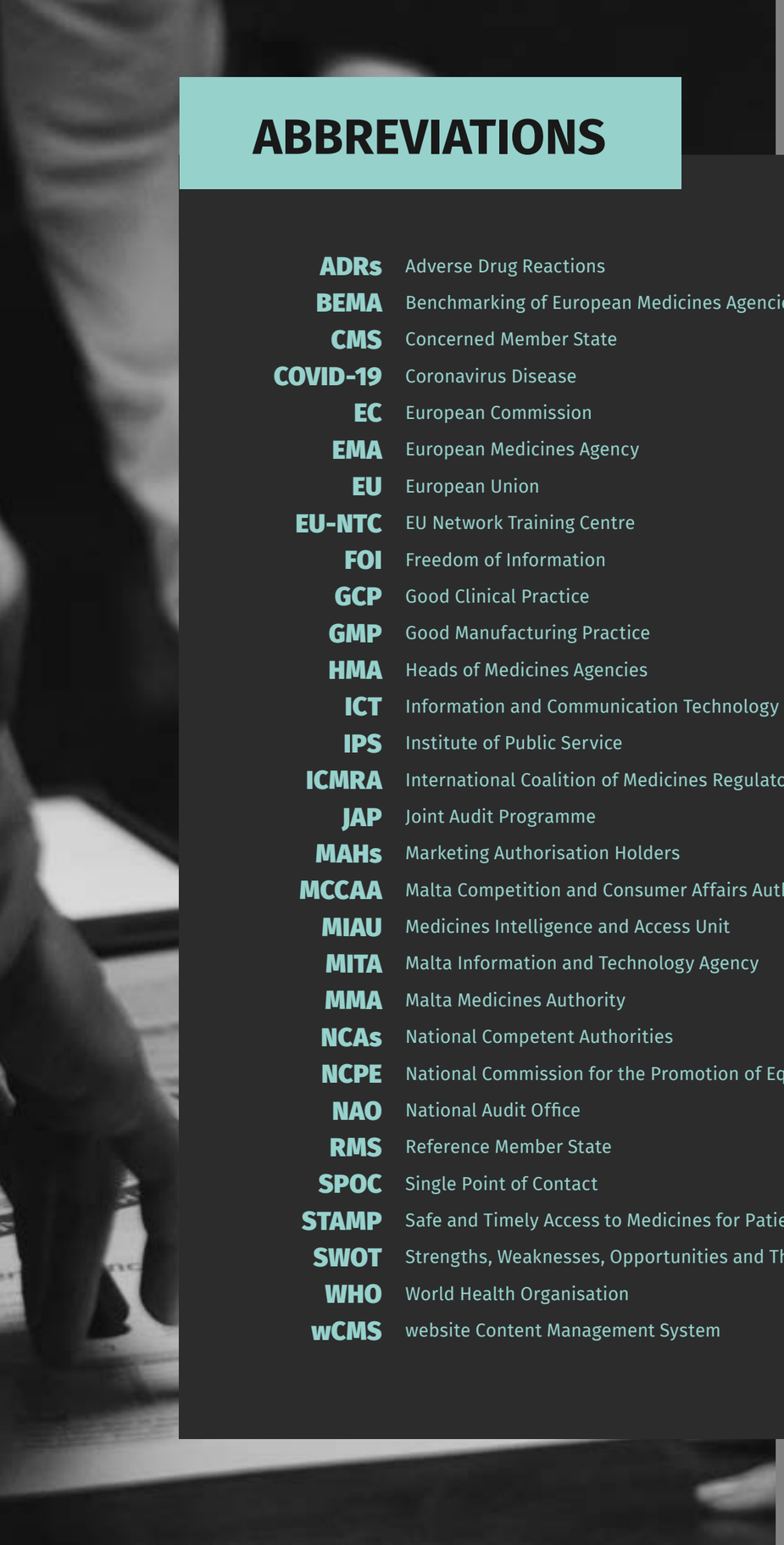
MALTA

MEDICINES AUTHORITY STRATEGY TO 2025



ABBREVIATIONS

ADRs	Adverse Drug Reactions
BEMA	Benchmarking of European Medicines Agencies
CMS	Concerned Member State
COVID-19	Coronavirus Disease
EC	European Commission
EMA	European Medicines Agency
EU	European Union
EU-NTC	EU Network Training Centre
FOI	Freedom of Information
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
HMA	Heads of Medicines Agencies
ICT	Information and Communication Technology
IPS	Institute of Public Service
ICMRA	International Coalition of Medicines Regulatory Authorities
JAP	Joint Audit Programme
MAHs	Marketing Authorisation Holders
MCCAA	Malta Competition and Consumer Affairs Authority
MIAU	Medicines Intelligence and Access Unit
MITA	Malta Information and Technology Agency
MMA	Malta Medicines Authority
NCAs	National Competent Authorities
NCPE	National Commission for the Promotion of Equality
NAO	National Audit Office
RMS	Reference Member State
SPOC	Single Point of Contact
STAMP	Safe and Timely Access to Medicines for Patients
SWOT	Strengths, Weaknesses, Opportunities and Threats
WHO	World Health Organisation
wCMS	website Content Management System

