

# Safety, quality, efficacy: regulating medicines in the UK



REPORT BY THE COMPTROLLER AND AUDITOR GENERAL  
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# executive summary

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- 1 Since 1989, the Medicines Control Agency (the Agency) has been responsible for protecting public health by ensuring the safety, quality and efficacy of well over a billion prescriptions and medicines sold over the counter in the UK each year. This role is rooted in the 1968 Medicines Act which was a response to the 1960s thalidomide tragedy and it involves licensing, regulation and surveillance of medicine manufacture, supply, promotion and provision. The Agency is an authoritative source of information on medicines for the UK and provides advice and information to a number of overseas governments and regulators.
- 2 The Agency's work supports the UK Licensing Authority for human medicines, a role generally discharged by the Secretary of State for Health on behalf of all interested UK Ministers. The Secretary of State is also advised by statutory expert committees established under the Medicines Act. A Ministerial Advisory Board oversees the performance of the Agency. As an Executive Agency of the Department of Health and a Trading Fund, the Agency's day-to-day management is the responsibility of a Chief Executive and Management Board.
- 3 The Agency's workload is on the increase, except in applications for innovative chemicals, where applications for marketing authorisations by the pharmaceutical industry have slowed down. The advent of products derived from biotechnology and gene therapy may represent a much larger portion of Agency workload in the future. European legislation introducing regulation to herbal medicines for the first time is being negotiated and legislation already passed will tighten the regulation of clinical trials in humans from May 2004. The licensing of new medicines is becoming increasingly centralised in Europe, as markets in the Member States become more similar, and discussions are ongoing about whether all innovative medicines should be required to go through a central licensing procedure.



- 4 The Agency is to merge in April 2003 with the Medical Devices Agency, which is responsible for ensuring the safety, quality and performance of medical devices, to form the Medicines and Healthcare products Regulatory Agency. Although the functions of the two agencies will not change materially, there will be a new Board, including non-executive directors and a new post of Agency Chair, whose remit will include representing the Agency in public.



## Protecting public health

- 5 The Agency has a good record in ensuring that licensed medicines for sale or supply in the UK have a favourable balance of risks and benefits when used as directed. Twelve licensed medicines have had to be removed from the market in the last five years because of safety concerns, but this compares well with more than 200 new marketing authorisations granted in the UK through national and European procedures during that period, and the four thousand different medicines already on the market. The Agency's licensing decisions also accord well with the views of independent experts in medicines safety in the UK and abroad. Through regulatory action (for example reducing the size of packs of paracetamol tablets to encourage a reduction in the number of tablets sold at one time without prescription) the Agency has, moreover, contributed to improving the safe use of medicines.
- 6 The quality of medicines in the UK is also generally high. This is testament to the Agency's rigorous licensing and inspection regime for laboratories, manufacturing plants and wholesale warehouses, which is internationally recognised. The Agency has also achieved some success in prosecuting those selling poor quality or illegal medicines and is currently targeting illegal sales over the internet.
- 7 The Agency has taken the lead internationally in developing the science of medicines safety surveillance or *pharmacovigilance*, which is still evolving. Voluntary reporting by health professionals of suspected adverse drug reactions is a key element of this work and the Agency continues with efforts to encourage better reporting, including extending the scheme to pharmacists, nurses and others.
- 8 The public will themselves be able to report suspected adverse reactions via NHS Direct from February 2003. This may help improve data on groups of medicines (e.g. herbals) and patients (e.g. children) that are not well covered by the current system. The Agency has developed a strategy for developing a more proactive approach to safety monitoring work and is taking it forward, although full implementation will require additional resources, new commitments from industry and acceptance at a European level.



## Communication and external relationships

- 9 While few medicines need to be withdrawn from the market for safety reasons, the Agency has a range of other regulatory options for ensuring they are used safely and effectively, including provision of additional information, warnings on labels and leaflets and direct communication with prescribers and pharmacists. However, the Agency does not routinely monitor the effectiveness of these warnings in changing prescribing habits and there is some evidence that safety messages do not always get through to those who need them.
- 10 Evidence from doctors, pharmacists and patients suggests that the information provided to patients on medicines is often confusing and inadequate. Moves to widen the availability of medicines without prescription make improving patient information leaflets and labels an even greater priority and the Agency is contributing to a European-level review of the relevant regulations.
- 11 The role of the Medicines Control Agency is not well understood by the wider public, and even many health professionals. This contrasts with the United States Food and Drug Administration which maintains a high profile and targets safety information directly to consumers and patients. To fulfil its role of protecting a public increasingly taking control of its own healthcare and using the internet to obtain information, the Agency has recognised the need to be more outward-looking and begun to produce more tailored information for the public. The new post of Agency Chair provides the opportunity to take this public communication work further.
- 12 To help deliver the government's pledge of a safer NHS for patients, the Department of Health (the Department) and the Agency are developing guidance to improve the labelling and packaging of medicines in hospitals, including reducing the scope for confusion between similarly packaged medicines. These factors are significant contributors to medication error. There is also scope for the Agency to work with others to raise the profile of medicines safety, beginning at the earliest stages of professional training of healthcare staff. Existing local and regional networks, building in particular on the enhanced role of the pharmacist both in the community and the hospital, could also contribute more to disseminating safety information.
- 13 The Agency consults regularly with patient groups and other stakeholders but we found there was scope to improve the transparency of these consultations, and to review the level of support provided for the lay membership of the Medicines Act bodies. The Agency's role requires it to keep in close contact with other bodies. It has a concordat with the National Institute of Clinical Excellence, a part of whose role is to appraise the clinical and cost effectiveness of medicines, as well as with the National Patient Safety Agency.





