ANNUAL REPORT 2007

Medicines Authority – annual report 2007

1.0 Corporate issues and capacity building

1.1 Management objectives, meetings and management review

The objectives for the process activities within the Medicines Authority for 2007 were defined through the Medicines Authority's high level objectives as well as the operational plans set by the different directorates and units. The main objectives for the Medicines Authority for 2007 were to prepare and build its capacity so as to be in a position to start work with Malta as a Reference Member State (RMS) as from 2008 and to gain international recognition for inspectorate activities (mutual recognition for GMP and joining Pharmaceutical Inspectorate Corporate Scheme PICS).

There were 4 management meetings held over 2007. Management meetings covered evaluation of ongoing operations and regulatory issues. Actions and assignments from previous management meetings were reviewed and reported back to members. Outstanding issues were noted and updated to reflect the actual real time situation.

Management Review at mid-year has become part of the Medicine's Authority corporate calendar. At this meeting management reviews the status and effectiveness of the organization's quality management system. Management Review was conducted in September, 2007 and covered all departments, personnel and processes. The Plan-Do-Check-Act approach was taken and it follows the typical process model with inputs, outputs and controls etc. This system took into account the Corrective and Preventive Action efforts put into place by the management through out the cyclic year July 2006 to July 2007 which acted as input to the Management Review. Appropriate data was gathered during the interim between Management Review 2006 and Management Review 2007. The data was analysed and condensed to present the result/performance for the period. All objectives were reviewed by management. While most of the goals were reached others were revised and set as taken from the current stand point i.e. July 2007. Corrective action and improvement was recommended where the objective's intended goal was not met.

1.2 Human resources

Throughout 2007 various meetings were held between the Collective Bargaining Unit within the MFIN, the Union Haddiema Maghqudin and representatives of the employees of the Medicines Authority and the CEO of the Medicines Authority to discuss a Collective Agreement for the employees of the Medicines Authority. Good progress was achieved by the end of 2007.

The plan for recruitment to prepare for the increased work load due to new activities submitted to MHEC was approved. During 2007 there was a process of recruitment. Six executives and one pre-clinical assessor were recruited externally. There were also internal promotions for the posts of two senior pharmacists, a quality manager and a director. In spite of attempts to recruit, the posts of Finance and Administration Manger, Operations and Regulatory Affairs Manger and some posts for senior pharmacists, pharmacists and medical assessors remained vacant.

1.3 Participation in EU and other Fora

Members of staff of the Medicines Authority participated in meetings organised by the European Medicines Agency (EMEA), the Heads of Agency Meetings, meetings organised by the EU Presidency as well as other meetings organised by the EU Council. The Authority is represented at the Head of Agency meeting and at the Management Board of EMEA by its CEO. Meetings and working parties attended regularly by staff of the authority include the Co-ordination Group for the Mutual Recognition and Decentralised Procedures (CMD), Quality Review of Documents (QRD), European Directorate for the Quality of Medicines (EDQM), Committee on Herbal Medicinal Products (HMPC), Clinical Trial Facilitation Group (CTFG), and the CHMP working groups on quality and efficacy, the EMEA meetings pertaining to GMP and GCP. Committee for Medicinal Products for Human Use, the Pharmacovigilance Working Party, the Eudravigilance Joint Implementation Group, Clinical Trials Joint Operations Group. Other important European Presidency meetings attended include EMACOLEX, Pharmaceutical Committee meetings, Meetings for Competent Authorities on Homeopathic Medicinal Products and the Ad hoc group for the development of implementing guidelines for Directive 2001/20/EC. The Medicines Authority covered the meetings of the Working Party on Pharmaceuticals and Medical Devices, where the main topic discussed was the Regulation on Advanced Therapies.

In 2007 through the Inspectorate Directorate, The Medicines Authority became a full member of the Pharmaceutical Inspection Cooperation Scheme (PICS) and attended meetings organised by the European Medicines Enforcement Officers (EMEO). The remit of the EMEO is to establish a networking activity

between the Enforcement units of the Competent Authorities with the primary aim to prevent and assist in the reduction of counterfeit drugs that find themselves on the markets of member states. The phenomenon of counterfeit medicines is on the increase and is of major concern for regulators responsible to ensure public health. Two members of staff from the Medicines Authority, attended 1 meeting of the European Pharmacopoeia on the 6th edition of the European Pharmacopea.

