Malta Medicines Authority

STRATEGY

2016 - 2020

"Our vision is to be a centre of excellence in advancing effective and innovative regulation and promoting quality and scientific rigour in the work we do. We strive to be a best in class regulator for the benefit of patients and stakeholders. We endeavour to be an internationally recognised, efficient entity and promoter of people development and sustainable growth."

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1. About the Malta Medicines Authority

The Malta Medicines Authority was established in 2003 and has developed into an autonomous body by virtue of Chapter 453 of the Laws of Malta. The Authority works to protect and enhance public health through the regulation of medicinal products and pharmaceutical activities.

The Authority is committed to providing high quality licensing, pharmacovigilance, inspection and enforcement services to its stakeholders for the ultimate benefit of the general public. The Medicines Authority is made up of four Directorates under the leadership of the Chairman. These are namely: the Licensing Directorate, the Post-Licensing Directorate, the Strategy, Operations and Regulatory Affairs Directorate and the Inspectorate and Enforcement Directorate. The core work is supported by four units, Finance and Corporate Services, Medicines Intelligence and Access Unit, Information Systems Unit, and Quality Management, International and EU Affairs.

The key *values* of the Medicines Authority are:

people	quality	integrity	innovation

The *roles* of the Medicines Authority are:

i) To perform duties delegated to the Medicines Authority by the Licensing Authority through the Medicines Act;

ii) To assist and advise the Licensing Authority on any matter relating to the regulation of medicinal products and related activities;

iii) To ensure, consistent with current medical and scientific knowledge, that medicinal products marketed in Malta and the European Union are of good quality and have a favourable risk to benefit profile through independent, science-based assessment, post-authorisation activities and participation in decision-making at European level;

iv) To scientifically evaluate requests and monitor clinical trials carried out in Malta;

v) To ensure, in so far as possible, that the medicines supplied on the local market through the regulated supply chain are of good quality;

vi) To provide high quality monitoring and inspection services for pharmaceutical activities;

vii) To monitor the safety of medicinal products;

viii) To monitor and enforce the relevant legislation through investigation of potential breaches of regulations and a range of measures;

ix) To enhance the effective, safe and rational use of medicinal products through the provision of objective and unbiased information which helps prescribers, healthcare professionals and patients make informed decisions on the choice and use of medicines;

x) To support the availability of medicinal products on the local market;

xi) To support competitiveness of the local market through scientific and regulatory advice and the implementation of principles of SMART Regulation;

xii) To utilise and develop tools, standards and approaches to assess and ensure the safety, quality and effectiveness of medicinal products and pharmaceutical activities;

xiii) To enhance the standard of medicinal products and pharmaceutical activities for medicines for human use in Malta;

xiv) To participate on European fora of the European Medicines Agency, Council and the Commission and perform assessment and give scientific and regulatory positions in various areas.

The Medicines Authority collaborates with diverse stakeholders including government and government agencies, manufacturing industries, healthcare professionals, and research communities, to maximise patients' access to products with a positive risk-benefit profile.
The core regulatory work of the Authority is delivered through advisory activities; acting as a reference member state and rapporteur for European procedures; authorisation and approval functions; providing monitoring and inspection services for pharmaceutical activities; regulating pharmacies, manufacturing, wholesale and distribution companies; enhancing the safe and rational use of medicines; and promoting continuous learning, research and innovation.

The Medicines Authority performs as an effective and innovative regulator, both nationally and internationally, and will continue its efforts to ensure that it is recognised as a centre of excellence for both the quality and scientific rigour it brings to the work done and the efficient manner in which it is completed for the benefit of patients.

2. Achievements

The Medicines Authority today hosts forty-nine (49) employees (18 male, 31 female), six (6) trainees (2 male, 4 female) and external experts on a contract basis. The Authority has undergone a major transformation to position itself as an independent science and health oriented public entity. Recent statistics on regulated products and companies include: twenty-three (23) manufacturers, twenty-one (21) importers, eighty-four (84) wholesale dealers, two hundred and forty-three (243) pharmacies and over five thousand, two hundred and seventy (5270) authorised medicines on the local register.