CONTENT

ABOUT THE MALTA MEDICINES AUTHORITY

The Malta Medicines Authority (MMA) was established in 2003 and has developed into an autonomous body that implements scientific decisions through a patient-centred approach. It is committed to provide high quality licensing, pharmacovigilance, pharmaceutical and pharmacy inspections, and enforcement services to its stakeholders for the ultimate benefit of the public. The MMA comprises of five (5) Directorates under the lead and guidance of the Executive Chairman. These are the Licensing Directorate, the Post-Licensing Directorate, the Inspectorate and Enforcement Directorate, the Advanced Scientific Initiatives Directorate and the Scientific and Regulatory Operations Directorate. Their core work is supported by eight (8) units, namely the Finance and Corporate Services Unit, the Information and Communications Technology Unit, the Medicines Intelligence and Access Unit, the Quality, Continuous Improvement and Internal Audit Unit, the Research, Scientific Affairs and Innovation Unit, the Educational Planning and Academic Development Unit, the Operations and Data Interpretation Unit and the Medical Devices Unit.

Mission

The MMA's mission is to protect and enhance public health through the regulation of medicinal products and pharmaceutical activities.

Vision

The MMA aims to be a centre of excellence in advancing effective and innovative regulation and promoting quality and scientific rigour in its work. It strives to be a best-in-class regulator for the benefit of patients and stakeholders, and endeavours to be an internationally recognised, efficient entity and promoter of people development and sustainable growth.

Values

The key values of the MMA are:

People

People are its most valued resource. The MMA is committed to sustain its ongoing efforts to improve the work-life through educational advancements and most importantly a healthy work life balance.

Quality

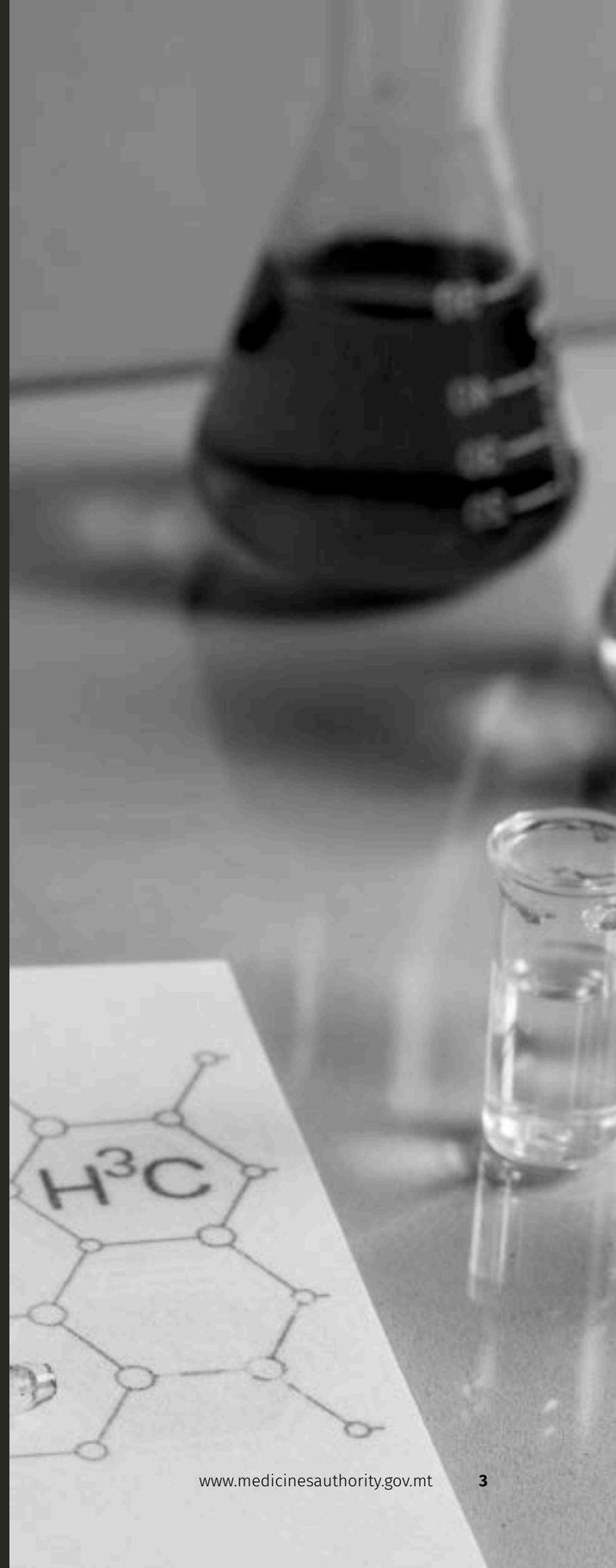
The MMA is committed to provide high quality licensing, pharmacovigilance, inspections, enforcement, and advisory services to its stakeholders in the best interest of consumers.

Integrity

Discipline and fairness are the utmost principles which guide the MMA to do what is right. Integrity lies at the very heart of its mission to uphold the best interests of Maltese consumers and beyond.

