or emerging issues in medicines advertising.

Recommendation 10 (paragraph 24): The PPRS should be used more effectively to influence the actions of the pharmaceutical industry in the public's interest. When Companies are found to be in breach of advertising regulations or to have published misleading findings the allowance for promotion and research, respectively, provided under the Scheme should be reduced. In addition, rewards for innovation should be limited to those drugs that are proven to offer clinical advantage.

The Government agrees that when companies are found to be in breach of advertising regulations or to have published misleading findings the allowance for promotion and research, respectively, provided under the scheme should be reduced.

The scheme currently sets out guidance on the activities qualifying for these allowances and precludes expenditure on medical symposia found to be in breach of the ABPI Prescription Medicines Code of Practice from being included as part of a company's allowable expenditure in their Annual Financial Returns to the Department.

The Government will undertake discussions with the ABPI as part of the next negotiations on the PPRS to make clear that when companies are found to be in breach of advertising regulations or to have published misleading findings the allowances for marketing, information and research and development, provided under the scheme should be reduced. The Government will also enter into discussion with the ABPI on the mechanism on how best to reward companies for innovation.

Recommendation 11 (paragraph 25): We recommend that the MHRA publishes, in some form of useable database, the material it receives from drug companies and the assessments it sends to advisory bodies at the time it sends them. We welcome the MHRA's plans to include lay members on every MHRA advisory committee, and recommend that these members receive sufficient training and support to allow them to fully contribute to decision making.

The Government agrees that the regulatory system should be as open and transparent as possible and the public should have access to information on individual applications and the data supporting its authorisation. It also supports the publication of material it receives and assessments it makes on marketed medicines after initial licensing and after regulatory action has been taken. The Government intends to continue this move to greater transparency in decision making in order to increase accountability and confidence in the ability of the regulator to protect public health. However, in all cases it is imperative that the Licensing Authority has reached a final decision before data is put into the public domain. The principle that the Licensing Authority will have taken a view on data before it is put into the public domain will remain central.

With the coming into force of the UK legislation implementing the 2001 Review (30 October 2005), the MHRA will publish a national Public Assessment Report (or UKPAR) within a short period of time of a licence being granted, for newly licensed products. The UKPAR will be an up-to-date record of the licensing history for a medicinal product, providing information on the data presented in support of licensing applications and the reasoning behind the Licensing Authority's decisions. The MHRA intends to publish these reports on its website.

The MHRA has already released summaries of clinical trial data to support major drug safety action. Summaries of clinical trial data have been released in respect of SSRIs as well as for anti-psychotics (risperidone) and for Hormone Replacement Therapy (HRT). This goes further than any regulator has ever done and demonstrates the MHRA's commitment to being as open as possible in drug regulation. The MHRA plans to publish assessment reports for both renewals of product licenses after the first 5 years and periodic safety update reports submitted three yearly thereafter.

As part of its normal procedures for new members of advisory committees, the MHRA will provide training and support to allow lay members to fully contribute to decision making.

Recommendation 12 (paragraph 26): We are concerned that the MHRA is not permitted to routinely inspect audit reports for compliance with standards of Good Clinical Practice (GCP). The Department of Health should reconsider its agreement to waive powers to inspect, on a routine basis, audit reports of compliance with GCP standards, including standards of patient care. The Department should review all current and proposed standards developed by the International Conference on Harmonisation that impose restrictions on MHRA staff relating to inspection of company-held data and records.

The Government does not support this recommendation. The ICH Note of Guidance on GCP is a guideline and is not legally binding in the UK. As such, it does not take precedence over the relevant EC and UK legislation (specifically, Directive 2001/20/EC on clinical trials, the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Medicines Act 1968). Therefore, while the ICH guidelines set out restrictions in the inspection of company-held data, MHRA inspectors acting under the enforcement provisions of the Medicines Act have full powers to request and inspect audit reports. In practice, however, MHRA inspectors only ask to see audit reports in relation to issues of serious non-compliance and in cases where we wish to confirm that an organisation has performed adequate audits of partner/contractor companies (e.g. as part of pre-selection checks). They always request audit plans and details of audit strategy, and always have the option to request audit reports, even if there is no issue of serious non-compliance.