1.4 Meetings and information sessions (communication) with Third Parties

Regular meetings were held with stakeholders to discuss and consult on the issue of fees, legislation and technical issues. A number of meetings were held with prospective companies showing an interest to set up base in Malta. During these meetings all the required information was provided to the companies and the system for obtaining the licences were clearly explained.

The Medicines Authority organised a seminar in collaboration with the Pharmaceutical Security Institute (PSI) on the topic of illegal activities, with particular emphasis being given to the phenomenon of counterfeiting. This seminar was held in June at the premises of the Authority and was very well attended by over 120 participants from the Customs, Police, Patent Office and Government Departments. The sessions were spread over two days. Representatives of the PSI gave lectures and presentations on the most recent topical issues and the new technologies to detect and combat counterfeiting. This seminar served as a good platform for the training of local enforcement people, to instill the concept and additionally promoted an opportunity for networking and establishing contacts in the field of enforcement. This seminar brought about a lot of interest, especially within the Customs department as can be evidenced by the increase in collaboration experienced after the seminar. Since this event the Medicines Authority and Customs have been working very closely together on a day-to-day basis.

1.5 Training

1.5.1 Training abroad

In accordance with the requirements of the Quality System for the Authority opportunities for training were provided to staff throughout 2007. This training covered a whole spectrum of activities. In the are of inspectorate and enforcement the following areas were covered: aspects of design space, counterfeit medicines, Process analytical Technology (PAT), and Risk Management; the PICS annual seminar attended by the Director; PICS expert circle on computerized systems attended by an inspector; ISPE training course on computer systems attended by an inspector; one week training course on GCP

inspections organized by the EMEA and for which two inspectors attended ; Workshop on Quality risk Management organized by the EMEA and PICS attended by an inspector.

Two employees attended a Pharmacokinetics training seminar in the UK focusing on bioequivalence issues.

Three staff members were trained on ADR data inputting into the European Network and 1 member of staff on Data mining from EVDAS.

1.5.2 Training in Malta

Three credits were delivered to all pharmacists and clinical assessors on pharmacokinetics, organic chemistry (validation issues) and pharmaceutics. This local training was delivered to give a knowledge base and a refresher in preparation for the Twinning-Light Project training scheduled for 2008.

In May the Medicines Authority invested in sending 8 employees from different directorates and units to a course on internal QMS audits. The training covered two days and the 7 of the 8 attendees were accredited with a certificate by The Chartered Quality Institute UK certified by IRCA.

1.6 Preparation for a Twinning-Light project to be delivered in 2008

To further enhance the technical capability of the Authority, a capacity building project was initiated in 2007. A proposal for EU funding of a "Twinning Light" project entitled 'Further Capacity building at the Medicines Authority' was submitted to the PPCD Funding for this project amounting to EURO 157,000 was approved in 2007. A tender was issued and two member states submitted a proposal to fulfill the submitted Project Fiche as drafted by the Medicines Authority. The National Institute for Public Health and Environment from the Netherlands was chosen as the EU Twinning Partner. The aim of the Twinning Light project will be to selectively improve the technical capacity of inspectors and assessors, in order to cover new areas that were not covered in the first twinning in 2004. Importantly, this twinning will cover areas such as assessment of generics (clinical points), pharmaceutical assessment, clinical trial assessment, haemovigilance, GMP and GCP inspections as well as inspections of blood establishments. Inspectors will be joining in inspections in the Netherlands and attending to class room training. The actual training was scheduled to start in January 2008, and was planned to run for 6 months (January to June 2008).

1.7 Information Management System

During 2007 the Information Management System (IMS) department continued to operate and maintain the existing in-house and European information systems and the ICT infrastructure. In 2007 the government issued a tender for the replacement of all PCs within the public sector. To conform to this

requirement, a detailed inventory of all PCs used by the Authority was submitted to the Government, with the objective to replace all PCs at the Authority.

The FoxPro-based Certificate for Pharmaceutical Products (CPP) application was transferred to the Authority's server and migration to a new e-mail system based on Exchange Server/Outlook 2003 was achieved. Major changes and enhancements were carried out on the Medicines Authority LinkLibrary intranet. The Dakar payroll and Sage financial package were upgraded to handle the Euro currency. A new network security measure was introduced which conforms to MITTS standards to help mitigate security breaches and the transmission of viruses and spyware. In January 2007, the EMEA launched a new service known as Managing Meeting Documents (MMD) to function as a central repository for all documents distributed during EMEA meetings. The Authority established access to this service and it is operational however a performance issue has arisen due to Internet bandwidth constraints.