In the last three years, the Authority participated in fifteen (15) centralised procedures and carried out the assessment of fifty-eight (58) procedures as Reference Member State. The first EU Good Manufacturing Practice third-country inspection was carried out in 2013 and in the past three years fifteen (15) inspections of such companies were carried out.

During 2013, the Authority actively supported the Department of Health to optimise the timely, equitable and affordable access to medicinal products. It improved its communication with stakeholders through ongoing interaction to better understand their needs and expectations and where possible translate into tangible initiatives.

Through 2014, the Medicines Authority was committed to move forward by focussing on two main pillars:

i) Regulating effectively and proportionally through a skilled workforce, good governance and an approach which listens and supports innovation;
ii) Improving the Medicines Authority's sustainability through the introduction of cost saving initiatives, revision of the fee structure and generation of new revenue.

The Authority signed important cooperation agreements with two National Competent Authorities. The first agreement was reached with the Health Products Regulatory Agency (Ireland) for collaboration with regards to an IT system, through which the Authority saved over two hundred thousand (200,000) Euros. The second with the Medicines Evaluation Board (Netherlands) through which MEB started outsourcing part of its quality assessment work to Malta. For the first time, Malta collaborated on joint scientific advice, whereby staff from the Medicines Authority collaborated with their counterparts in Austria to deliver consistent and scientifically sound advice to industry. The Authority during this period noted that Malta and the Medicines Authority began to be selected for their scientific and regulatory work.

The Medicines Authority also strengthened its governance and management structures and the Authority was certified by the International Standard Organisation as ISO 9001 compliant. In 2014, a traineeship programme for students undergoing doctoral studies was also launched and four students started a traineeship with the Medicines Authority.

During 2015, the Medicines Authority focused on enhancing the accessibility to medicinal products, and empowering patients, consumers and prescribers to take more informed choices with regards to medicines.

The Authority is investing approximately ten percent (10%) of its budget on training, capacity building, international and European exposures for employees. Over thirty percent (30%) of the employees at the Medicines Authority are carrying out studies at Master's and Doctoral level.

The Medicines Authority aims to continue working with all stakeholders and enhance the status of the Authority to create a best in class regulator.

Recent key achievements of the Medicines Authority include:

i) Improved service delivery timelines across a broad range of regulatory procedures;

ii) Reached top five positions among agencies in the European Union with regards to the assessment of generic medicines through the centralised procedure;

iii) Implemented new legislation for pharmacovigilance and falsified medicines;

iv) Successfully participated in Benchmarking European Medicines Agency (BEMA);

v) Extensive capacity building throughout the Authority and shift towards paperless office;

vi) Developed new projects such as the Medicines Intelligence and Access Unit as an example of how regulators can strengthen their regulatory role whilst providing a service to patients and consumers; in collaboration with MCCAA, this initiative has led to a reduction in prices of one hundred and fourteen (114) medicines in the last two years where consumers could save up to sixty-seven percent (67%);

vii) Carried out a simplification exercise, allowing businesses to submit applications in electronic format with a reduction in administrative burden to the business community of 31.5% and a reduction of 15.2% in man hours;

viii) Planned relocation to new, state of the art premises, with savings of about a quarter of a million Euros on rent and bills over a period of three years.

3. Developing the Strategy

Meetings with internal and external stakeholders were carried out (Appendix). During 2015 the Medicines Authority participated in a strategic review which was carried out in collaboration with the Management Efficiency Unit (OPM). Strategic analysis was based on stakeholder analysis, pestle analysis, and strengths-weaknesses-opportunities-threats (SWOT) analysis. Prioritised opportunities for improvements were implemented in line with the Medicines Authority's commitment to protect and enhance public health.

