

Medicines Control Agency
Management Report

16 January 2003

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Summary and main points for action

- 1 This report sets out our more detailed findings in several operational management areas to which we refer in our main report: performance measurement; accountability; human resources; and the information management strategy.

Findings

- 2 The Agency has developed performance indicators related to its fee-based outputs and has also attempted to demonstrate the quality of its public health protection work in a "balanced scorecard" style performance statement. The performance indicators and targets included have been agreed with Ministers. However, the performance measurement arrangements are not yet providing the sort of focused, balanced and appropriate information required by all stakeholders, and have not been well-integrated with business planning.
- 3 The Agency has been at pains to develop performance measures and targets which are capable of accurate measurements and are attributable to the work of the Agency. However, there is scope to improve the relevance of the information they provide to give the reader more information about the Agency's success against its objectives, even if this involves sharing some outcome measures with other parts of the Department. There is also scope to draw on best practice guidance in constructing measures which are reliable and avoid creating perverse incentives.
- 4 One of the early Executive Agencies, the Medicines Control Agency has also operated as a self-sufficient Trading Fund for nine years. A recent Cabinet Office/Treasury review found that a number of agencies have tended to become detached from their parent departments and need to reconnect at a strategic level. By following the recommendations of this review, the new merged Agency could contribute to improved policy-making and delivery through strengthened relationships with the Department.
- 5 The Agency has taken important steps to improve all aspects of its Human Resources management function, which was previously weak. At a time of change and external threats to the Agency, a clear focus on people management is a key priority.
- 6 After identifying the need for a major upgrade of its IT provision, the Agency managed a complex procurement project effectively. It sought professional advice and put in place new arrangements for managing risks. After a procurement exercise, the Agency has now signed a contract with Accenture to design, build and operate the new systems, on which work begins in January 2003. As the Agency moves to implementation, continuity in strong risk management arrangements will be needed to ensure a successful outcome.

Action points for the Agency and Department of Health

- The Agency could look to published best practice when developing performance measurement systems as part of the merged Agency. It should aim to put in place as soon as possible systems that meet the needs of stakeholders as well as helping drive improvements in performance.
- The Agency should consider seeking independent validation of its performance information, which could be provided by the Department's internal auditors or another independent body.
- The Agency and Department should take into account the recommendations of the joint Cabinet Office/Treasury review of agencies when putting in place arrangements for the governance of the merged Agency.
- The Agency and Department should continue to focus on managing uncertainty and communicating a vision of the future Agency to staff to help address current and future problems of staff recruitment and retention.
- The Agency and Department should continue to ensure risk management arrangements for the Information Management Strategy remain a priority in the merged Agency.

Measurement of performance

- 1.1 Management of an organisation's performance requires a measurement system capable of producing performance information, a set of reported performance indicators designed to help management and stakeholders, and targets related to objectives, to help the organisation achieve success. Achievement of targets may also be linked with performance pay arrangements, most often for senior staff.
- 1.2 In 2000, as part of the external audit of the Agency, it was provided with a management report which concluded that systems in place for collecting performance data were generally reasonable with some examples of good practice. It also made recommendations for improvement. In 2002, as part of our study, we looked at the Agency's key targets and reported performance information against the best practice guidance produced in 2001 by the Treasury, the National Audit Office and others. We also sought advice from our in-house performance measurement specialists.

The performance information system

- 1.3 The guidance indicates that performance information systems and the information they produce should be **Focused, Appropriate, Balanced, Robust, Integrated and Cost-effective**¹. With each criterion comes a set of key questions to help the organisation identify whether it is being met.