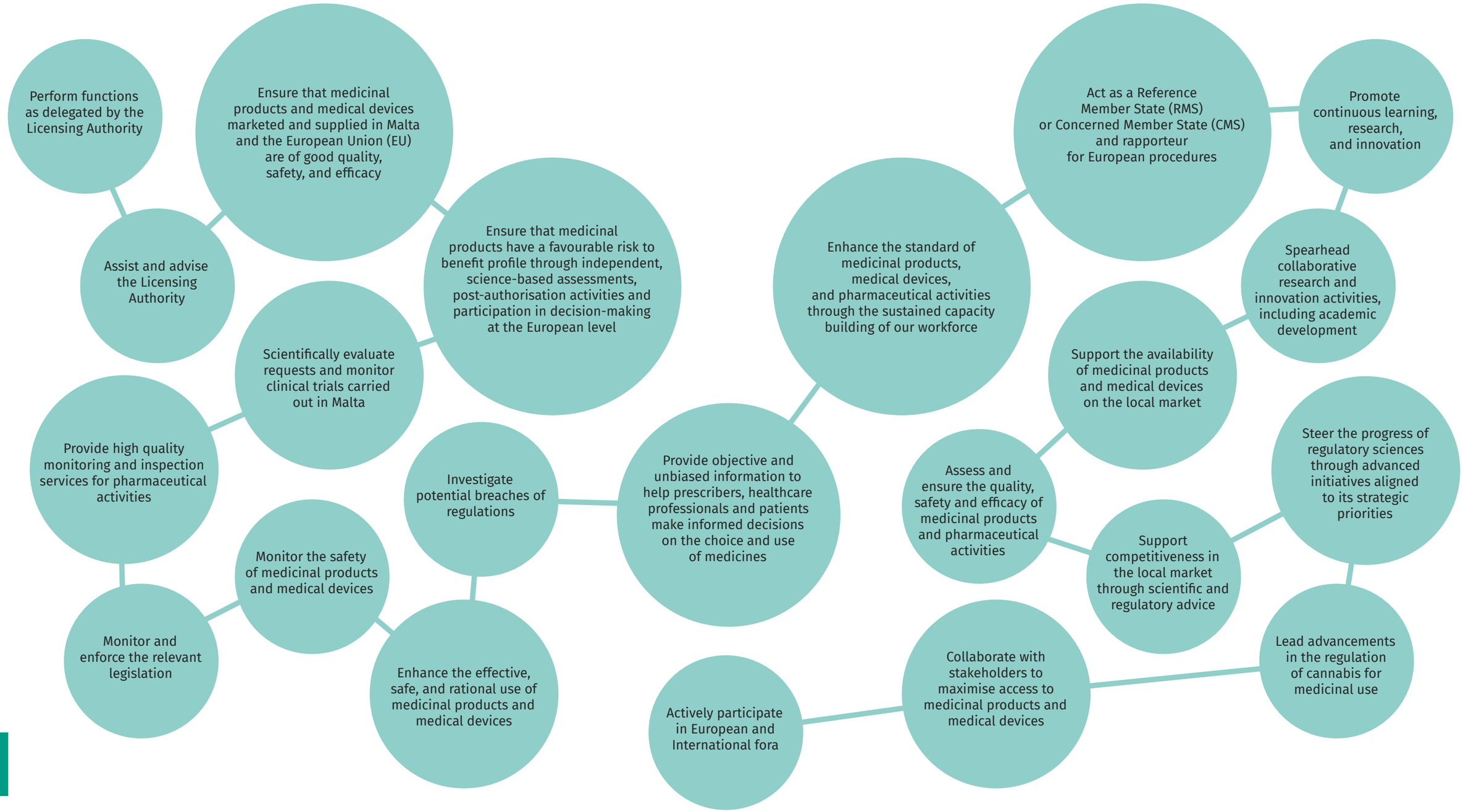
Innovation

In an ever-changing environment, innovation is what drives the MMA forward and keeps it up to speed with the constant technological and scientific advancements. This ensures it remains both valid and effective



WHAT WE DO

The MMA works to sustain its reputation as a recognised centre of excellence for European Regulatory Sciences through the highest quality and scientific rigour with which it undertakes the core functions outlined below in a patient-centred approach.



KEY ACHIEVEMENTS OF 2016-2020 STRATEGY

The MMA has been re-engineered to enable it to broaden its scope of operations, fulfil new obligations and cope with the increasing volume of activity, entailing the Authority to sustainably invest in manpower. In view of the expansion of the Authority's regulatory portfolio, the MMA:

Relocated its offices to the Malta Life Sciences Park in a cost-saving measure which provided new outstanding facilities and an optimal working environment

Doubled its workforce and it currently employs ninety-three (93) officers: sixty-three (63) females and thirty (30) males

Tripled its third country EU Good Manufacturing Practice (GMP) inspections, thereby strengthening its international reputation

Increased the number and complexity of assessment of Marketing Authorisation procedures, with further plans to embark on new types of assessment following training of new assessors

Improved access to medicinal products through one hundred and seventy-nine (179) price reductions and the introduction of one hundred and one (101) new generic medicinal products with a price difference of up to 82%

Strengthened collaboration with other National Competent Authorities (NCAs) in the EU

Excelled in the European networking commitment by hosting twenty-four (24) meetings of European committees and working groups as part of the Maltese Presidency of the Council of the EU in 2017

The key achievements founded the successful outcome of an National Audit Office (NAO) audit on the human resources and cost-effectiveness of the MMA, which concluded that the Authority's 'strategic direction placed it on a sound foundation to fulfil its stated vision as a centre of excellence'.