The planning process included holistic organisational consultation through assessment of previous strategies, Staff Meetings, Management Review Meetings, and discussions with stakeholders on a National and European level. Analysis of benchmarking and audit outcomes and amalgamation of government strategies ensued. Open communication, collaboration and stakeholder engagement were strengthened and the Authority organised its first structured Stakeholder Meeting to share achievements and better understand the needs and expectations of its clients. The findings of the various meetings indicated the strategic dimension of the Authority and helped identify a number of strategic elements which impact the plans and goals of the Medicines Authority in relation to the expected drivers of change over the next five years.

4. Challenges and Opportunities

The success story of the Medicines Authority is based primarily on a model which supports innovation and flexibility while reducing bureaucratic practices. The Authority is committed to the identification and management of risk using good risk and innovation management practices through which employees, at all levels of the organisation, recognise and manage risk effectively to enable the delivery of the objectives of the Medicines Authority. Strategic reviews assist in identifying actions which may be taken in order to mitigate risks and capitalise on opportunities within the context of the administration's programmes and objectives. Challenges which the regulator faces include:

i) Rapid advances in technology and medical research;

ii) Expectations of access to new medicines;

iii) The threats resulting from counterfeit or substandard medicines sourced via cross border procurement, dubious sources or through rogue Internet pharmacies, which point towards the importance of the Authority establishing the necessary links with security, customs, and communication services;

iv) The need for the provision of more timely, accessible and effective information and reporting channels to medical practitioners, pharmacists and patients;

v) Development of a centralised information system and seamless implementation of a national information system to bring together the entire supply chain of medicinal products;

vi) Rigour in ensuring compliance to local and EU regulations in license issuing, review and renewal in both the qualitative aspect but also in terms of the sustainability and recovery of applicable fees;

vii) Growing interest from other EU agencies, stimulating the Authority to continuously diversify into new sectors.

Changes in the environment are major drivers of change in the Medicines Authority. The most significant driver is EU and national legislation, and the competencies and functions that government assigns to the Authority as a result. Communication and stakeholder engagement is shaped by changes in society's expectations of regulators, while technology advances have the potential to transform manufacturing and medicinal products and challenge the system to effectively regulate innovative processes.

The growing interest in Malta as a centre for medical research, the supply of quality healthcare and in the further expansion of the pharmaceutical industry presents many opportunities for growth for the Medicines Authority. It places a greater onus on the Authority as a regulator and active stakeholder within the national health policy framework.

The achievements and involvement at European and international level registered by the Medicines Authority are exposing the Authority to many opportunities for growth. This, in turn, generates the financial stability necessary for immediate investments in gaining increased expertise and resources to not only meet the challenges of new pharmaceutical products and innovations but also allow the Authority to be more effective in regulation and enforcement in Malta.

The prospect of greater regulation at EU level in relation to new drugs, e-prescriptions, and Internet pharmacies are all challenges which create the opportunity for further growth for the Medicines Authority. This greater exposure carries additional responsibility as to the institutional role the Authority has in the wider regulatory context of health and consumer protection.

5. Strategic Goals and Objectives for 2016 – 2020

Building on the achievements and in response to the challenges and opportunities envisaged, five goals were identified for 2016 – 2020.

In addition, a central initiative for which preparations are already in progress is the hosting of sixteen (16) meetings during the Maltese Presidency in 2017 and a number of International conferences.

The Authority remains mindful of the need for contingency capacity, to effectively manage issues relating to the areas regulated that may arise from time to time.

5.1. Strategic Goal 1 – Optimised regulatory systems

In its core regulatory systems, the Medicines Authority plays a pivotal role in ascertaining that medicinal products deliver their intended benefits while being as safe as possible for the patient. The vigour of the system stems from the high standards required by National and European legislation and from the widespread network of experts who contribute to quality, scientific decision-making. It is a major goal for the Authority to maintain the high level of regulation which is inherent in its core work, and to improve it with the following strategic objectives.

Strategic Objective 5.1.1

To strengthen the effectiveness of surveillance systems for medicinal products

- Contribute to strengthening of pharmacovigilance across the EU network and explore new methods for monitoring products and rapidly evaluating safety issues, through involvement in Pharmacovigilance Risk Assessment Committee and Strengthening Collaborations for Operating Pharmacovigilance in Europe;
- Introduce and review guidelines for industry and healthcare professionals;
- Strengthen the role of the Responsible Persons (RPs) through the introduction of a list of RPs.

