

Themes and comparisons in international medicines regulation

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Introduction: themes in international medicine regulation

- 1 As part of our study of the UK Medicines Control Agency we visited medicines regulators in five other countries. During these visits we noted a number of broad similarities, as well as some important differences in how each national regulator operates. The purpose of this supplementary report is to draw out common issues, and highlight distinctive features of the different systems, which may be of interest to the regulatory field and the lay reader alike.
- 2 All the regulators we visited base their work on the need to evaluate the safety, quality and efficacy of medicines. However, there is no exact equivalence between the work of the different agencies we studied. Each operates within its own legislative and regulatory framework and each has its own performance targets and funding arrangements. Nevertheless, our visits revealed a number of issues affecting all or most of the regulators we examined. These include:
 - globalisation of the trade in medicines;
 - the decreasing rate of new drug discoveries;
 - the increasing complexity of modern medicines;
 - increasing demands from consumers for information and involvement;
 - the increasing availability of medicines (particularly via the internet);
 - pressures on funding arrangements for regulation; and
 - the challenge of measuring performance in the light of all these changes.

A tension exists between national regulations and the global trade in pharmaceuticals

- 3 The globalisation of trade and mergers between pharmaceutical companies have internationalised pharmaceutical production, with the result that national regulators are no longer isolated from trends and developments in other countries. Nevertheless, registration and licensing of medicines has remained to a large extent a national responsibility, creating a tension between the national role of regulatory authorities and the international scope of the pharmaceutical industry.
- 4 The development of the European single market has been an important step towards the harmonisation of national regulations for medicines. Such developments not only introduce price competition between generic drugs, but also ease the introduction of medicines into new markets. The increasing expectations of consumers and industry stakeholders have prompted national regulators to explore ways of making national requirements conform with international standards in order to make new medicines available with the minimum of delay, especially when the medicine is already available in another country.

- 5 Within the European Union, the harmonisation of regulatory requirements has been addressed since 1985 by a number of directives aimed at achieving a single EU-wide market for pharmaceuticals. More widely, the International Conference on Harmonisation¹, set up in 1990, brings together the medicines regulatory authorities of Europe, Japan and the USA and aims to improve, through harmonisation, the efficiency of the process for developing and registering new medicinal products in those countries. The purpose of this project is to harmonise the technical requirements of the various regulatory systems as much as possible, thereby eliminating unnecessary testing, delay and duplication for companies, without compromising safeguards to public health.
- 6 Reflecting the global nature of the market, several regulators including the UK Medicines Control Agency, have negotiated bilateral agreements with their overseas counterparts, particularly in the area of inspections of Good Manufacturing Practice. This allows licensed medicines to be imported where the inspection systems in the manufacturing country are recognised by the importing nation. However, whilst efforts by regulators to share information on drug safety are increasing, mutual recognition of drug licences from one continent to another is still some way off.

Although new drug discovery is declining, medicines are more powerful and carry greater risks

- 7 Medicine regulators work in a complex and evolving scientific field, and assess ever more complex drugs with potentially greater risks to public health. In recent years a number of national regulatory agencies have experienced a decline in the number of applications for the approval of new active substances. This reflects a reduction in the number of new drug discoveries by the pharmaceutical industry. On the other hand, as new uses are discovered for existing drugs, or drugs are used in different strengths, different forms and in different combinations, most regulators have experienced an increase in less novel licence applications.
- 8 Although scientific data from clinical trials gives important information on the safety of medicines, they are by nature limited in size, and introduction into the wider population brings a risk of unexpected adverse reactions. The increasing strength of modern drugs has also contributed to the growth in the incidence and seriousness of adverse reactions. The inherent risk that is associated with even well-tested, licensed medicines means that national regulatory authorities have an essential role in monitoring the safety of licensed drugs on the market.
- 9 In all the countries we looked at, manufacturers of medicines are obliged to report adverse reactions to medicines to the regulatory authority, and there is also a legal obligation for health professionals to report adverse reactions to medicines in two countries (France and Sweden). In the others, voluntary reporting systems for health professionals are generally acknowledged to produce low rates of reporting. Only the USA and Canada have provisions for patients and consumers to report adverse reactions themselves.