Undergone intensive international assessments by the Joint Audit Programme (JAP) involving the United States FDA, the rigorous Benchmarking of European Medicines Agencies (BEMA), and the recertification of ISO 9001:2015 in 2017 and 2020

Invested in capacity building related to regulatory and scientific operations, research, scientific affairs and initiatives, innovation, educational planning, academic development and data interpretation

Twenty-one (21) MMA officers attained a post-graduate degree at Master and Doctorate level, enhancing the Authority's academic and regulatory capacity

Took up the role to act as an Authority to regulate the use of cannabis for medicinal and research purposes in 2018, positioning Malta as a leader in the dynamic regulatory sciences while optimising its regulatory systems and supporting development and innovation within the Authority

Established the Academy for Patient Centred Excellence and Innovation in Regulatory Sciences in 2019

Expanded the MMA's portfolio towards patient-centred functions through the transposition of new European regulations for medical devices in 2020, thereby becoming the National Competent Authority in the field

Re-certified with the National Commission for the Promotion of Equality (NCPE)'s Equality Mark in 2020 for a further three years

Maintained all key operations in all Directorates, in spite of disruptions resulting from Brexit preparations and the coronavirus disease (COVID-19) situation

DEVELOPING THE STRATEGY

The Scientific and Regulatory Operations Directorate within the Authority set up an internal task force mandated with the planning, development and implementation of key targets for the next strategic cycle. It acted as the focal point for all Directorates and Units, funnelling their input into a roadmap which paves the way for a resilient and sustainable future for the MMA in the next five (5) years and beyond.

The development of the Strategy involved a two-pronged process which identified the internal views on on the organisational and regulatory priorities of the Authority and catered for the needs of external stakeholders. In this regard, a series of internal meetings were held to identify the key priority areas and lay the foundations for the strategic planning of the MMA. These were followed by consultation sessions with external stakeholders to gather knowledge and understand their needs and expectations. This is considered essential to maintaining healthy industrial relations based upon mutual respect, which is considered vital to attain the strategic goals set out for the next five (5) years. To that end, the main stakeholder representative groups were provided with a platform to discuss strategic issues, voice their views on market opportunities and threats, express their opinions on customer relations and determine the Authority's strengths and potential improvements. In addition, a stakeholder satisfaction survey was conducted to more broadly assess the MMA's performance as perceived by external actors, and to gain further insight into their aspirations which will help in identifying key performance indicators moving forward.

Furthermore, a longitudinal analysis of all stakeholder meetings held throughout the past years by the Office of the Chairperson helped identify areas of continuous importance. Finally, the task force drew on strategy plans adopted by partners within the European and International Medicines Regulatory Network, which fed into the main themes for the development of the strategic goals and objectives of the MMA.

These exercises were conducive in formulating the landscape of the Authority for the next five (5) years within the current challenges and evolving contexts.

STRATEGIC GOALS AND OBJECTIVES

The strengths, weaknesses, opportunities, and threats (SWOT) approach was employed and six (6) overarching goals were identified as the core areas to be addressed by the MMA throughout the next five (5) years.

A set of objectives corresponding to each goal were subsequently developed, through which the Authority aims to reinforce its power to navigate through market challenges and continue contributing towards a level of excellence in medicines and pharmaceutical regulation and ultimately, the protection of public health.

Concurrently, the MMA aims to sustain its contribution towards the implementation of the European Commission (EC) Pharmaceutical Strategy and the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) work programmes, arising from the Joint HMA-EMA network strategy to 2025.

Strategic Goal 1

Resilience against current and potential market disruptors

With multiple market disruptors coinciding, including Brexit, the implementation of EU Regulations concerning falsified medicines and the COVID-19 pandemic, the MMA has proactively confronted these challenges to protect potentially vulnerable supply chains against risks posed by these circumstances. The Authority commits to continue to navigate through the storm by adapting its workflows, proving resilient in the face of adversities emerging in the sphere of medicines and pharmaceutical regulation.

1.1

Strategic Objective

To act in coherence with partners in designing supply chain strategies

1.2

Strategic Objective

To optimise the allocation of the Authority's resources in response to major events

1.3

Strategic Objective

To monitor developments related to the COVID-19 pandemic

1.4

Strategic Objective

To sustain support structures in the areas of Brexit and falsified medicines

Strategic Objective 1.1:

To act in coherence with partners in designing supply chain strategies

· Maintain healthy collaboration and communication with EU partners to implement effective harmonised measures that address risks associated with volatilities affecting supply chains across the EU.

· Ensure that the Authority works in tandem with government and private entities to pre-empt medicines shortages resulting from extraordinary situations and assess their consequential impact.