In early 2007, the Eudra GMP database by the EMEA was launched. Some issues arose with accessibility and inputting of data. All issues were resolved and all the manufacturing authorizations and GMP certificates for the local companies were entered. It is anticipated that the new database will enable quick and up-to-date searches about the GMP status of manufacturing sites.

In line with legislative requirements that Marketing Authorisation Applications have to be submitted in eCTD format a proposal was submitted to CITAC for a licensing information system that can handle eCTD submissions as well as have the facility of transmitting medicinal product information to the European Union EudraPharm database. The new system should also include a workflow module to help manage licensing procedures more efficiently. The CITAC board approved the project. The Authority is considering the possibility of tapping EU funds under the ERDF Operational Programme I, eAccessibility programme to fund the project.

2.0 Quality Management

2.1 The Quality Management System

In 2007 there were 44 quality improvement requests to improve the Quality Management System which indicates an increase in requests from last year's figure of 38. The increase was mainly due to corrective action from the Canadian Audit report which resulted from the MRA audit by Health Canada which took place in November 2006. Other directorates also sought to improve the effectiveness and efficiency of the processes within their responsibility.

The Quality System ensures that each process is fully documented and allows for a full audit trail of all activities and ensures that each member of staff is fully accountable. Priority over last quarter 2006 and

2007 has been given to requirements outlined in the Canadian Audit and a number of SOPs within the Inspectorate and Enforcement Directorate were in their 5th revision status thus signifying that continual improvement is being achieved. These maturing SOPs together with the input of historical data have addressed the points raised during audits that the system is based on continuous improvement towards achieving customer satisfaction both aimed at internal customers and external customers.

One of the issues listed as critical under sub-component 11A Quality Management in the Canadian was that there was no person acting as a quality manager. A Quality Manager was appointed in July 2007.

2.2 EU Benchmarking of European Medicines Agencies (BEMA)

One assessor participated in benchmarking seminars held at EMEA under the hospice of Head of Agencies. The first round of benchmarking designated BEMA I ended in 2007 with 47 agencies visited and benchmarked. In April a mandate of the BEMA Steering Group decided by the HMA was given to continue with BEMA. All National Competent Agencies (NCA) were to be benchmarked through a three-year rolling cycle under BEMA II.

2.3 Internal Audit

Two internal quality audits were conducted during the last quarter 2007: a global audit of the Information Systems Unit and an audit on three procedures pertaining to the Pre-Licensing Directorate.

3.0 Update of legislation

By the end of 2007 all the new provisions set through the amendment of Directive 2001/83 through its amendment by Directive 2004/27 were transposed into the Medicines Act and its subsidiary legislation except for the provisions on data exclusivity where Malta was asked for a derogation from the European Commission.

The Medicines Authority was involved in the update of the Medicines Act and its subsidiary legislation:

Medicines Act, 2003 [Cap. 458] *Amended by* Act XI of 2007.

Legal Notice 165 of 2007: Availability of Medicinal Products within the Government Health Services Regulations, 2007.

Legal Notice 490 of 2004: Clinical Trials Regulations, 2004. *Amended by* Legal Notice 248 of 2007: Clinical Trials (Amendment) Regulations, 2007.

Legal Notice 324 of 2007: Medicines (Marketing Authorisation) Regulations, 2007.

Legal Notice 67 of 2007: Prescription Forms for Free Medicinals Rules, 2007.
Legal Notice 243 of 2007: Authorisation of Dispensing of Medicinal Gases from Premises other than a Pharmacy Rules, 2007.
Legal Notice 368 of 2007: List of Active Substances in a Medicinal Product (Requirement of Prescription) (Repeal) Regulations, 2007.

The "Medicinal Products (Injunction to Advertising) Regulations, 2007" were published. These regulations affectively transpose Article 2 of Directive 98/27/EC of the European Parliament and of the Council on injunctions for the protection of consumers' interests, concerning the entities qualified to bring an action under this Directive. The authority was also involved in the drafting of guidelines issued by the Broadcasting Authority on "Advertising concerning Medicines, Treatments, Health Claims, Nutrition and Dietary Supplements".