## Providing a service to industry

- 14 Since its creation, the Agency has achieved major improvements in the quality of service to companies wishing to license medicines. The time to market for innovative products is now much faster, with benefits for both patients and industry. The Agency has achieved this without direct costs to the taxpayer. With a decline in the number of new applications for innovative medicines and increasing centralisation of regulatory work in Europe, though, the Agency's clients have new priorities. They are looking to regulators for advice and guidance and efficient processing of changes to licences throughout the lifecycle of medicines, and they are willing to pay for these services.
- 15 Recognising the need to remain competitive, the Agency is addressing these concerns through client surveys and quality improvement measures. It is also reviewing the fee structures to ensure they reflect the real costs of the work done. Ultimately, however, the level and structure of fees and the Agency's powers to charge for additional services are a matter of policy for Ministers.
- 16 In deriving all its funding from industry fees, the Agency differs from some of its overseas counterparts, who have a proportion of direct governmental funding. The Agency is also unusual in having a stated objective to facilitate the development of the UK pharmaceutical industry. This is a matter of concern to some stakeholders, regarding the Agency's independence, although there are various safeguards in place to prevent conflicts of interest. As part of establishing the new Agency, the Department will review the way in which the relationship between the new Agency and industry is reflected in its objectives.

## The future Agency

- 18 The creation of the new Medicines and Healthcare products Regulatory Agency provides the opportunity to build on the undoubted strengths of the Agency, which continues to be a world leader in terms of its scientific expertise and regulatory experience. In the management of resources, the Agency has already taken action to address weaknesses in financial management and human resources support. It has also put in place improved corporate governance and risk management arrangements to meet Treasury requirements on all government departments.
- 19 Most importantly, the new Agency will be faced with the challenges and opportunities of shaping and working within a new European regulatory system, which may come into being in the next three to five years. All stakeholders agree that a strong UK medicines regulatory agency is needed to protect the public health although much more licensing work may be carried out centrally in the future. Preserving a strong Agency, and retaining and enhancing the expertise within it, may involve the Agency and Department in some key decisions about its priorities. As the Agency's role evolves in future the Department may need to consider the financial sustainability of the current funding arrangements.

## Structure of the report and methodology

- 20 Against this background we looked at the way the Agency regulates medicines for sale or supply in the UK. The report, which aims to provide a helpful analysis on which the new merged Agency can build, examines:
- the background and accountability arrangements of the Medicines Control Agency, and the strategic threats facing it: Part 1;
  - how well the Agency has addressed the first part of its Mission Statement to protect public health, through ensuring the safety, quality and efficacy of medicines in the UK: Part 2;
  - how well the Agency has tackled the second part of its Mission Statement to protect public health through communicating information about medicines: Part 3; and
  - the level of service the Agency provides to the pharmaceutical industry: Part 4.
- 21 Our methodology involved detailed examination of documentation and interviews with Agency staff, consultation with a wide range of stakeholders, surveys of doctors, the public and patients and consultation with an expert panel. Appendix 2 sets out our methodology in more detail and Appendix 4 details the expert input.



# Recommendations

The Agency ensures a high standard of medicines safety and quality in the UK and is a source of good practice for many nations in medicines regulation. We found much good practice and some innovative plans for the future. More detailed recommendations are at Appendix 3, and the main areas where the Agency and its successor can build on this record are as follows:

## On protecting public health by regulating medicines

The Agency should:

- (a) identify resources and work with others to fully implement and deliver its excellence in pharmacovigilance strategy, which is designed to make safety monitoring less reactive.

The Department and the Agency should:

- (b) ensure transparency in the arrangements for preventing conflicts of interest in the Medicines Act bodies that advise Ministers.

## On protecting public health by communicating information on medicines

The Agency should:

- (c) continue to work to identify what improvements to medicines labelling and information leaflets can be made in the UK within existing legislation, building on new guidelines for industry and involving the public;
- (d) build on actions already taken to ensure that the Drug Alert distribution system for recall of defective medicines across the UK reaches all appropriate health professionals, especially in the light of widened prescribing powers;
- (e) continue to inform the public giving higher profile to the risks of purchasing Prescription-only medicines on the internet and publicise its work in this area, subject to the need to avoid jeopardising the Agency's covert investigation activities;
- (f) consider whether its public profile is sufficient to enable it to fulfil effectively that part of its mission involving the provision of information that contributes to the safe and effective use of medicines and consider in what ways this profile can be strengthened;
- (g) build on its existing regional networks, and work with others, such as hospital and community pharmacists and consultants, to disseminate key information on medicines safety more effectively to health professionals including GPs.

The Department and the Agency should:

- (h) work with Royal Colleges and other professional organisations to integrate a greater knowledge of medicines regulation and surveillance into health professionals' training.

## On providing a service to the pharmaceutical industry

The Agency should:

- (i) continue its client survey work across all services to industry and publish details of how it has responded to feedback.

## On the management of the Agency's own resources and performance

The Department and the Agency should:

- (j) ensure where necessary that the Department's and the Agency's objectives are better integrated;
- (k) identify clearly for stakeholders and managers the Agency's key performance objectives, ensuring that they reflect the full breadth of its functions;
- (l) examine the scope to adopt performance indicators which measure progress towards outcomes, rather than simply outputs;
- (m) ensure, when setting objectives for the new Agency that, in achieving the dual objectives of protecting the public and providing a service to industry, potential conflicts of interest are minimised and effectively managed.

The Agency should:

- (n) review the strategic plan to ensure that the Agency can continue effectively to protect UK public health within the changing European regulatory environment;
- (o) implement a permanent cost and time recording system to allow continuous review of its costs against income streams.