Recommendation 13 (paragraph 27): The MHRA should put in place systematic procedures to randomly audit raw data. The results of such audits should be published. We also recommend that, like the US Food and Drug Administration, the MHRA play a greater role during the early stages of drug development. Guidance should be provided by the MHRA to the industry as to the types of clinical trial likely to prove the degree of therapeutic gain. NICE should also be involved in this process to provide advice on the type of data more likely to lead to the drug being included in NICE guidance.

The procedures for obtaining a marketing authorisation for a medicinal product are set out in European law. Rather than an analysis of raw data it requires data to be presented as a series of modules including a **Clinical Overview** (a critical analysis of the clinical data included in the clinical summary and all the clinical documentation), a **Clinical Summary** (a detailed summary of all the clinical information) and the **Clinical Study Reports** (where all reports of individual clinical studies must be provided). The textual part of each study report can be 50–60 pages or more and can be supplemented by several volumes of appendices and supplementary tabulations and listings of data. In a new drug application, the number of volumes of clinical documentation could be in the hundreds.

As part of the assessment process assessors may and frequently do request further data. This can include raw data where applicable. In addition, the MHRA GCP Compliance Unit does routinely inspect reported data against source data for ongoing trials. The Unit may also inspect data from final clinical trial reports against source data. Plans are in place to increase the number of inspections of trial reports and, under the new clinical trial legislation (Directive 2001/20/EC and the Medicines for Human Use (Clinical Trials) Regulations 2004), the MHRA will carry out a number of random GCP inspections linked to marketing authorisation applications.

The Medicines (Provision of Misleading Information and Miscellaneous Amendments) Regulations 2004 (SI 2005/1710), which came into force on 1 August 2005, introduce the new criminal offence of failing to provide or providing false or misleading information to the Licensing Authority in support of an application for a marketing authorisation for a medicinal product. The legislation will also make it an offence to provide false or misleading information during the currency of a manufacturers' or wholesale dealers' licence in relation to medicinal products.

The MHRA and the EMEA have provided extensive guidelines on data requirements including the type of clinical trial required for a marketing authorisation. These guidelines cover many different types of products and different therapeutic indications. In addition, the MHRA offers companies clinical, toxicological, statistical and pharmaceutical scientific advice as well as regulatory advice at all stages of drug development from early clinical trials through all stages of development.

Topics are selected for referral to NICE by Ministers in the Department of Health. In deciding which topics would be referred to NICE, Ministers take into account a number of factors such as whether the topic is a clinical priority. Provision of guidance by NICE on the data required to consider the relative and cost effectiveness of a medicine would result in companies funding the collection of data that may never be used if the product is not referred to NICE. However, NICE has published guidance for manufacturers which gives a comprehensive overview of the processes it follows and the data used in appraising topics once referred by NICE.

Recommendation 14 (paragraph 28) The adverse drug reactions reported in the clinical trials that are considered in the medicines licensing process typically prove unreliable as a guide to routine clinical practice. Moreover, the adverse effects that may be linked to stopping treatment are insufficiently investigated. The MHRA should focus more intensely on updating drug benefit:risk profiles in the Summary of Product Characteristics, following systematic post-marketing review.

The Government supports the recommendation to continue to update risk:benefit profiles in the Summary of Product Characteristics, following systematic post-marketing review. The amended EU medicines legislation includes new provisions for the re-evaluation of the risk:benefit balance, which will apply throughout the life cycle of a product. This, together with more frequent Periodic Safety Update Reports (PSURs), and a renewal process targeted on new medicines will strengthen the current systematic review.