Strategic Objective 1.2:

To optimise the allocation of the Authority's resources in response to major events

· Allocate the Authority's resources effectively and systematically according to areas of highest need and priority.

· Update the disaster recovery plan as necessary to reinforce the MMA position against similar future phenomena.

· Support and maintain business continuity by implementing innovative work schemes which allow the transition to different occupational environments.

Strategic Objective 1.3:

To monitor developments related to the COVID-19 pandemic

· Strengthen the pharmacovigilance systems of medicinal products authorised for the treatment and/or prevention of COVID-19 through participation at an EU level and support other governmental entities with the aim of protecting public health.

· Channel relevant updates and information to patients and health care professionals in a timely manner to foster trust in science towards the successful management of the pandemic.

· Implement a full resumption of on-site pharmaceutical regulatory activities in the post-COVID era.

Strategic Objective 1.4:

To sustain support structures in the areas of Brexit and falsified medicines

· Ensure the provision of technical and administrative support to stakeholders during and after the transitional periods applicable to both scenarios.

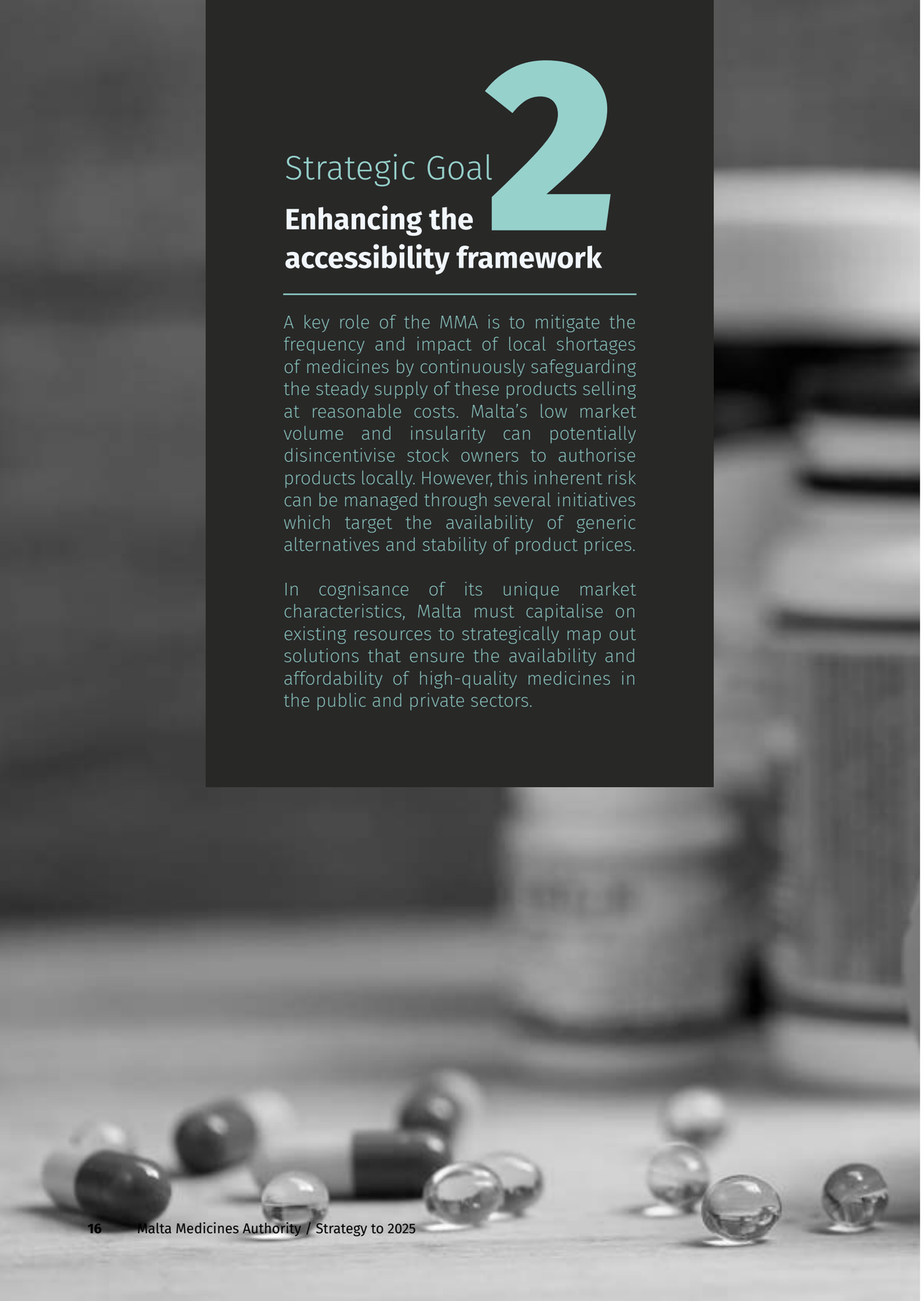
· Communicate EU updates and direction using streamlined and agile means to allow for adequate preparations by supply chain actors.

· Engage in steady dialogue with Marketing Authorisation Holders (MAHs) and counterpart agencies to encourage the necessary operational and regulatory actions that offset the effects of Brexit on medicines availability.