Focused

- 1.4 The Agency's aim is to protect public health through regulation of medicines and provision of information to facilitate the safe use of medicines, but it actually carries out a vast array of different activities. Until recently the Agency had not formally identified and quantified all these activities and this has been reflected in its performance measurement arrangements. For example, the Annual Report contains no reported objectives or performance targets for providing medicines information to the public and others, or for support for the development of European medicines regulation, although these activities are highlighted in narrative form elsewhere in its Annual Report. No explicit link is made either between the Agency's work in managing the General Practice Research Database or the British Pharmacopoeia and achievement of its overall objectives.
- 1.5 This mismatch between activities and performance information is partly explained by the fact that Agency funding has been linked explicitly to certain activities only (i.e. licence- and inspection-based work) and that therefore the information collected has been focused mainly on these. However, if Ministers decide that the Agency is to focus more, for example, on its provision of information role in future, the performance measurement system will need to expand to cover this aspect more fully.

Why is the information being collected?

Is the performance information focused on the core aims and objectives of the organisation?

What actions could the performance information provoke management to take?

¹ *Choosing the right fabric: a framework for performance information*, HM Treasury, Cabinet Office, National Audit Office et al., March 2001.

Do stakeholders receive the performance information they need?

Is the right information presented in the right way for each group of users?

Appropriate

- 1.6 Agency performance information has not so far been designed with the public, as a stakeholder, in mind. While there is information relating to the monitoring of medicines in use, it is difficult to gain any impression of exactly how safe, good quality or efficacious medicines are.
- 1.7 The Agency's other main stakeholder is industry. Currently the main measure of the quality of its service to industry is the speed of completion of licence application assessments. However, the Agency acknowledges that it has now reduced the time taken to a near minimum and that speed of assessment, at least for new active substances, is not necessarily the main factor concerning companies applying to the Agency. The latter are now more concerned with the level of support and advice provided by the regulator during and after the application process. The Agency held over 300 company meetings in the past year, but have not thus far had the power to charge for these services and have not focused on measuring the quality of any support and advice given.

Balanced

Do measures cover all significant areas of work in the organisation?

Are both financial and non-financial measures collected?

Are indicators of future performance included as well as measures of past results?

- 1.8 As mentioned at paragraph 1.4 above, there are a number of areas of activity that are not covered by performance information or measures. Current targets also appear to focus more on speed than on other aspects of performance in delivering outputs such as quality or customer satisfaction. However, the Agency does report both financial and non-financial measures. There has, moreover, been an attempt to balance the performance statement by dividing it into four groups of measures: on safety and quality; on standards of service; on financial control and efficiency; and on the focus on people.
- 1.9 As well as developing further this "balanced scorecard" type approach, it might be instructive to identify what percentage of the value of the Agency's business is covered by the target regime and examine any reasons why particular areas are not covered. For example, high-level targets focus on the 22 new active substances - but the 887 abridged licence assessments are relegated to lower-level operational targets.
- 1.10 There is a lack of performance measurement in the areas where the Agency faces key threats and opportunities. The setting of targets might help the achievement of the strategic success factors. For example, the Agency could set targets which:
- drive improvements in those aspects of performance that are most valued/important to the business; and
 - communicate the importance of retaining and winning the types of business that maintains staff skills. For example, targets could be set for income earned from specific activities.

Robust

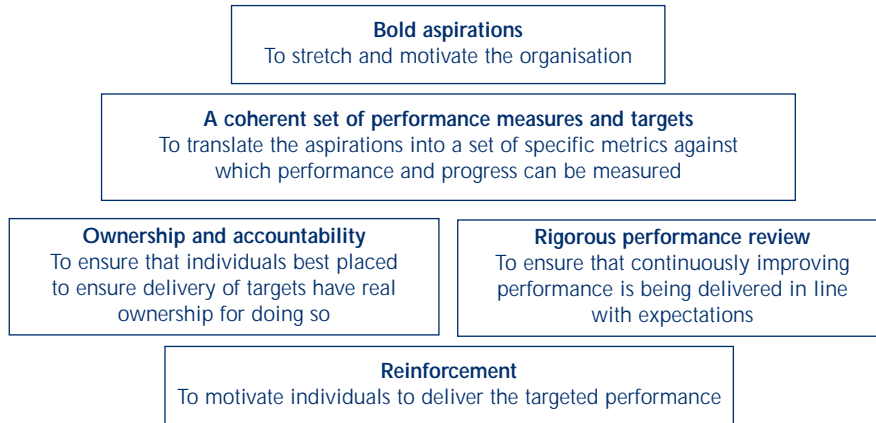
Can the system survive changes in personnel and changes in the structure of the organisation?