Recommendation 15 (paragraph 29): We recommend that

- a. the MHRA employ sufficient numbers of staff to monitor effectively drugs which have been recently licensed.**
 - b. Given the limited value of clinical trials in predicting drug impact in naturalistic settings, the MHRA should investigate options for the development of more effective post-marketing surveillance systems. Consideration should be given to the establishment of post-marketing surveillance and drug safety monitoring systems independently of the Licensing Authority.**
 - c. We also recommend that the MHRA enhances its re-licensing procedures five years after launch. During the renewal procedure, the MHRA should again assess in detail the product's efficacy, safety and quality.**
- a. The MHRA has a dedicated team of multidisciplinary staff in place which focuses on newly licensed products. In a planned reorganisation of the Agency, the resources necessary for proactive pharmacovigilance will be further strengthened. The UK has led Europe in developing the Excellence in Pharmacovigilance model to further enhance drug safety monitoring, including post marketing surveillance systems. This includes, for example, making use of the best available evidence for decision making rather than relying on data from spontaneous reporting. The Agency will also undertake further partnering with competent authorities in other member states and with academia to demonstrate that any suggestion of a lack of independence is not well founded. The MHRA will continue to investigate how such systems can be developed and enhanced to make use of the best evidence available for decision making.
 - b. The Government does not support the recommendation that consideration should be given to the establishment of post-marketing surveillance and drug safety monitoring systems independently of the Licensing Authority as this would impede the continuous examination of the risk:benefit balance while the product is on the market. The amended EU medicines legislation provides new provisions for the re-evaluation of the risk:benefit balance, which will apply throughout the life cycle of a product. This together with more frequent PSURs and a more targeted renewal process will strengthen the current systematic review. Product licensing and safety monitoring take place in different parts of the Agency and different teams look at the data from a safety angle to make sure that there is no internal conflict of interest.
 - c. Changes to the legislation from October 2005 will mean the process of renewal of a licence will be better targeted and will include a review of safety, quality and efficacy.

Recommendation 16 (paragraph 30): We recommend that the MHRA is given the same authority to propose restrictions on drug use as it has when approving them.

The Government agrees that the MHRA should have the same authority to propose restrictions on drug use as it has when approving them. However, new powers are not needed as there are tools already in place to propose restrictions on products in use ranging from the variation of a marketing authorisation through to its suspension and revocation of the marketing authorisation as necessary. Other steps, such as compulsory changes to the leaflet and label may also be required of pharmaceutical companies. The amended EU legislation will provide a new provision which requires the competent authority to refuse an application if the risk:benefit balance of the product is not favourable, if the therapeutic efficacy is insufficiently substantiated, or if its qualitative and quantitative composition is not as declared. The unfavourable risk:benefit balance is the new ground for refusal, suspension or revocation and replaces the existing ground that the product is "harmful in the normal conditions of use".

Recommendation 17 (paragraph 31): We recommend that:

- a. the system of patient reporting to the Yellow Card Scheme country-wide be put in place as soon as possible;**
- b. that steps be taken to improve rates of healthcare professional reporting of adverse drug reactions;**
- c. that greater efforts be made to investigate signals of possible problems;**
- d. and that maximum transparency be combined with concerted efforts to explain the uncertainties of risk.**

- a. The Government supports this recommendation. The Independent Review of the Yellow Card Scheme published its final report on 4 May 2004. One of the recommendations of the review was that, in addition to healthcare professionals, patients should also be able to report their experience of Adverse Drug Reactions (ADRs) directly to the CSM/MHRA. Patients can directly report suspected ADRs at www.yellowcard.gov.uk and also through the pilot paper-based Patient Yellow Card, available from GP surgeries and directly from the MHRA. To develop the patient reporting scheme, a Working Group of the Committee on Safety of Medicines, which includes patient and consumer group, pharmacist and medical representatives, is actively engaged in advising on further pilots to help in gauging effectiveness of systems to enable patients to send reports of the suspected ADR experiences in order to have final systems in place by 2006.

- b. The value of spontaneous reporting schemes, such as the Yellow Card Scheme, in early detection of drug safety issues is universally recognised. It has a proven track record of identifying new drug safety hazards and is recognised to be one of the best in the world in terms of the level of reporting. Under reporting of ADRs is an inherent feature of spontaneous reporting schemes. Although this means that data from the Scheme have limited usefulness in terms of quantifying the frequency of an ADR, it does not detract from the ability of the scheme to identify new drug safety hazards. The Government supports the recommendation that steps should be taken to improve rates of healthcare professional reporting of ADRs – recommendations from the review to encourage reporting and to improve professional and public education about the Yellow Card Scheme have all been accepted. This will include expanding the scheme to all healthcare professionals, enhancing the profile of the Scheme through publicity and medical/professional education and facilitating reporting, for example electronically.
- c. The MHRA has pioneered the development of methodologies to enhance signal detection and the opening up of the Yellow Card Scheme for public health research will add to the progress already made in this area. An enhanced information technology system designed to greatly enhance the existing capability for signal detection is in development and will further strengthen the system.
- d. The Committee on Safety of Medicine Expert Working Group on Patient Information published its guidance *Always Read the Label* on 19 July 2005 (ISBN 0 11 703409 6). This contains a guide on risk communication and is available on the MHRA website.