¹ Full name: *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use*

While the public is making more demands for information on medicines, regulators are trying to keep pace with changes in consumer behaviour

- 10 Each regulatory decision involves identifying and managing the balance between risk and benefit and this has traditionally been the preserve of medical and pharmacological experts. However, consumer groups, patients' associations and other stakeholders are increasingly demanding access to, and involvement in, these decisions. In a number of countries we noted calls for greater transparency and public participation in the regulatory process. Although there are concerns from the pharmaceutical industry that greater openness would infringe on Intellectual Property Rights, there are also strong arguments for the view that transparency would lead to better decision-making and greater public trust in the regulatory process.
- 11 The increasing sophistication of modern patients and consumers has manifested itself in an increasing desire for clear information about their medicines. The regulation of information given to patients and consumers about their medicines, for example through patient information leaflets, advertising or other means, is another activity of the medicine regulators we studied. Regulators in several countries have made moves to improve the presentation of information provided to consumers. Some regulators (e.g. in the United States) already have a more active role in communicating with the public, through various public meetings and consultations, while others are recognising the need to increase their commitments in this area.
- 12 Consumer behaviour has also changed, as patients seek alternative means of purchasing medicines. Buying medicines over the internet can be quicker and cheaper than traditional methods. However, with the increase in internet retailing a number of regulators, including the UK Medicines Control Agency, have taken enforcement action over non-compliance with medicine regulations, including illegal sales of prescription-only medicines, as well as medicines not licensed in that country. The internet does not respect national boundaries and agencies are now beginning to take a coordinated approach to tackling the obvious public health risks.

Funding from the pharmaceutical industry can enhance efficiency, but reliance on industry fees is a cause for concern for stakeholders

- 13 All the regulators we visited are funded to some extent by fees charged to the pharmaceutical industry, although the proportion of funding raised from industry varies. The last decade has seen a general trend towards increased fee-based funding. These extra resources have enabled the regulatory authorities to keep up with the overall increase in volume and complexity of work coming from industry. Charges have in general been accepted by the industry in return for more efficient processing of applications, and consumers and patients have benefited from products reaching the market more quickly. To varying degrees, the income from fees has also enabled regulators to invest in improved safety monitoring and public information work, although the level of funding allocated to these activities is rarely explicit.

- 14 However, patient groups and some regulatory sources particularly in mainland Europe have sounded a note of caution more recently about the increased dependence of regulators on fee income. Co-operative working with industry offers many advantages over a more separate relationship, but the perceived closeness between regulators and the pharmaceutical industry has led to calls for greater transparency and more public funding. European Parliamentarians noted in 2002 that some aspects of regulation, for example pharmacovigilance, might be more suited to direct public funding. Coming at a time when increasing demands from the public for medicines information require resourcing, these concerns point to either a new contract with industry or a potentially large bill for governments.

Regulators face challenges in measuring their performance effectively

- 15 The regulatory agencies we visited measured their performance in different ways, reflecting not only different legislative and accountability arrangements, but also the inherent difficulty of the task. Most regulators focus on measuring the efficiency of their operations by reference to the speed with which they assess new drugs. And most are required to report on their performance in financial management. In the European Union, where companies can choose where to place their business based on speed and quality of service of the regulator, success in competition for regulatory work can also be used as a performance measure.
- 16 However, most regulators are at the early stages only of measuring and reporting the effectiveness of their public health protection work. Measurement in this area is inherently difficult because of the separation between the regulator, who takes action or issues guidance, and the resulting patient outcomes, which are delivered by healthcare professionals or even consumers themselves. Several regulators told us they were looking at using drug utilisation data to monitor outcomes, but this type of evaluation is still very much in its infancy.