- 1.11 Systems within the Agency appear to have been robust enough to withstand changes in personnel and structure thus far. The Agency will need to ensure that the arrangements are able to continue following the merger and creation of the new Medicines and Healthcare products Regulatory Agency in April 2003.

Integrated

1.12 The Public Services Productivity Panel business planning model (**Figure 1**) sets out how performance measures and targets can form part of an integrated performance management system.

1 Performance measurement should be integrated with business planning



Source: Public Services Productivity Panel

1.13 Currently, the key Agency performance measures are monitored and used by management, with some being reported quarterly to the Ministerial Advisory Board. But in implementing the above model fully, it is important to ensure that targets actually help to drive improvement. Currently, with many Agency processing targets set at "100% in x days" it is likely that most items will be processed well within the target date, with only a few coming close to the "X days" limit, and there is no incentive to improve the average time taken. There may be a question therefore over how much these targets actually influence performance.

1.14 Another important point relates to the link with performance pay. The Treasury's guidance on Trading Fund Accounts makes it clear that, where performance against a target may lead to payments being made to staff, the performance against the target must be formally and independently validated. Independent validation has been recommended by the National Audit Office and Committee of Public Accounts on several occasions specifically in relation to Executive Agencies, including the Driver and Vehicle Licensing Agency (1994), the Meteorological Office (1996), and the Benefits Agency (1998). The Meteorological Office in particular have found validation a useful management tool.

1.15 In the Medicines Control Agency, currently the pay of the Chief Executive only is explicitly linked to achievement of overall Agency objectives. If the targets are to be more closely related to performance pay, this indicates a role for an external validator.

Are the results of the performance information system monitored and used as part of the business planning and management process?

Is there consistent performance information at all levels of the organisation?

Are performance measures for individuals and teams consistent with measures of the organisation?

Do people within the organisation own the system? Do they take notice of the results and use them? Did they contribute to its design?

Are the resources put into collecting performance information proportionate to the benefit for the organisation?

What is the actual cost to the organisation of the performance information (including the burden of form-filling and time spent reviewing the information)?

Cost-effective

1.16 From our examination, there was no evidence that excessive costs were associated with the performance measurement arrangements. Plans for upgrading of IT provision should make collection of this information easier in future. In making arrangements for the new merged Agency, management will wish to consider the costs of any new measures they may wish to introduce.

The performance measures and targets

1.17 Regarding the performance measures and targets themselves, published best practice suggests a number of key criteria². Measures and targets should be:

- well-defined;
- relevant;
- attributable;
- reliable;
- verifiable;
- able to avoid perverse incentives; and
- comparable.

We looked at the Agency's existing measures and targets against these criteria. Our key findings are set out below.

1.18 For the lay reader the Agency's measures and targets are not always **well-defined**. For example, a new decision-making target introduced in 2000-01, measures "concordance" with expert opinion. However, the meaning and significance of "concordance", which refers to agreement with scientific experts, is not explained and it is not clear to the reader which and what proportion of decisions the measure covers.

1.19 Although the Agency is dedicated to protecting the public health, the information it reports on its performance at that task is not always clearly **relevant** to the public, or health professionals, or easy for them to interpret.

1.20 One aspect of this is that reported performance measures at present focus almost solely on the *outputs* achieved (e.g. number of GLP Inspections carried out) rather than the *outcomes* of these actions for public health, which might be more relevant to the reader. The Agency rightly draws attention to the difficulties of developing outcome measures, but examples of measures that do focus on outcomes are the number of unsafe medicines found through the medicines testing scheme, or the number of packages of unsafe medicines recalled. **Figure 2** shows some possible input, output and outcome measures across key areas of the Agency's activities.

1.21 One reason for the absence of more outcome-based measures in the Agency's performance statement is that it has been at pains to devise performance measures which are solely **attributable** to itself. Some of the activities in which the Agency is involved cut across other areas of the Department or other departments and there is no one body responsible for the final outcome.