4.0 Licensing of medicinal products for the local market

4.1 Preparations to start licensing of medicinal products with Malta as Reference Member State

The plans for licensing of medicinal products reflected the changing demands in line with the policy decision and commitment given to local stakeholder to start operating the European procedures with Malta acting as Reference Member State (RMS). As discussed in relevant areas of this report preparations included capacity building in the area of ICT infrastructure, recruitment and training. There was extensive communication with prospective applicants. In December 2007 the first application for Malta acting as RMS was submitted to the Authority.

4.2 Licensing activities

4.2.1 National Marketing Authorisations

The finalisation of the assessment of applications for marketing authorisation received through the national procedure (PMA/MA Project) represented a major part of the workload within the Pre-Licensing Directorate for the first two months of 2007. Some applicants who had not submitted dossiers or replied to requests for missing information were requested to do so. An official deadline for the 31 March 2007 was given by the Licensing Authority in DH Circular 46/2007. Line extension applications for products issued with a marketing authorisation through the national procedure, were also processed during 2007.

A total of one thousand, eight hundred and fifty-six (1856) national marketing authorisations were granted up to the end of 2007. These included all products authorised through the PMA/MA process, line extensions of these products and products authorised through MRP and DCP.

As on 31 September 2007, the total number of variation applications received in 2007 was one thousand, one hundred and forty-six (1146), 54% being of Type 1 and 46% of Type 2.

Notifications in line with article 61(3)

Forty two (42) notifications in line with article 61(3) were received until the end of 2007. This is a relatively new procedure which was implemented in 2007 following the review of the pharmaceutical legislation during 2005. This allows for Marketing Authorisation Holders to notify the Competent Authorities to make minor changes in the package leaflet, where no changes to the Summary of Product Characteristics (SPC) are required.

Transfer of Marketing Authorisation Holder

The number of transfer applications increased as the number of authorised products increased from the previous years. One hundred forty seven (147) applications were received.

Renewals

No national renewal applications were received in 2007.

4.2.2 Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP) Applications

New applications

The number of applications received through the Mutual Recognition Procedure and the Decentralised procedure represented a significant part of the licensing workload. Seventy nine (79) MRP and one hundred and fifty-nine (159) DCP applications were received and started being processed in 2007. As compared to the number of applications received in 2006, the number of MRP applications increased by 21% and the number of DCP applications increased by 1,888%. Moreover work on the applications which were submitted prior to 2007 and which were still ongoing continued to be processed. By the end of 2007 the total number of products approved was two hundred and fifty-nine (259) through MRP, forty (40) through DCP and forty-two (42) renewal applications.

The number of variations also increased considerably as more new procedures for MRP and DCP were processed and finalised. A total of eight hundred and sixty-three (863) variation applications were received in 2007. 70.5% were of Type 1 and 29.5% were of Type 2.

4.2.3 Authorisations in accordance with article 4(2) of the Medicines (Marketing Authorisation) Regulations (Article 126(a) of Directive 2001/83/EC, as amended)

Following several discussions on the implementation of Article 126(a) of Directive 2001/83/EC, as amended in the Medicines (Marketing Authorisation) Regulations, the policy for implementation was adopted and the guidelines and the application form were published on the Medicines Authority website. The Medicines Authority received five hundred and seventy-nine (579) applications through this licensing procedure. Two hundred ninety five (295) licences were granted by the end of 2007.

Twenty two (22) applications were refused. The main reasons for refusal of applications were if the product already had a marketing authorisation or a pending application for a marketing authorisation in Malta (14 applications) or the product did not have a valid marketing authorisation in the country of source or in any other EU/EEA Member State (7) as is required by the legislation.

4.2.4 Parallel Importation (PI) applications

Up to the end of 2007 a total of seventy-three (73) licences for parallel importation were issued.

4.2.5 Traditional Herbal Medicinal Products and Homeopathic products

To date no applications for authorisation of herbal and homeopathic medicinal products have been received. Products which fall under directive 2004/24/EC currently on the market will have to start being considered for authorisation in 2008. The implementation of this directive will have to be discussed and a policy decided in liaison with the Licensing Authority and Food Safety Commission. Training on the assessment of these products was included in the plan of training through the Twinning-Light project.

4.3 Linguistic check process of centrally authorised product information

Following the end of the derogation on translation into the Maltese language of official documents on the 31st December 2006, which included European Commission decisions on centrally authorised products, the Medicines Authority started to review the product annexes for products authorised through this procedure. The linguistic checks for old products (not previously translated as they had been first

authorised during the derogation) resumed. This issue was discussed with the European Medicines Agency and the workload was planned such that translation checks would be carried out during the product life-management cycle, for example, at the next product variation or renewal. The translation checks for ongoing procedures were carried out in accordance with the timelines for each procedure. All product information and annexes of centrally authorised products authorised and procedures finalised in 2007 (variations/renewals/safety update/extensions and referrals) translated into the Maltese language were reviewed.