· Consolidate the Authority's supervisory role in the implementation of EU Regulations concerning falsified medicines.

Strategic goal targeted outcomes
Accessibility to medicinal products and medical devices on the Maltese market amid market disruptions.
Acting as a united front when facing supply chain challenges through collaboration and harmonisation of actions at a national and European level.
Optimising the allocation of the Authority's resources and adapting workflows in unprecedented circumstances.
Secure compliance to Regulations on falsified medicines by enacting the necessary national legislation and continue monitoring through inspection activities with the stipulated requirements.

Strategic goal performance indicators
Support the uninterrupted, continuous supply of medicinal products on the local market.
Coordinated actions executed to overcome challenges mediated by market disruptors.
Business continuity and the periodic review of the disaster recovery plan.
Increased awareness of end-users on their obligations with regards to operations and practices required by EU legislation on falsified medicines.



Strategic Goal **2**

Enhancing the accessibility framework

A key role of the MMA is to mitigate the frequency and impact of local shortages of medicines by continuously safeguarding the steady supply of these products selling at reasonable costs. Malta's low market volume and insularity can potentially disincentivise stock owners to authorise products locally. However, this inherent risk can be managed through several initiatives which target the availability of generic alternatives and stability of product prices.

In cognisance of its unique market characteristics, Malta must capitalise on existing resources to strategically map out solutions that ensure the availability and affordability of high-quality medicines in the public and private sectors.

2.1 Strategic Objective

To gather intelligence systematically and expediently

2.2 Strategic Objective

To operate in a global context to address shortages

2.3 Strategic Objective

To maintain current regulatory approaches to accessibility

Strategic Objective 2.1:

To gather intelligence systematically and expediently

- Consolidate the resources of the Medicines Intelligence and Access Unit (MIAU) to maintain the provision of value-added interventions in accessibility issues.

- Facilitate the conduct of market research for the purposes of increasing transparency of the products marketed locally.

- Prioritise cases related to accessibility by implementing an electronic risk-based matrix that measures the severity impact of each case.

Strategic Objective 2.2:

To operate in a global context to address shortages

· Expand the MIAU and Licensing Directorate stakeholder network by increasing outreach with national and international bodies, organisations and institutions through the use of appropriate media.

· Participate actively in notification and discussion platforms on accessibility to human medicines to ensure that forecasted scenarios of shortages are intercepted hastily and effectively.

Strategic Objective 2.3:

To maintain current regulatory approaches to accessibility

· Ensure the affordability of medicines by encouraging competition with regards to the introduction of generics and biosimilars.

· Sustain dialogue with the Malta Competition and Consumer Affairs Authority (MCCAA) and pharmaceutical stakeholders to secure reasonable medicinal product prices for patients and consumers.

· Monitor the fees of pre- and post-authorisation activities for medicinal products with the aim of remaining competitive in attracting pharmaceutical companies and operators to register medicinal products locally.

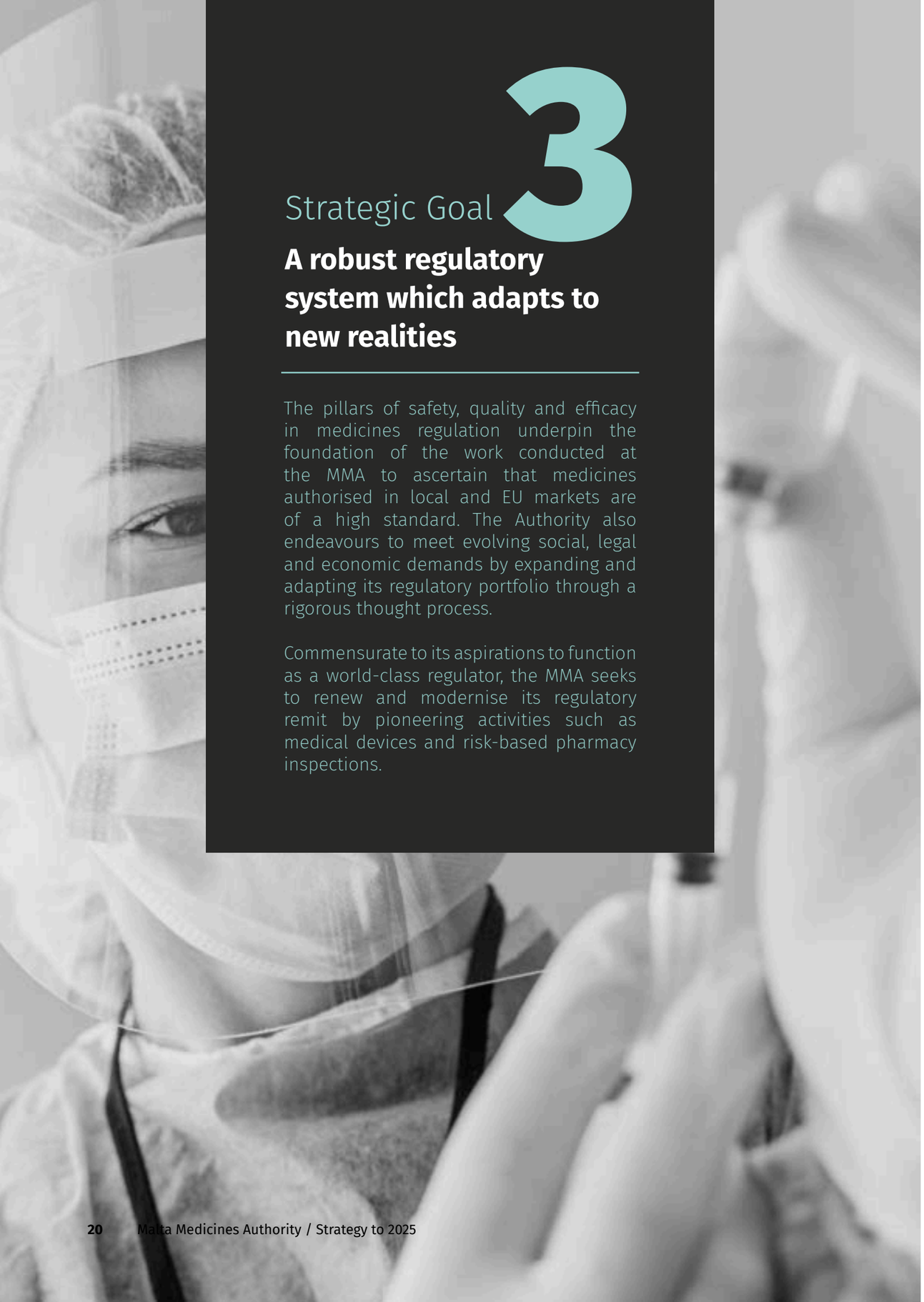
· Promote diverse regulatory registration routes with prospective applicants and encourage the involvement of Malta in European centralised and decentralised medicinal product authorisation pathways.