1.22 Whilst it is not always appropriate for an agency's targets to be focused on outcomes, it is important that the Agency has access to information so that it can assess whether objectives are being achieved, and whether activities are contributing to the desired outcome. In these cases, the actual collection of outcome data may not fall to the Agency but could, for example, be undertaken by the Department. Moreover, it may not actually be appropriate

² *Choosing the right fabric: a framework for performance information*, HM Treasury, Cabinet Office, National Audit Office et al., March 2001.

2 Input, output and outcome measures

| Inputs | Outputs | Outcomes |
|--|---|--|
| Number of adverse drug reaction reports received | Percentage of adverse reactions entered onto the database in x days | Total time taken for the Agency to learn of and act upon incidence of unexpected adverse reaction from the time it took place |
| Number of variation applications received | Number of variations processed in x days Number of changes to marketing authorisations made on safety grounds | Estimated percentage of doctors changing their prescribing habits as a result of new warnings |
| Percentage of facilities regulated by the Agency | Percentage of facilities inspected within x months | Percentage of facilities found to be compliant with good practice standards Number of improvements made as a result of inspections |

Note: measures shown in bold are currently reported by the Agency

to set a target in each of the outcome areas chosen because setting a desired level, say, of product recalls may be too difficult and could be misleading. Instead the information could be used to track performance over a period, as part of a package of measures.

- 1.23 Our examination indicated that the performance measures are produced in a generally **reliable** and **verifiable** way, although there is scope for improvement. Several of the Agency's performance measures have associated targets in the form "x per cent in y days" and reported performance at or near 100 per cent (e.g. the number of abridged licence applications or licence variations completed). With little change year on year it appears that several of these targets are no longer very stretching and do not give a useful picture of actual performance.
- 1.24 Moreover, the use of "percentage cleared in x days" targets can mask a small number of very slow outputs, and this was the case with the Agency's large backlog of licensing variations in 1999. In our 1998 report on the performance measurement arrangements of the Benefits Agency we recommended that targets of the "average time taken" type should generally be used as well as "x in y days".
- 1.25 There may be good reasons why an Agency may not wish to raise targets year on year. For example, because it believes that existing performance is sufficiently good. If that is the case then the target could perhaps be given lower "operating" status. If, however, the Agency does wish to improve performance it could consider an average time to complement the existing "x in y" format.
- 1.26 The way that some Agency service levels are currently measured, while accurate, makes it difficult for a reader to gain a real impression of the activity taking place. For example, in measuring the time to assess an application, the time during which the company is responding to further questions raised by the Agency is not included (the measurement "clock" is said to have "stopped"), with the result that assessments appear to take as little as 33 days, when in fact the elapsed time could be several months. There is also *potentially* a **perverse incentive** for the Agency to send unnecessary enquiries to the company whilst continuing to work on the assessment. However, we found no evidence to suggest that this was actually taking place.
- 1.27 We noted that this measurement method is in line with European and most overseas national approaches. Any change could therefore make comparisons with other countries more difficult and indeed the Canadian Agency has recently decided to change from measuring total elapsed time to conform with the Medicines Control Agency's and others' practice. Nevertheless, use of both measures could clarify the information for readers.

1.28 Most of the Agency's performance measures have been consistent year on year and thus performance is **comparable** with the past. Comparison with other medicines regulators overseas, with whom the Agency is in direct competition is, however, more difficult. Published benchmarking information by the consultants CMR International of the work of a range of regulators worldwide has highlighted the differences in terminology and measurement approach at different stages of the licensing process in the various countries³. The Medicines Control Agency has not thus far participated in this project, partly because of constraints over the information it can release on licensing work. There may be scope, however, for both quantitative and qualitative benchmarking, possibly through bilateral agreement, to help management identify priorities for improvement.

3 *Improving the regulatory review process*, Centre for Medicines Research International, 1996.