Recommendation 18 (paragraph 32): We recommend that there should be a public inquiry whenever a drug is withdrawn on health grounds.

The Government does not support this recommendation. It would not be appropriate to make a blanket decision on the need for such inquiries, which must be judged on a case by case basis. Any decision to hold a public inquiry would need to be proportionate to the need identified taking into account the expense, time and likely benefits. The MHRA will, however, commit to publishing an account of the circumstances, and the lessons learnt on withdrawals of UK licensed medicines, within a year of the date of completion of regulatory action.

Recommendation 19 (paragraph 35): A healthy generics market is important for the NHS and patients. We recommend a systematic review of so-called evergreening and other practices that impede the entry of generic drugs onto the market.

The Government agrees that practices that seek to impede the legitimate entry of generic drugs on the market should be prevented. We believe that there is a case for further research in this area and we will investigate with potential partners the possibility of defining and taking forward such an initiative.

Recommendation 20 (paragraph 36): We recommend that there be an independent review of the MHRA. The earlier review by the National Audit Office was designed expressly to assess the public expenditure aspects of the work of the agency; a more wide-reaching and in-depth review needs to be carried out to determine whether the processes now used for decision-making are adequate and reflect patients' health needs and society's expectations. The following principles should govern the review: the need for greater independence from Government; the need for greater independence from the pharmaceutical industry; the need for policies of greater transparency and accountability in light of recent freedom of information legislation; the effectiveness of the post-licensing department and the need for the MHRA to become pro-active rather than re-active; scrutiny of the regulatory standards underpinning clinical and non-clinical new drug review; the reporting and evaluation of adverse drug reactions; the prioritisation of new marketing applications; and inclusion of the public in policy-making and implementation.

The Government recognises the need for the regulatory system, and the regulator, to be as transparent as possible. The work of the MHRA is already open to a great deal of public scrutiny. The National Audit Office's Value for Money Study of 2003 into the operations of the Medicines Control Agency was in fact a wide ranging investigation of all of the Agency's activities and of its overall contribution to the protection of public health. Indeed, the Report has been one of the building blocks of the MHRA and has been highly influential in the development of the MHRA.

Since the creation of the MHRA there have been a number of other reviews and public consultations which have addressed many of the principles outlined in this recommendation. These include the report into the operation of the Yellow Card Scheme, a review of the Agency's communications and a public consultation on its medicines advisory structure. The issues identified are currently being addressed by the Agency as part of a development programme which is bringing changing attitudes, practices and processes to the Agency.

The Government believes that a suitably planned Review of the operations of the MHRA, perhaps on a four-yearly cycle, would examine whether the Agency is meeting the needs of patients and the expectations of society. The Terms of Reference, the methodology and timing of such a Review need further consideration. However, we believe that it should be informed by expert knowledge of the relevant scientific and social issues, international benchmarking against other Agencies and an understanding of the principles underpinning regulation. The development programme, clearly based on a number of reviews and public consultation, also needs to be further implemented before a review is launched.

Recommendation 21 (paragraph 37): We recommend that all medical students be taught how to judge clinical trial results effectively, recognise adverse drug reactions, and deal with drug company representatives. There should be mandatory post graduate training for all prescribers to keep up to date with prescribing changes. In addition, stricter regulation of individual prescriber's practices is required.

The undergraduate and postgraduate curricula for health professionals are matters for the appropriate regulatory body but the department must influence this process effectively. For example, the MHRA has approached organisations responsible for training healthcare professionals and drug safety and pharmacovigilance are part of the curriculum for training some medical and pharmacy students.