5.0 Assessment and activities related to special regulatory areas

5.1 Clinical Trials

Four (4) clinical trials were approved in 2007. Seven (7) amendments to trials which are being conducted in Malta were also received.

5.2 Implementation of the Paediatric Regulations

Malta submitted its nominations for the member and the alternate for the newly set Paediatric Committee of the EMEA. The Committee meets every month. Malta started participating in the Paediatric data assessment procedure. In 2007, eighteen (18) products were submitted for assessment under this EU work-sharing procedure.

6.0 Pharmacovigilance

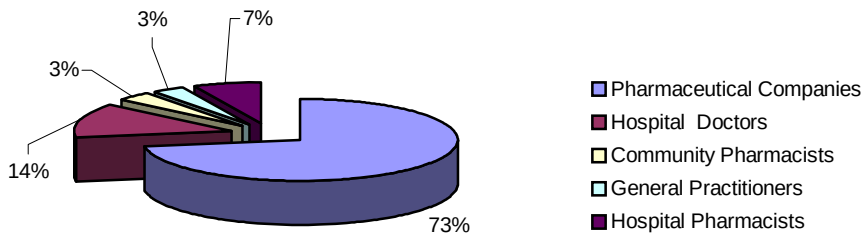
6.1 National pharmacovigilance activity

The activity of pharmacovigilance, functioning within the Medicines Authority, was developed in line with the regulations entered in force throughout 2005, namely Legal Notice 22 of 2004 which transposes Directive 2001/83/EC Title IX.

In 2007, pharmacovigilance activity involved the management of eight (8) Individual Case Safety Reports (ICSRs) from healthcare professionals in Malta and 21 CIOMS forms of Adverse Drug Reactions occurring locally which forwarded by industry. A local ADR Database (MDIS) was maintained in order to record data from locally occurring 29 ICSR reported to the Medicines Authority in 2007.

Analysis of the ICSRs received showed that the pharmaceutical industry was responsible for most reports submitted in 2007 to the Medicines Authority (Figure 1). Healthcare Professionals (doctors, pharmacists) also submitted ADR reports to the Medicines Authority.

Figure 1: Maltese ICSR reports for 2007 according to source of data



n =29

6.2 International relations on pharmacovigilance

The establishment of the ADR reporting system by the Medicines Authority and the participation of Healthcare Professionals, through reporting of ADRs encountered during their practice enabled Malta to comply with existing EU regulations. Besides, the transmission of 54 reports to the WHO Collaborating Centre for International Drug Monitoring, in 2007 the Medicines Authority renewed its full membership for Malta in the WHO programme.

7.0 Inspections and licensing of pharmaceutical activities

7.1 International recognition of local GMP inspectorate

Malta was accepted as a full member of the Pharmaceutical Inspectorate Cooperation Scheme (PICS) as from 1st January 2008. Moreover following the onsite visit by Health Canada in November 2006, Malta was granted equivalence by Health Canada and consequently was granted Mutual Recognition Agreements on Good Manufacturing Practice with Canada and Australia.

7.2 Manufacturing and import authorisations

During 2007, ten (10) manufacturing authorizations were issued. Six (6) authorisations were issued to new companies manufacturing products in Malta, three (3) of which were for re-packaging operations, one (1) for medicinal gas production, one (1) for IMP`s and another for API manufacture. The other four (4) authorizations issued were for the scope of renewing the licence. Additionally three (3) authorisations were issued to new companies engaging in import activities from third countries. Nineteen (19) GMP certificates have been issued. Two inspections have not been closed and a follow-up inspection would be necessary to verify the corrective actions. One manufacturing licence was not renewed and has been terminated at the request of the company.

Four new applications, one for gases manufacture, another for API manufacture and two for importation are being processed following the relevant inspections conducted on site.

Eleven (11) applications for variation of a manufacturer's licence were processed and new licenses issued within the stipulated time frame of 30 days.

Two hundred and thirty-one (231) export certificates were issued to local manufacturing companies. Export certificates serve as a means to demonstrate that a manufacturing company has been inspected by the Competent Regulatory Authority and found to be in compliance with GMP.