Accountability arrangements

2.1 Since 1993, when it became a Trading Fund, the Medicines Control Agency has operated under these arrangements in an independent way from its parent Department. Day-to-day activities are the responsibility of the Agency Chief Executive, who acts as Accounting Officer, and the Management Board. Oversight of the Agency is formalised by means of a Ministerial Advisory Board, composed of representatives from the Department of Health, the pharmaceutical industry, the NHS and devolved regional administrations.

Agency status can lead to remoteness from the sponsoring Department

2.2 In July 2002 a joint Cabinet Office/Treasury review of *Executive Agencies in the 21st Century*, led by the former Chief Executive of English Heritage⁴, reported on the delivery of services across central government through Executive Agencies and non-Departmental public bodies. It concluded that in general:

- despite success in improving performance some Executive Agencies had drifted apart from their parent departments and were seen as separate from them, which hampered both policy development and service improvement;
- there was a need to reconnect with Ministers' aims and departmental objectives, if agencies were to play a full part in delivering effectively in the future;
- agencies needed to be more closely connected with policy-making if staff at the 'frontline' are to deliver more effectively.

2.3 The Agency is required to assist Ministers in achieving their high-level objectives on health. There are numerous ways in which the Agency does this, for example through providing information and briefing. More specifically, the Agency makes a contribution to the achievement of a number of medicine-related objectives set out in the NHS Plan. But links between Agency and Departmental objectives are not always clearly articulated in the performance information.

2.4 Moreover, the highly technical nature of the Agency's work, in which there are few experts outside the Agency itself, means that there may be little scope for day-to-day dialogue until an issue becomes important for policy-making or public safety reasons.

⁴ *Better Government Services: Executive Agencies in the 21st Century*, Office of Public Services Reform, July 2002.

Communication between the Agency and Department has not always been effective

- 2.5 The Department and the Agency consider that they generally have a good working relationship. However, the Department became concerned in 2000 over the quality of information in one specific area provided to Ministers by the Agency. This arose out of the withdrawal of an oral polio vaccine from use in the NHS because of a potential safety risk from the use of bovine material in its manufacture. Although the risks to the public were deemed by the Agency, and later the Committee on Safety of Medicines to be "incalculably small", the Department was concerned that it had not been made aware immediately of the issue by the Agency. The Secretary of State for Health requested a subsequent examination by the Chief Medical Officer⁵ of the events surrounding the withdrawal. It identified that on a number of occasions in 1999 Ministers had unwittingly given inaccurate answers to questions in the House of Commons about the use of bovine material in vaccines because of unintentionally misleading information provided by and to the Agency.
- 2.6 The Agency has taken steps to remedy the general concern about the quality of information provided. In November 2001 a report it commissioned from an expert on corporate governance recommended changes including improved internal audit arrangements, and the introduction of a dedicated risk manager, which the Agency has taken on board. The Agency also reviewed its Standard Operating Procedures, some of which had not been looked at for some years. Provision of information was one area covered by this initiative.
- 2.7 The Cabinet Office/Treasury report's recommendations for effective service delivery and proper governance will be useful to the Department and Agency in putting together plans for the merger of the Medicines Control Agency and Medical Devices Agency. They include:
- a senior sponsor within the Department of Health to provide strategic direction and strategic performance management for the Agency;
 - a two-way 'no surprises' rule;
 - external challenge and support introduced via the Agency's management board;
 - clear roles for, and induction of, non-executive directors; and
 - better integration of Agency business planning with Departmental business planning.

5 *The withdrawal of an oral polio vaccine: analysis of events and implications*, Chief Medical Officer, June 2002.

Human resources

3.1 The Medicines Control Agency, like its overseas counterparts, faces strong competition in recruiting and retaining the best scientists and experts. While industry can offer financial rewards, the university sector can offer professional and academic recognition. Regulatory work has not historically offered the opportunity for gaining academic qualifications or recognition, which might compensate for lower pay. This means that for some posts there are difficulties in attracting the best candidates.