· Put in place the necessary checks and balances which shift the reliance of product registration from the legal basis of Article 126(a) authorisation of Directive 2001/83/EC to registration on the grounds of a Marketing Authorisation.

· Engage with European counterparts to discuss ways by which they can assist stakeholders and Malta in the registration of medicines through the established routes.

Strategic goal targeted outcomes
Avert situations of acute crisis of medicines accessibility by securing a continuous supply of authorised medicines on the local market, with special attention to critical items.
Assess the landscape of EU and other foreign pharmaceutical markets to detect early signs of restricted accessibility to medicinal products.
Ensure equitable access to medicines by monitoring for and responding to undue price spikes.
Capacity building of the MIAU functions in terms of handling and recording queries and cases concerning medicines access.
Sustain and improve the inclusion of Malta in European authorisation procedures.

Strategic goal performance indicators
Rollout of the MIAU comprehensive case database, which is to be updated accordingly.
Number of information seminars and communication initiatives to amplify the visibility of services offered by the MIAU.
Actions taken, by means of updates to the national pharmaceutical legislation or otherwise, to enable the research of products marketed locally.
Representation in relevant EU fora that discuss accessibility issues (EC Pharmaceutical Committee, EC Expert Group on Safe and Timely Access to Medicines for Patients (STAMP), HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use and HMA/EMA Single Point of Contact (SPOC) system).
Number of products registered on the local market and identification of products with no registered alternatives or supply chains.
Number of European procedures and ranking therein, where Malta is acting as CMS, RMS and (co-)/rapporteur across all committees of the EMA.



Strategic Goal 3

A robust regulatory system which adapts to new realities

The pillars of safety, quality and efficacy in medicines regulation underpin the foundation of the work conducted at the MMA to ascertain that medicines authorised in local and EU markets are of a high standard. The Authority also endeavours to meet evolving social, legal and economic demands by expanding and adapting its regulatory portfolio through a rigorous thought process.

Commensurate to its aspirations to function as a world-class regulator, the MMA seeks to renew and modernise its regulatory remit by pioneering activities such as medical devices and risk-based pharmacy inspections.

3.1 Strategic Objective
To further bolster the surveillance for safety and quality of medicines

3.2 Strategic Objective
To spur initiatives related to the clinical development of medicinal products

3.3 Strategic Objective
To reinforce the regulation of medical devices

3.4 Strategic Objective
To instil change in pharmacy practice

Strategic Objective 3.1:

To further bolster the surveillance for safety and quality of medicines

· Contribute to the pharmacovigilance system across the EU network through the involvement in EMA Pharmacovigilance Risk Assessment Committee and other EU/international initiatives, and by maintaining a leading role in post-authorisation safety assessments.

· Support national reporting rates for adverse drug reactions (ADRs).

· Adopt a more personalised approach to relay the most recent safety data on medicinal products to healthcare professionals practicing in specialised fields.

· Develop communication plans to cascade important information and increase awareness on obligations related to pharmacovigilance to stakeholders operating in the pharmaceutical and health sectors.

· Pursue training opportunities for EU GMP inspections of advanced formulations such as sterile preparations and radiopharmaceuticals.

· Explore possible new modalities for quality testing of medicinal products sampled by the MMA that could increase the efficiency and autonomy of the process.