We expect prescribers to deal with the individual circumstances of their patients based on assessments of their clinical needs. It is a fundamental requirement that patients obtain the benefit from the prescriber's expertise. PCTs can identify and subsequently investigate unusual or aberrant prescribing behaviour if their analysis of the data available from the Prescription Pricing Authority's database suggests further enquiries are called for. These enquiries may be conducted through peer review, established clinical governance channels, leading to formal disciplinary action in the most serious cases. PCT advisors have access to practice records to facilitate whatever enquiries might be necessary. We consider that current mechanisms are suitably fit for purpose.

Recommendation 22 (paragraph 38): There is a lack of consistent and reliable independent advice, information and oversight of prescribers. We recommend that the Department of Health look into ways of making Use of Medicines Committees/Drug and Therapeutics Committees of a uniformly high standard, so that they can reliably carry out this vital educational role. Wherever possible, clinical pharmacologists and specialist pharmacists should be included on such Committees, as should lay representatives. Formularies established in hospital Trusts should be shared with affiliated PCTs with a view to adoption by the entire local health community. Ideally, new drugs should not be prescribed until they have been approved by such a committee. New drugs that might represent significant advances should be fast-tracked through these committees.

The Government does not accept that there is a lack of independent advice to prescribers on medicines. They receive advice from NICE, the National Prescribing Centre, and through the British National Formulary, and the Drugs and Therapeutics Bulletin. These are all independent of any advice provided by pharmaceutical companies themselves.

The specific focus of this recommendation is about hospital-based Drug and Therapeutics Committees (D&TCs) and means to promote greater consistency in their scope and effectiveness. We consider that it is important to secure improved working relationships within a whole health community, particularly between PCTs and their NHS Trusts. In September 2000 the National Prescribing Centre published a valuable resource document – "Area Prescribing Committees – maintaining effectiveness in the modern NHS" – which signposts good practice in terms of the structure and functions of an effective Area Prescribing Committee (APC). We will consider whether this guidance could be updated and amplified to include material on D&TCs along with APC.

Recommendation 23 (paragraph 39): We recommend that a register of interests be maintained by the relevant professional body (General Medical Council, Royal College of Nursing, Royal Pharmaceutical Society of Great Britain etc), detailing all substantial gifts, hospitality and honoraria received by members. The register should be made available for public inspection. Individual practitioners should be responsible for maintaining their entry on the register. Professional bodies should provide advice to their members about the levels of hospitality and payments that are acceptable.

The Government agrees that NHS staff should adhere to proper standards when dealing with business representatives, such as those from pharmaceutical companies. However, the regulatory bodies for healthcare professions are statutory, autonomous self-financing organisations responsible for the training standards and professional conduct of their members. They will also have a large numbers of members, for example the GMC will have thousands of members. Due to the numbers involved it may transpire that any poor conduct is not identified by a professional body, and there is no way of a professional body knowing whether a member is in fact entering gifts or hospitality on the register.

We believe that monitoring of dealings between NHS staff and business can only be successfully carried out at local level. The Department of Health has issued two sets of guidelines on these issues, the "*Standards of Business Conduct for NHS Staff*" published in 1993, and "*Commercial Sponsorship – Ethical Standards for the NHS*" published in 2000. These guidelines cover situations where NHS employees should declare any business or financial interests they may have. It also advises NHS employers to establish a register of interests so that employees can declare casual gifts or hospitality received. This should be audited as appropriate, and be available on request to the public. Employers can more effectively monitor the implementation of this guidance, and take appropriate action where this is required.

Recommendation 24 (paragraph 40): We recommend that the current guidelines on disease awareness campaigns be strengthened. When a campaign is sponsored by a company that is developing or marketing a product to treat the condition that is the subject of the campaign, any related literature should carry a statement to this effect.

The Government agrees it would be helpful to draw attention to the commercial interest of companies who promote the awareness of particular diseases or conditions and will consult with industry and patient groups on how this might be achieved without introducing the potential to make any such campaign promotional.

Recommendation 25 (paragraph 41): We recommend that patient groups be required to declare all substantial sources of funding, including support given in kind, and make such declarations accessible to the public.