United States of America: Center for Drug Evaluation and Research

- 1.1 The Center for Drug Evaluation and Research (The Center) is part of the Food and Drug Administration, a regulatory body which estimates it has responsibility for some 25 per cent of all consumer goods in the United States. The Food and Drug Administration itself is an Agency of the Department of Health and Human Services. In contrast to some European countries, the Agency Head, rather than a Government Minister, makes regulatory decisions, and is accountable to Congress.
- 1.2 While the Center regulates pharmaceutical drugs for use on humans, other parts of the Food and Drug Administration are responsible for regulating biologics, medical devices, food safety, animal feed, veterinary drugs and cosmetics. The Center employs around 1,800 staff, of whom about half are scientists or physicians.
- 1.3 The Center evaluates and approves all new medicines before they are sold, and monitors marketed drugs for unexpected health risks. It collects information about adverse reactions from manufacturers, health professionals and consumers, and provides information about medicines. It also sets standards for drug testing and manufacturing quality, and carries out scientific research and testing.



The work of the Center is partially funded by industry

- 1.4 The Prescription Drug User Fee Act of 1992 authorised the collection of fees in the US for the first time from the pharmaceutical industry to supplement centrally appropriated funds. Fees are charged for reviewing drug applications and issuing product licences and establishment licences. No fees are charged for carrying out inspections. The Act was renewed and revised in 1997 and again in 2002. Currently around 52 per cent of funding for the Center comes from fees.

Communication of information about medicines is an important part of the regulator's role

- 1.5 Communication with the public is seen as an integral part of the role of the Food and Drug Administration and its Centers. Surveys show a high awareness of the Food and Drug Administration among the general public. Recently, major public education campaigns have addressed issues such as the benefits versus risks of medication use, drug interactions, buying medicines over the internet, and new, simplified over-the-counter medicine labels. Patient and consumer views are represented on Advisory Committees, and opportunities for wider consultation are offered through public meetings, workshops, conferences, the internet and other media.

- 1.6 Advertising of Prescription-only medicines direct to the public is allowed in the United States, in contrast to Europe. The Center actively monitors drug information and advertising of prescription drugs to ensure that information is accurate (the Federal Trade Commission monitors advertising of over-the-counter drugs). Before a drug is approved, the proposed name of the drug is evaluated as part of the assessment process to avoid possible name confusion. A standard 'number plate concept' has recently been devised for all over-the-counter medicines, to standardise content and format of the Patient Information Leaflets. Black boxes can be used on labels to highlight special problems. In addition to Patient Information Leaflets, special Medication Guides are sometimes published where adherence to directions is crucial for effectiveness or safety.

The public as well as health professionals can report adverse reactions

- 1.7 A distinctive feature of the adverse drug reaction reporting system in the United States is that patients as well as healthcare professionals can submit reports to the system, Medwatch. Manufacturers are also required to report adverse incidents to the Adverse Events Reporting System. After evaluating reports, the Center may take regulatory actions to further improve product safety (e.g. by updating product information) in a similar way to other countries' regulators. Despite the addition of patient reports, however, the Center estimates it receives reports on only 1-10 per cent of adverse reactions, and it has been working towards a more active surveillance approach.

The Center has been focusing on risk management

- 1.8 The Center has recently organised workshops with industry and academia on managing risk. And the Food and Drug Administration held a recent public meeting on risk management more widely. The increasing focus on risk management is reflected in the most recent Prescription Drug User Fee Act revision, which allocated funds specifically to drug risk management for the first time and will fund 100 additional staff to undertake this work. A new advisory committee is also expected to be formed to advise the Center on risk management issues.