Strategic Objective 5.1.2

To ensure appropriate national regulation of medicinal products and contribute to national health policy

- Examine the broader framework for regulating medicinal products and determine any potential new areas of competence appropriate for the Medicines Authority to assume;
- Introduce a self-assessment process for pharmacies.

Strategic Objective 5.1.3

To enhance the Medicines Authority's commitment to strengthening the European and International regulatory network

- Actively contribute to discussions for new regulatory and legal proposals at EU and International level;
- Contribute to the implementation of the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) work programmes, arising from the Joint HMA EMA High-level Strategy, for the period 2016 – 2020;
- Build on current strategies for lead Member State roles in pre- and post-authorisation licensing and pharmacovigilance procedures to enhance existing ranking in centralised and decentralised procedures;
- Contribute at management level to international fora for medicines to address global challenges, promote convergence of regulatory standards, and sharing of information across international regulatory areas.

Outcomes

- National and EU pharmacovigilance systems provide improved monitoring of the safety of medicinal products;
- Medicines agencies' collaboration enhances the effectiveness of the services and medicinal products provided to patients;
- More robust international network with better co-ordinated regulatory activities and reduced duplication of effort.

Performance indicators

- Range of European projects and International initiatives;
- Number of new or improved surveillance and monitoring methods or tools used;
- Series of collaborative agreements with other competent authorities;
- Ranking in European procedures.

5.2. Strategic Goal 2 – Better informed users

The Medicines Authority has adopted a more proactive approach to ensure that patients and their healthcare providers have adequate information on medicinal products to inform their treatment decisions, and knowledge of the regulatory system to understand the risk: benefit concept and the lifecycle approach. The regulator aims to work in collaboration with stakeholder groups, exploring ways to improve the value and impact of the information provided and the way it is communicated, while maintaining public trust and confidence in the system.

Strategic Objective 5.2.1

To promote rational and safe use of medicinal products

- Ensure prompt communication to target audiences on new and emerging issues in a consumer-friendly format;
- Enhancement of the Malta Medicines List to include accessibility from mobile devices;
- Provide information on issues relating to unregulated products, ensuring that consumers can clearly differentiate between legal and illegal internet sellers of medicines and that the risks associated with falsified medicines are understood.

Strategic Objective 5.2.2

To promote greater engagement in the role of the Medicines Authority

- Expand the traineeship programmes at undergraduate and postgraduate levels, using engaging methods linked to the relevant curricula.

Strategic Objective 5.2.3

To ensure public awareness and knowledge of the Medicines Authority

- Extend participation in media programmes and continue to expand exposure on social media.

Outcomes

- Clear understanding among healthcare professionals and patients about safe and effective use of medicinal products and continuous improvement of risk communications;
- Educational activities relevant to and making effective use of the resources of the Medicines Authority;
- Increased awareness among patients, healthcare professionals and the regulated sectors, of legislative requirements and the role of the Medicines Authority in the regulatory system and in public health.

Performance indicators

- Publication of risk minimisation information and tools directly through the Medicines Authority website;
- Number of stakeholder and general public consultations;
- Broadened programme of training activities and modalities;
- Easy online access to high quality stakeholder targeted content.

5.3. Strategic Goal 3 – Access to medicinal products

The desired outcome of the Medicines Authority is that patients have constant access to authorised medicines at reasonable cost to themselves or the State. In practice, availability depends on many issues including health economic pressures that apply in Malta due to our small population size and product shortages which may occur sporadically. The greater use of generics within the local health system lowers the costs of medicines, providing the opportunity to improve access. Reclassification of medicines from prescription to non-prescription status, when considered safe and appropriate, may also provide wider access for patients and consumers.

Strategic objective 5.3.1

To work with national agencies and European regulators to address the challenges of medicines shortages

- Prioritise measures within the remit of the Medicines Intelligence and Access Unit to manage potential medicine shortages;
- Allow further new applications for authorisations in accordance with different regulatory routes.