The Government recognises the concerns raised by the Committee about the possible influence donors may have on charities or voluntary organisations. Where a charity enters a commercial relationship, it is the duty of the charity's trustees to ensure that entering such a relationship is in the best interests of the charity, consideration that would include both financial and reputational risks. Charity trustees may also refuse to accept a donation where to accept such a donation would not be in the Charity's best interests.

The Government believe that self-regulation should be the first resort in improving fundraising standards and practice, with a reserve power for the Home Secretary to introduce statutory regulation, should self-regulation fail (which the Charities Bill provides for). It is expected that the voluntary self-regulation scheme will be established by April 2006, and we will ask that they consider the Committee's recommendation with a view to promoting best practice.

Recommendation 26 (paragraph 42): We recommend increased funding of NICE to allow it to evaluate more medicines more quickly. Consequent improvement in prescribing standards should make such investment cost-effective.

We have noted the committee's recommendation, however, increased funding for NICE will be a matter for future spending review settlements where additional resourcing for the Institute will be considered against competing priorities for the NHS as a whole.

Recommendation 27 (paragraph 43): The Government should look at the levels and range of expertise required by the pharmaceutical industry and, with universities, take action to ensure that appropriate numbers and quality of staff are trained.

Closure of some university science departments recently prompted an Inquiry by the Science and Technology Select Committee into strategic science provision in English universities. The inquiry concluded that there is no immediate crisis in provision, but found that a key underlying problem is a decline in student demand for science courses.

Before the inquiry was announced, the (then) Secretary of State for Education and Skills wrote in December 2004 to the Higher Education Funding Council for England (HEFCE) to seek advice on whether and what intervention might be appropriate to protect strategic subjects, including science subjects. HEFCE responded in June 2005 (<http://www.hefce.ac.uk/>) and Ministers are now considering HEFCE's advice.

In evidence to the inquiry, the (then) HE Minister restated Government's commitment to science, which is backed up by significant additional investment in the research base. He also outlined work underway to gauge and stimulate demand at all levels from school onwards. The Government is reviewing with key stakeholders the evidence on participation in a number of "shortage subjects" in schools, in Further and Higher Education, and in employment, annually. Chemistry, biology and physics are among the Science, Technology, Engineering and Mathematics (STEM) shortage subjects. The review will help to judge the balance between supply and demand of skills, and consider whether there is a need for further action by Government or others.

The Government's response to the inquiry report, submitted to the Committee on 19 July 2005, provides further details of Government action in this area.

Recommendation 28 (paragraph 44): We recommend that the Government fund: a multi-disciplinary investigation of existing medicines, combinations of medicines and medicines use where there is a reluctance of the industry to fund such research; research into the adverse health effects of medicalisation; and trials of non-drug approaches to treatment.

UK funders of health research support a wide range of studies on clinical treatment and the UKCRC will be important in co-ordinating efforts to build capacity to fill important gaps in the evidence. With its partners in the UKCRC, the Department of Health will incorporate studies of other treatments into the new disease-specific research networks as they are established alongside the existing networks in cancer and mental health. The Department already funds studies on the safety aspects of managing treatment (see answer to recommendation 29), as well as trials of non-drug approaches to treatment.

Recommendation 29 (paragraph 45): We recommend that the extent, cost and implications of illness resulting from the use of medicines be systematically investigated by the Department of Health in conjunction with the MHRA.

A large amount of information is already known about the extent, cost and implications of iatrogenic disease. For example, the MHRA funded a major research project into hospital admission resulting from suspected adverse drug reactions (ADRs). This showed that the burden of ADRs on the NHS is high and that 6.5% of hospital admissions looked at in the study were due to ADRs and of those, 2% of patients died.

Building on the information available on iatrogenic disease the Government wants to minimise risk to patients through medication errors. The Chief Pharmaceutical Officer's 2004 report "Building a safer NHS for patients – improving medication safety" sets out what is known about the known causes and frequency of medication errors and, drawing on experience within the NHS and worldwide, contains recommendations for good practice to help health professionals and NHS organisations achieve this aim.