Enforcement activity takes a variety of forms and has included action against internet firms

- 1.9 The Center initially aims to work with the drug manufacturer to correct any problems voluntarily. Enforcement actions result in either administrative action or judicial proceedings. Administrative actions can include warning letters, import alerts (which prevent products entering the United States), detentions, and voluntary recalls. Judicial actions for medicines include seizure, injunctions, civil penalties, and prosecution. The Food and Drug Administration cannot suspend a licence without a public hearing. However, if there is an imminent hazard the Secretary of Health and Human Services can withdraw a licence.
- 1.10 The Center has undertaken extensive enforcement activity in relation to internet drug sale. A media campaign alerted the public to the risks of illegal medicine sales on the internet, and the Food and Drug Administration has issued a number of formal warnings to internet vendors.

A number of performance measures exist to reflect the Center's goals

- 1.11 The Food and Drug Administration has set performance goals in four key strategy areas: a strong and effective Food and Drug Administration; counter-terrorism; assuring medical product safety; and bringing new technologies to a wider market. Targets are mainly activity-based rather than outcome-based. A substantial proportion of the Center's current goals are milestones for the development of new activities rather than performance targets for established programmes. Pay levels for senior executives (Assistant Commissioners) are related to performance against targets, but this does not extend to lower down the organisation.
- 1.12 The Food and Drug Administration must produce a plan three times a year with performance measurements, which is examined by the Department of Health and Human Services and linked with their budget. The plan is also scrutinised by the Office of Management and Budgets. The President presents the final version to Congress. A new Presidential initiative has introduced 'traffic light' style performance measurement assessing all agencies, including the Food and Drug Administration, against five key criteria: e-government; outsourcing; financial management; procurement; and performance measurement.
- 1.13 The Center has different targets for the assessment of standard drug applications (drugs that are similar to those on the market) and 'priority new drugs' that represent significant improvements compared to existing therapies. The Center aims to assess 90 per cent of standard new drug applications within ten months, and has a goal of reviewing 90 per cent of priority new drugs within six months.

Canada: Therapeutic Products Directorate



- 2.1 The Therapeutic Products Directorate is the national authority that evaluates and monitors the safety, effectiveness and quality of pharmaceutical drugs, medical devices and disinfectants available in Canada. The Directorate is currently part of the Health Products and Food Branch of Health Canada, rather than an independent agency. Besides the work done by the National Centre and Regional Centres, the Provincial/ Territorial governments have responsibility for the distribution and reimbursement of medicines.
- 2.2 The Therapeutic Products Directorate is responsible for regulating pharmaceutical drugs, medical devices and disinfectants. Other directorates within the Health Products and Food Branch also have a role in medicine regulation. For example, adverse reaction reporting and other post-marketing activities are co-ordinated by the Marketed Health Products Directorate, while compliance and enforcement activities are the responsibility of the Health Products and Food Branch Inspectorate.

An ongoing review may lead to a change in the Directorate's status

- 2.3 Recognising that the efficiency of drug assessment and regulation in Canada has not always matched the standards set by overseas counterparts, the Canadian Government is currently reviewing the status and functions of the Directorate. The review is looking at a range of options for change and is expected to report in early 2003.

Canadian regulation places reliance on overseas counterparts

- 2.4 Canada has Mutual Recognition Agreements covering Good Manufacturing Practice with the European Union and the European Free Trade Association and is working towards a similar agreement with Australia.

The work of the Therapeutic Products Directorate is partially funded by industry

- 2.5 A cost recovery programme set up in 1995 allows the Therapeutic Products Directorate to charge fees to industry. Fees are charged for the pre-market evaluation of drugs and medical devices; for the right to market drugs and medical devices; for establishment licences; and for other services to industry such as issuing Export Certificates and the maintenance of Drug Master Files. No fees are charged for routine inspection activity. Around 66 per cent of funding comes from industry. The Canadian Treasury Board requires revenues be used to finance only the service from which they are generated, and that there be a direct relationship between the costs incurred and the charges collected.