QP interviews were held in March 2007. Two (2) applications were received and both applicants were successful in the interview.

Thirteen (13) requests received from the Licensing department for the verification of the licensing status and/or GMP status of third country manufacturing sites were processed.

7.3 Authorisations for wholesale dealing

Thirty-eight (38) wholesalers have been issued with a wholesale dealer's licence. Four (4) new applications for wholesale dealing were received and these have been processed satisfactorily and the licences issued. 8 inspections have been scheduled and will be carried out in December (2007) and the first week of January (2008). One company decided not to renew their licences. There were two variations for a wholesale dealer's licence.

7.4 Pharmacies

All the licences for pharmacies for the year 2007 were issued, and all pharmacies paid the applicable fees. Following the publication of LN 279 of 2007 Pharmacy Licensing Regulations, the implementation of this LN was delegated to the Medicines Authority. A plan was set for a system to process the pending applications that have been lodged over the past 20 years. Clear criteria and the modus operandi were established and agreed to with the Licensing Authority. By the end of 2007 the plan and the system for licensing were in place and the process was to be initiated as from January 2008. It was established that all such applications be processed through the IRG prior to submission to the Licensing Authority for final approval.

Due to the heavy workload as regards GMP inspections, pharmacy inspections could only be undertaken as from October (2007). As a result only a small number of pharmacies were inspected. One application for transfer of pharmacy a licence involving a change in licence holder was approved. No revocations of pharmacy licenses occurred in 2007.

8.0 Enforcement and surveillance of the local market

8.1 Enforcement

Seven (7) complaints were received and all of these were investigated. Two (2) cases were referred to the police but the others were closed by the Medicines Authority.

8.2 Batch Defect Reports

During this year the Inspectorate received and processed sixty-nine (69) rapid alerts in respect of product quality defects. Seven (7) batch recalls were affected following these reports. No batch recalls were affected in relation to locally manufactured products.

8.3 Sampling of Medicines

A total of fourteen (14) products have been sampled. All results showed a satisfactory outcome.
The Medicines Authority participated in the annual Centrally Authorised Products testing organized by the EDQM by sampling and testing of the product Proteleos.

9.0 Internal Technical Committees of the Medicines Authority

9.1 Inspection Review Group

The remit of this group is to consider action in cases of critical deficiencies and serious non-compliance. Four meetings of the Inspection Review Group were held in relation to eight (8) cases.

9.2 Borderline Classification Committee

During 2007 the Borderline Classification Committee (BCC) held three official meetings. In addition, a number of ad hoc meetings were held during the year between the Chairperson and sections of the committee to discuss straight forward cases that did not require calling a meeting with the full Committee. This was the case where similar products had already been classified by the Committee. Products were referred to the BCC mainly from local companies, other products from the Malta Standards Authority (MSA), the Government Pharmaceutical Services (GPS), and from Competent Authorities in other Member States. Throughout 2007 the Borderline Classification Committee reviewed a total of 101 products. Nine of these were considered to be medicinal products while 80 were not considered to be medicinal products. Another twelve (12) products contained herbal ingredients. These products may be considered to be traditional herbal medicinal products (THMP) in accordance with Directive 2004/24/EC once the registration procedure will be implemented in Malta. In the absence of safety concerns, the Medicines Authority did not object to the marketing of these products, provided that no medicinal claims are made regarding the products. The BCC also received requests for information regarding adverts or

products either from other National Competent Authorities, Healthcare professionals, the Malta Standards Authority and government entities. These were discussed with the Advertising Committee.

When applying for the classification of a product, applicants regularly used the application form which could be downloaded from Medicines Authority's website. This process ensured that the necessary information and material was provided to the BCC thus facilitating the classification process. The fee for the BCC started being charged since the publication of the new fee legal notice. A list of products classified as medicinal products was published on the Medicines Authority's website and was regularly updated, thus ensuring transparency.

9.3 Regulation of advertising and promotional material

In 2007 the Authority handled forty-seven (47) cases related to advertising which included: addressing 19 formal queries from a variety of sources on implementation of the advertising regulations, investigating and evaluating 10 complaints from stakeholders, advising on 3 advertisements forwarded to the Authority prior to publication and reviewing 10 advertisements forwarded to the Authority for our advice as part of the monitoring system. The Advertising Committee met twice during 2007.

One member of staff actively participated in the Advisory Committee meetings of the Broadcasting Authority.