Strategic objective 5.3.2

To optimise the use of the current regulatory system to maintain authorised products on the market in Malta at reasonable prices

- Seek to influence European and National discussions to ensure legal frameworks promote medicines' availability and do not restrict supply;
- Maintain close collaboration with the Malta Competition and Consumer Affairs Authority (MCCAA) and stakeholders in the pharmaceutical sector to sustain active commitment to ensure fair and affordable pricing of medicines for consumers.

Strategic objective 5.3.3

To protect supply chain integrity

- Implement mechanisms for a risk based approach to target the supply lines of falsified/unauthorised medicinal products;

- Oversee the effective implementation of repository and verification systems for safety features for human medicines to ensure these operate in line with the Commission Delegated Regulation (EU) 2016/161.

Outcomes

- Identified shortages of medicinal products managed effectively to reduce impact;
- Improved affordability of medicines for consumers when compared to other countries in the EU;
- Greater continuity in the medicines supply chain to ensure accessibility to authorised products at sensible prices;
- Patients not exposed to the risks of falsified medicinal products in the local supply chain.

Performance indicators

- Good practice implemented to handle shortages and mitigate risks;
- Full implementation of the National Market Surveillance Plan for medicinal products;
- Number of price reductions of medicinal products.

5.4. Strategic Goal 4 – Supporting innovation

In the life sciences, promising new trends are predicted to significantly change how products are designed, made and supplied. Personalised medicines and cell-based products are two of the known and expected developments. For future growth, strong links between academia, industry and regulators are critical to focus on effective research and development for the benefit of patients and the pharmaceutical sector itself.

Strategic objective 5.4.1

To support research and development in the Maltese life-sciences sector

- Consider enhancing capacity for research, training, development and innovation;
- Strengthen the Medicines Authority International Traineeship Programme to include different streams for the Malta Qualification Framework level 6, 7 and 8;
- Continue to endorse projects in advanced therapies, stem cell research, pharmacogenetics, regulatory affairs and scientific innovation.

Strategic objective 5.4.2

To look for opportunities to build an innovative portfolio

- Develop capacity to carry out inspections for sterile manufacturing and radiopharmaceuticals;

- Widen the range of assessment capabilities for European procedures;
- Facilitate the progress of the pharmaceutical and life sciences sector in collaboration with Malta Enterprise.

Outcomes

- Build a new generation of pharmaceutical leaders by investing in proactive researchers;
- Extend functions in the areas of scientific advice, assessments and inspections.

Performance indicators

- Structured function catering for Research, Technology, Development and Innovation (RTDI);
- Enhanced participation within the European network in procedures for more diverse medicinal products and also at International level for inspectorate activities.

5.5. Strategic Goal 5 – Organisational development

To achieve the strategic goals set out above, and to deliver its core work, the Medicines Authority will continue to develop its organisational capabilities to meet the challenges of the ever-changing regulatory environment. Over the next five years the Authority shall sustain the scientific and regulatory expertise needed to enhance its contribution to European procedures and to monitor the quality, safety and efficacy of products on the Maltese market. Finances will continue to be managed prudently; ensuring sufficient resources are available to function in a cost-effective manner while focusing on operational efficiency through the harmonisation and simplification of processes whenever possible.

Strategic objective 5.5.1

To ensure that optimal workplace and organisational structure is in place

- Keep roles and responsibilities under review to ensure adaptation to the developing role of the Authority and the changing regulatory environment;
- Relocate the Medicines Authority to the Malta Life Sciences Park which provides outstanding facilities in terms of laboratories, offices, lecture theatres, meeting rooms and shared facilities.

Strategic objective 5.5.2

To appropriately manage finances and human resource

- Negotiate and implement a new collective agreement for employees of the Medicines Authority;
- Explore potential for further revenue-generating work with other regulatory authorities;
- Introduce a new HR information management system for prioritised areas;
- Encourage employees in career development through training and support in obtaining recognised qualifications;
- Ensure employee engagement, commitment and motivation endorsing a culture of performance and accountability.