The regulatory authorities are looking at improving communication with the public about medicines

- 2.6 An Office of Consumer and Public Involvement exists to support and encourage public participation in the activities of the Health Products and Food Branch. Several consultative workshops have been held with stakeholder groups, and consumer representatives have been involved in advisory committee meetings. The Health Products and Food Branch has appointed a Public Advisory Committee to assist in the Branch's decision-making process by providing advice on broad issues and initiatives from the consumer/public perspective.
- 2.7 The new Marketed Health Products Directorate communicates product-related risks to healthcare professionals and the public. The Directorate produces "Advisories to Consumers" and Fact Sheets on medicines. Besides a toll-free telephone number for adverse reaction reporting, information lines have also been established to handle queries on specific topics and address issues having a greater impact on the general public. Provincial and Territorial governments also play a role in communication with the public.
- 2.8 A 'product monograph project' currently underway in the Directorate is expected to produce a standardised format for medicine information which is appropriate to a consumer audience, and will include the relative risk of listed adverse incidents. Information for Prescription-only medicines already includes adverse incident data from clinical trials. The Health Products and Food Branch has held workshops with health professionals and other stakeholder groups to look at ways of improving the communication of drug safety information further.

Review times are seen as important in measuring performance

- 2.9 The objective of the Directorate is to ensure Canadians have timely access to drugs that are effective, safe and of high quality. Performance targets are based on the type of data submitted (i.e. clinical, manufacturing, etc.) and whether or not the submission is accepted for priority review. The Directorate is currently focusing on improving performance, particularly in dealing with priority new drug submissions.

France: Agence Française de Sécurité Sanitaire des Produits de Santé



- 3.1 The Agence Française de Sécurité Sanitaire des Produits de Santé is a government Agency which reports to the Ministry of Health. The Director General of the Agency takes all decisions about drug authorisations and acts as the licensing authority. The Agency employs 882 staff, of whom two thirds are doctors, pharmacists or other scientists.
- 3.2 The products regulated by the Agency include medicines, medical devices, laboratory reagents, blood products, cosmetics, and products of genetic and molecular engineering. Herbal products which qualify as medicines are regulated, and there is a new national scheme for registration of homoeopathic medicine under EU legislation.
- 3.3 Sanctions against manufacturers who do not comply with legislation include legal prosecutions or administrative action by the Agency. The Agency currently carries out only a limited amount of enforcement activity, but has recently formed a new section which will take a more proactive role in this area.

The Agency's funding from industry is capped

- 3.4 Funding from industry is based on company turnover, or the number of applications submitted, and currently accounts for around three-quarters of income. Inspection activity does not generate fees for the Agency. In a deliberate move to prevent over-reliance on industry fees and to illustrate the Agency's independence, the Agency is required to maintain a level of at least 25 per cent state funding.

Health professionals are obliged to report adverse reactions to medicines

- 3.5 France is the only country we visited where all health professionals, including pharmacists and nurses, are obliged to report adverse reactions. This may explain why estimates suggest there is less under-reporting in France than in other European Union states. Manufacturers are also legally obliged to report adverse reactions, and Agency inspectors check periodically to see whether pharmacovigilance systems are in place.
- 3.6 Adverse reaction reports are made to one of 32 regional centres, which are usually based in hospitals funded by the Agency. The regional centres acknowledge reports and analyse data, and are proactive in communicating with health professionals in the area. A co-ordinating group links all the different pharmacovigilance systems at the Agency. There is no direct patient reporting of adverse drug reactions, although any person can report quality defects.

The Agency is looking at ways to improve communication with the public and others

- 3.7 The Agency has recently taken steps to improve its communication strategy. Although the Agency communicates information about medicine safety risks through its website and press releases, public awareness of the Agency is believed to be low.
- 3.8 A fund of €20m has been set aside to set up an independent body within the Agency to assess what information doctors would like to receive from the Agency. A new internet service offers health professionals and public alike the ability to search a database of medicines approved since January 2002, using the product name or the active substance. The information contained on the website will eventually include marketing authorisation and commercialisation, Summary of Product Characteristics and the Patient Information Leaflet. Patient Information Leaflets also provide information on the relative risk of side-effects categorised by terms such as 'frequent' and 'rare'.
- 3.9 The Agency has focused to date on improving the efficiency of its review process and on meeting key milestones for the development of its other regulatory activities. A key target is now to achieve the same review time for both EU applications and national applications. However, the Agency is also looking to develop wider performance measures covering its public health and communication roles.