To further understand the true extent of medication errors, and action that will help to further reduce these, the Department of Health with the DH Patient Safety Research Programme, the NPSA and the MHRA, has commissioned specific research in centres across the UK to determine the frequency of medication errors of different magnitude, at different stages in the patient journey, and to identify ways of reducing them (including IT based solutions such as electronic prescribing and decision support). The research extends across primary and acute services to minimise risk to patients.

Recommendation 30 (paragraph 46): We recommend that the Government adopt a National Drugs Policy to encourage the availability of medicines to all types of patients, the safety and efficacy of these medicines and their rational use and to ensure that medicines are compared to non-drug approaches.

The Government agrees with the sentiment of this proposal but it would be difficult to implement a National Drugs Policy as described by this recommendation. A national policy would take away the prescribers clinical judgement. It is up to the doctor to assess the clinical need of the patient, and consider the best course of treatment. It would be impossible for a national policy to take account of the range of needs a patient might have, so we believe that these decisions must be left to those who are trained to make these judgements.

We agree that medicines must be safe and efficacious, and this is ensured by the strict licensing process that all medicines have to comply with before they come on to the market in the EU.

We also agree that the effectiveness of a treatment must be considered. It is for this reason that the Government established the National Institute for Health and Clinical Excellence (NICE) as an arms length body to provide independent advice to the NHS on the clinical and cost effectiveness of drugs and other treatments. It publishes guidance in the form of health technology appraisals and clinical guidelines. These enable clinicians to make decisions on the rational use of medicines.

Recommendation 31 (paragraph 47): We recommend that the NHS adopt a policy regarding the role of drug treatment in relation to non-drug treatment, emphasising the importance of both approaches.

The Government agrees with this approach. The public health white paper *Choosing Health* has a chapter on how the health service should be 'A Health Promoting NHS'. This highlights the need for the NHS to become a health improvement and prevention service. Ways of implementing this are through putting health and prevention at the centre of existing programmes (eg NSFs); adapting existing approaches to maximise their impact and to mainstream a comprehensive approach to health improvement across the NHS; giving PCTs the means to tackle health inequalities and improve health. By fostering and expanding a range of community health improvement services that include specialist practitioners who know how to help people develop their understanding and skills to improve their own health; strengthen community action for health to tackle inequalities; and work with communities offering training, advice and support to a broad range of health professionals.

Alongside of this the British National Formulary (BNF) advises that Medicines should be prescribed only when they are necessary, and in all cases the benefit of administering the medicine should be considered in relation to the risk involved. It is important to discuss treatment options carefully with the patient to ensure that the patient is content to take the medicine as prescribed. In particular, the patient should be helped to distinguish the side-effects of prescribed drugs from the effects of the medical disorder.

Recommendation 32 (paragraph 48): We recommend that responsibility for representing the interests of the pharmaceutical industry should move into the remit of the Department of Trade and Industry to enable the Department of Health to concentrate solely on medicines regulation and the promotion of health.

The Government appreciates that it may appear that the roles of promoting health and representing the interests of the pharmaceutical industry in the same department may not serve the public as well as it should. However, the interests of patients and the industry are not exclusive.

Having a strong industry that is properly regulated by the MHRA brings benefits to patients, the NHS, and the wider community. Patients benefit by receiving innovative medicines, which have saved the lives of thousands of patients who may have died in the past from diseases such as cancer or coronary heart disease. The NHS benefits through its clinicians being recognised as world leaders in research, and through the resources it receives for carrying out clinical trials. It is this positive environment that makes the pharmaceutical industry invest in the UK, and it is important that these roles be brought together in a balanced and effective way. The Government believes that at present the Department of Health is the right place to balance all of these interests.

The Government does agree with the Committee that the DTI also has an important role in representing the interests of the industry. The pharmaceutical industry invest around a quarter of all UK industry investment in R&D. As the leading industry investing in R&D it is an important stakeholder in helping to achieve the R&D investment levels set out in the Science and Innovation Framework. It is therefore important for the public, the NHS, and industry that these interests are considered effectively within Government. The Department of Health and DTI will put in place formal arrangements that will ensure close co-operation between both Departments, which is in the best interests of these stakeholders.



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