Strategic objective 5.5.3

To enhance quality management systems

- Strengthening quality management and auditing functions of the Medicines Authority through capacity building and updating of the quality management system in line with ISO9001:2015;
- Enhance the quality management system in tandem with the European benchmarking exercise and principles from International Conference on Harmonisation quality and risk management guidelines.

Strategic objective 5.5.4

To further develop ICT systems

- Introduce an information system covering core processes of the Medicines Authority;
- Gradually replace legacy hardware with hardware which supports flexibility and the requirements of new technologies;
- Complete scanning project in an effort to move towards more electronic records.

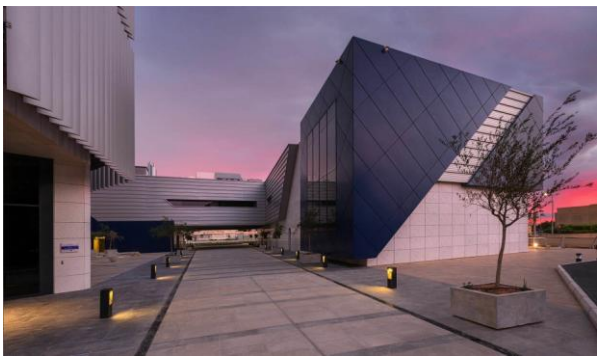
Outcomes

- Optimised learning and development capabilities;
- An ideal workplace to achieve further in value, service and excellence within the strategic and scientific environment of the new premises;
- Continuous quality improvement culture;
- Successful implementation of IT system and staff training as necessary.

Performance indicators

- Competence and skills mix in the Authority;
- Percentage of employees with formal recognised qualifications;
- Expenditure and procurement continue to comply with relevant legal requirements and best practice;
- Average rating in benchmarking visit in 2017, and number of strengths and opportunities for improvement identified.






6. Communicating and Implementing the plan

A key prerequisite for efficient implementation of the strategy is an effective communication approach. This shall be undertaken through continuous feedback with all stakeholders.

The timeframe for this strategy is in line with the timelines of the strategic plans of the European Medicines Agency and the Heads of Medicines Agency. It is understood that the Medicines Authority will continue to monitor and review its environment and adapt to change through the annual planning process. The Medicines Authority commits to develop and evaluate an annual document outlining the key tasks and performance targets in line with the strategy and environmental changes occurring.

7. Appendix

Schedule of workshops carried out as part of the Review Process

Workshop	*Date*	*Attendees*
Workshop 01	18/09/2014	Consumer Affairs Council including representatives from the Malta Communications Authority and MCCAA
Workshop 02	09/03/2015	Staff Meeting
Workshop 03	25/03/2015	Medicines Authority management
Workshop 04	01/04/2015	Medicines Authority management
Workshop 05	09/04/2015	Medicines Authority management
Workshop 06	09/04/2015	Chairperson/CEO - Medicines Authority
Workshop 07	15/04/2015	Malta Enterprise and Malta Life Sciences Park
Workshop 08	23/04/2015	Malta Qualified Persons Association (MQPA)
Workshop 09	24/04/2015	Medicines Authority management
Workshop 10	24/04/2015	GRTU – Malta Chamber of SMEs
Workshop 11	24/04/2015	University of Malta
Workshop 12	27/04/2015	Malta Health Network
Workshop 13	28/04/2015	Malta Competition & Consumer Affairs Authority (MCCAA)
Workshop 14	30/04/2015	Ministry of Energy & Health
Workshop 15	30/04/2015	Malta Chamber of Pharmacists
Workshop 16	04/05/2015	The Malta Chamber of Commerce, Enterprise and Industry
Workshop 17	06/05/2015	Ministry for Social Dialogue, Consumer Affair and Civil Liberties
Workshop 18	03/06/2015	Malta Police Force and Customs Department (working group of enforcement officers)
Workshop 19	26/10/2015	Management Review
Workshop 20	02/12/2015	Staff Meeting
Workshop 21	02/12/2015	Annual Stakeholder Meeting