Sweden: Medical Products Agency



- 4.1 The Medical Products Agency is responsible for establishing standards and requirements for the development, manufacture and sale of drugs and other medicinal products. The Medical Products Agency is also responsible for providing information about medicines, giving permission to carry out clinical trials, approving licences and controlling herbal and homoeopathic medicines and other medicine-related products. Besides carrying out statutory inspections for Good Manufacturing, Distribution, Clinical and Laboratory Practice, the Agency also inspects hospital pharmacies, dialysis clinics and manufacturers of medical gases and Investigational Medicinal Products. The Agency acts as both a formal regulatory authority and an informal promoter of the rational development and use of new and existing medicinal products.
- 4.2 The Medical Products Agency is a government body under the aegis of the Ministry of Health and Social Affairs with almost 300 employees, most of whom are doctors or pharmacists. The Director General of the Medical Products Agency has the power to take all decisions about medicines.

The Medical Products Agency is mainly funded by industry

- 4.3 The Medical Products Agency aims for 100 per cent cost recovery and its activities are almost entirely financed through contracts and fees. The Swedish Government funds the Medical Products Agency's information service to County Councils, and the regulation of medical devices, which together account for around 5 per cent of total income. The remaining 95 per cent of income comes from fees charged to industry.
- 4.4 No fees are charged for inspections, although fees are charged for scientific advice to industry. A time recording system allows the Agency to calculate how much activities cost, although the Agency is free to move funds between different regulatory activities.

The Medical Products Agency actively cultivates its relationship with industry

- 4.5 The Medical Products Agency holds regular conference-style meetings with pharmaceutical companies to provide updates on changes to legislation and other information. When quality deficiencies are identified, as well as seeking appropriate corrective action, the Agency collates and feeds back broad lessons to industry. The Medical Products Agency also gives feedback to companies on the quality of licence applications through seminars and open days. The Agency's Good Manufacturing Practice inspection team is involved in extensive dialogue with companies from the very beginning of the construction of a manufacturing facility.

- 4.6 Many applicant companies value the Agency's efforts to maintain an excellent relationship with industry and it has received a growing share of regulatory work. The scientific advice the Medical Products Agency gives is also highly regarded by industry. The Agency is focusing strongly on reducing assessment times for applications other than those in the centralised procedure.
- 4.7 Building on its relationship with industry, the Agency is considering using industry sponsorship as a means of carrying out pharmacovigilance safety research, and two such projects are currently underway so far.

Reporting of adverse reactions is compulsory for industry and doctors

- 4.8 Pharmaceutical manufacturers and doctors are obliged to report adverse reactions to medicines, although there is no such obligation for other health professionals. The reporting system is set up to receive reports from doctors, who are the source of the vast majority of adverse reaction reports, although a very limited number also come from other health professionals. There is no route for the public to report adverse reactions, although there are calls from patient groups for this to be developed in future.

The Medical Products Agency's communication activities are focused on prescribers of medicines

- 4.9 The Medical Products Agency is active in communicating with prescribing health professionals, such as doctors, trainee doctors, prescribing nurses and surgeons. The Agency sends regular bulletins containing information about new medicines and pharmacovigilance information to prescribing health professionals and pharmacies. The Agency also provides information on the relative efficacy of medicines, and produces good practice guides and holds workshops on specific disease areas. The website at www.mpa.se provides a range of information for health professionals and others in both Swedish and English.
- 4.10 Although it is not part of the Medical Products Agency's remit to communicate with the public, Freedom of Information legislation means that the public can approach the Agency for information. The information provided to the public in Swedish Patient Information Leaflets reflects the relative frequency of adverse reactions, allowing consumers to make a more informed decision about the benefits and risks of medicines.
- 4.11 The number of queries the Agency receives from the public is increasing, and the Agency is looking to develop a strategy for dealing with the public. The Agency sees its role in public communication as building relationships with important journalists and actively managing news stories: the Agency has a relatively high profile and all expert staff receive media training. Other information on medicines is available to the public through medicine information lines run by county councils, and the call centre run by the state-run pharmacy chain.