Recruitment and retention difficulties have not been helped by weak human resources management

3.2 The Agency acknowledges that its human resources function has not always contributed to improving staff recruitment and retention by supporting managers. Historically, the post of Human Resources Manager in the Agency also incorporated the role of Facilities Manager. A small Human Resources team, with few qualified human resources management professionals and more recently, a high proportion of temporary staff, lacked customer focus.

3.3 The Agency's Human Resources function has also suffered from a lack of appropriate management information. Attendance and sick leave records for staff at the Agency are unreliable. Its work is supported by an old computer system, requiring extensive manual intervention. There was also until recently no co-ordinated central approach to management training and development for staff across the Agency.

The Agency has now taken steps to improve matters

3.4 In late 2000 the then Human Resources and Facilities Manager of the Agency was suspended pending an investigation into disciplinary matters. Although the investigation was not concluded by the Department until March 2002, the Agency recognised that it needed to make changes in this area and began work during this period, putting a professional Human Resources manager in post during the disciplinary process.

3.5 As part of a wider programme of cultural change, the Board consulted staff in 2000, following which it set up in 2001 three high-level working groups to identify and implement improvements. The working groups, each led by a Board member, are focusing on: management and leadership; personal development and performance management; and communications. Activities undertaken during 2002 include:

- management development training for operational managers and seminars for senior staff provided by professional consultants;
- redesign and simplification of the Agency's pay and reward system;
- a best practice communication guide; and
- recruiting an experienced head of Human Resources.

New Human Resources staff and a restructured team have improved the customer focus of the function and improved IT facilities are planned as part of the overall Agency upgrade.

3.6 There remain risks to recruitment and retention of the best staff. As discussed in more detail in our main report, proposed changes in the European regulatory system could potentially lead to a reduction in high-profile work and a shift towards a greater information provision role. The merger with the Medical Devices Agency also brings uncertainty about the future shape of the merged body, which the Agency have identified as a business risk.

Information management strategy

The Agency recognised the need to upgrade IT and has to date managed the project to good standards

- 4.1 The Agency currently uses a range of largely free-standing information systems designed to support its different business activities, including managing licence applications, tracking adverse drug reaction reports, and managing inspection work. When they were developed in the early 1990s these systems represented an important advance, and they are still a source of good practice for developing countries. But for modern working requirements the Agency has concluded that the systems are too inflexible, too slow and lack the capacity to share and manipulate data adequately.
- 4.2 In common with several other European medicines regulators, the Agency has identified the need for major investment in IT in order to help it evolve and remain competitive. In August 2001, with advice from consultants and legal advisers the Agency asked for initial expressions of interest and received 23 formal responses. The Agency was concerned to ensure an appropriate level of competition and a "level playing field" between bidders in the procurement, so they took expert advice on the information they should provide to bidders. Five were invited formally to negotiate and only three responded with a formal bid, of which one was the incumbent IT provider, Accenture. One of the other bidders withdrew and after taking legal advice, and following an evaluative review, the Agency decided to proceed to detailed negotiations with Accenture only.
- 4.3 Although there was a lack of real competition in the latter stages of the procurement, the Agency and its advisers consider that they maintained competitive pressures and were able to obtain price savings as a result.
- 4.4 The Agency took advice from a range of experts regarding the IT procurement and the strategy in general. They employed external IT consultants who advised on continuing project management arrangements and, from August 2001, they engaged an expert with expertise in the procurement and management of major IT change programmes to advise the Board. The cost of the project was to be subject to "target pricing" arrangements designed to incentivise both parties to control costs through sharing of any savings as well as any overruns.
- 4.5 The contract with Accenture for design, build and operation of the new system, worth some £50 million over 10 years, was signed in December 2002, following Departmental approval. Strong risk and programme management arrangements will be needed to address the continuing risks to the project, including:
- that the project does not fully meet the needs of Agency staff as users through poor design or implementation;
 - that the systems developed become rapidly obsolete because of changes in the external environment or the role or structure of the Agency, e.g. the merger with the Medical Devices Agency; further centralisation of medicines licensing in Europe; and
 - that excessive user requirements or changes to requirements mean the project is delayed or goes over budget.