Regulation of marketed medical products is made easier as all pharmacies are state-run

4.12 Online pharmacies are a relatively new phenomenon in Sweden, having operated for less than one year. The Medical Products Agency recently ran a large public awareness campaign on the dangers of purchasing medicines over the internet, although since pharmacies in Sweden are operated as a state-run monopoly, compliance with medicine regulation is assured. Since doctors can already send e-prescriptions to pharmacies, it is expected that eventually prescription-only medicines as well as over-the-counter medicines will be available over the internet.

The Medical Products Agency is currently looking to improve its performance

4.13 The Medical Products Agency's high-level targets are agreed with the Government, or are set down by law. Internal targets are also set, and progress is monitored every four months. The Agency meets its performance target of carrying out inspections of manufacturing sites every two years, although a large backlog of work has meant that review times for new products are relatively long. The Agency is aiming to improve its performance on review times for new medicines, and is focusing on meeting European Medicine Evaluation Agency standards for the approval of New Active Substances (i.e. within 120 days). Performance-related pay structures are in place at all levels.

The Netherlands: Medicines Evaluation Board Agency

- 5.1 The Medicines Evaluation Board is a board of 16 doctors, pharmacists and scientists who are responsible for pharmacovigilance and the evaluation of medicinal products and homoeopathic medicinal products. The Board is an independent administrative body whose members are appointed by the Crown.
- 5.2 The Medicines Evaluation Board Agency, which has a staff of more than 100, supports the Board in its decisions. The Medicines Evaluation Board is independent and separate from Government, although the Agency that supports it is currently part of the Ministry of Health, Welfare and Sport. However, there are proposals for the Agency to become independent in future.



The work of the Medicines Evaluation Board Agency is almost entirely funded by industry at present

- 5.3 One hundred per cent of funding for the Medicines Evaluation Board and Medicines Evaluation Board Agency comes from fees charged to industry. Fees are increased usually by the rate of inflation but can be increased for other reasons with approval from Ministers. The Agency must notify industry about increases, but is not required to consult them.
- 5.4 The Medicines Evaluation Board Agency does not have the power to charge separately for scientific advice, the costs of which are currently covered by licence fees. Forthcoming legislation is expected to change the arrangements so that the Government funds pharmacovigilance activities while licences are still funded by fees. The new arrangements will also provide funding for the Agency to commission original pharmacovigilance research, including research on the comparative safety of different therapies.

The Medicines Evaluation Board and the Medicines Evaluation Board Agency are responsible for registering homoeopathic medicines

- 5.5 The Medicines Evaluation Board Agency evaluates both human medicines and homoeopathic medicines. The Netherlands was the first country to evaluate homoeopathic medicines compulsorily, although a backlog in applications means that some homoeopathic medicines are still being assessed. Homoeopathic products are assessed for their safety and quality. A register of licensed homoeopathic medicines is posted on the Medicines Evaluation Board website.

Pharmacovigilance activity is formally separate from the Medicines Evaluation Board

- 5.6 The pharmacovigilance activities of the Medicines Evaluation Board Agency are carried out on a day-to-day basis by the Netherlands Pharmacovigilance Foundation. The Foundation was set up a decade ago to take over from the previous voluntary arrangement which had been operated by a group of concerned pharmacists. Fully funded by the Agency, the Foundation evaluates reports from doctors and pharmacists, then submits the information to the Medicines Evaluation Board.
- 5.7 The Agency is currently looking at introducing new internal and external performance measures following a reorganisation of its operational activities.

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