Strategic Objective 3.2:

To spur initiatives related to the clinical development of medicinal products

· Support the provision of scientific advice to pharmaceutical developers and to attract the conduct of clinical trials and clinical studies for medicinal products locally in accordance with applicable Regulations.

· Invest in competence development of technical personnel on Good Clinical Practice (GCP) standards and requirements through professional training.

Strategic Objective 3.3:

To reinforce the regulation of medical devices

· Structure and expand the resources for the regulation of medical devices for the MMA to continue aptly executing its roles as the Competent Authority in Malta for this sector, in line with applicable national and EU Regulations.

· Strengthen the regulatory framework and provision of services for medical devices by integrating operations and documentation with the MMA quality management system.

· Enhance the professional standards of personnel involved in the regulatory activities for medical devices through both internal and external training initiatives.

· Establish international partnerships and engage in the exchange of best practices with organisations having expertise in the regulation of medical devices.

· Continue providing the necessary support for the local medical devices sector to evolve into a niche industry which attracts the (re-)location of Notified Bodies to Malta.

· Monitor the safety of medical devices through controls that ensure optimal market surveillance and vigilance on the performance and use of these products.

Strategic Objective 3.4:

To instil change in pharmacy practice

· Transform the tenet of pharmacy inspections from regulatory affairs to regulatory sciences by moving from a product- or procedure-centred approach to a patient-centred approach.

· Streamlining and simplifying the frequency of community and hospital pharmacy audits by incorporating a risk-analysis in the inspection process.

Strategic goal targeted outcomes
National and EU pharmacovigilance systems providing improved monitoring of the safety of medicinal products.
Consolidation of the regulatory activities for medical devices.
An infrastructure that attracts the clinical research and development of medicines in Malta.
A rationalised pharmacy inspection process on the basis of objective evidence and risk criteria.

Strategic goal performance indicators
Rate of ADRs reported and the quality of data submitted.
Number of information seminars on pharmacovigilance activities for different target audiences.
Conformity with EU Directives and Regulations on medical devices in order to meet changing expectations.
Maximisation of national resources towards independent testing of medicinal products sampled by the MMA.

Strategic Goal 4

Organisational growth and sustainability

Throughout the duration of this Strategy, the MMA commits to continue investing in the holistic needs of the organisation sustainably and efficiently. Manpower is recognised as the core asset of the Authority and resources are primarily directed in this regard to attain the skillset and aptitude required in scientific decision-making for the fulfilment of regulatory functions and obligations.

The MMA prides itself in being a financially self-thriving entity and the current impetus in operations, revolving around meticulous planning of projects, resources, expenditure and revenue-generation, will be sustained.

4.1

Strategic Objective

To offer workspaces with in-built ergonomics

4.2

Strategic Objective

To continue improving systems for performance monitoring, people management and financial planning

4.3

Strategic Objective

To continue acting as a global player

4.4

Strategic Objective

To implement a forward-looking Information and Communication Technology (ICT) Governance system

4.5

Strategic Objective

To enhance the quality management system and auditing functions

Strategic Objective 4.1:

To offer workspaces with in-built ergonomics

- Continuously adapt the workplace design by implementing a worksite ergonomics improvement process which allows for improved human performance and productivity.

- Consider alternative work premises which cater for the expanding needs of the Authority in line with more novel areas of regulation and operation being assumed.

Strategic Objective 4.2:

To continue improving systems for performance monitoring, people management and financial planning

- Realise corporate commitments through prudent logistical planning and project management, keeping measures on track by means of periodic reporting and updating.

- Perform data-driven analytics for the MMA to identify trends and facilitate forecasting.

- Review roles and responsibilities, including senior and managerial positions, in tandem with current and forecasted demands of an ever-changing regulatory environment.

- Continue to appropriately manage the allocation of human resources, including the recruitment of employees in Directorates and Units, to equip the Authority for the successful implementation of its mission.

- Remove insularity amongst sections of the workforce to promote a culture of inter-disciplinary collaboration, leading to a high-powered team.

- Gauge the output and deliverables of staff members through performance appraisals and other performance assessment tools.

- Maintain healthy industrial relations between the MMA, employees and concerned parties for a positive and harmonious occupational experience.

- Ensure that the execution of organisational decisions is guided by sound financial planning in order to sustain the Authority's operations.

Strategic Objective 4.3:

To continue acting as a global player

- Maintain the international recognition of the MMA to promote it as a centre of excellence possessing scientific prowess in regulatory sciences.

- Support the diplomatic relations of Malta in areas concerning pharmaceuticals and medicines by contributing in joint agreements with EU and third country States.

Strategic Objective 4.4:

To implement a forward-looking Information and Communication Technology (ICT) Governance system

• Embrace change in the age of digitalisation by transforming the ICT infrastructure into a highly efficient and strategic technological foundation to meet the Authority's evolving requirements

• Align process re-engineering with the national strategic plan for the digital transformation of the Public Administration and the Malta Information and Technology Agency (MITA) Strategy.

• Interact with EMA and other NCAs to be able to make full and timely use of common information technology services implemented in line with the EU Telematics Strategy

Strategic Objective 4.5:

To enhance the quality management system and auditing functions

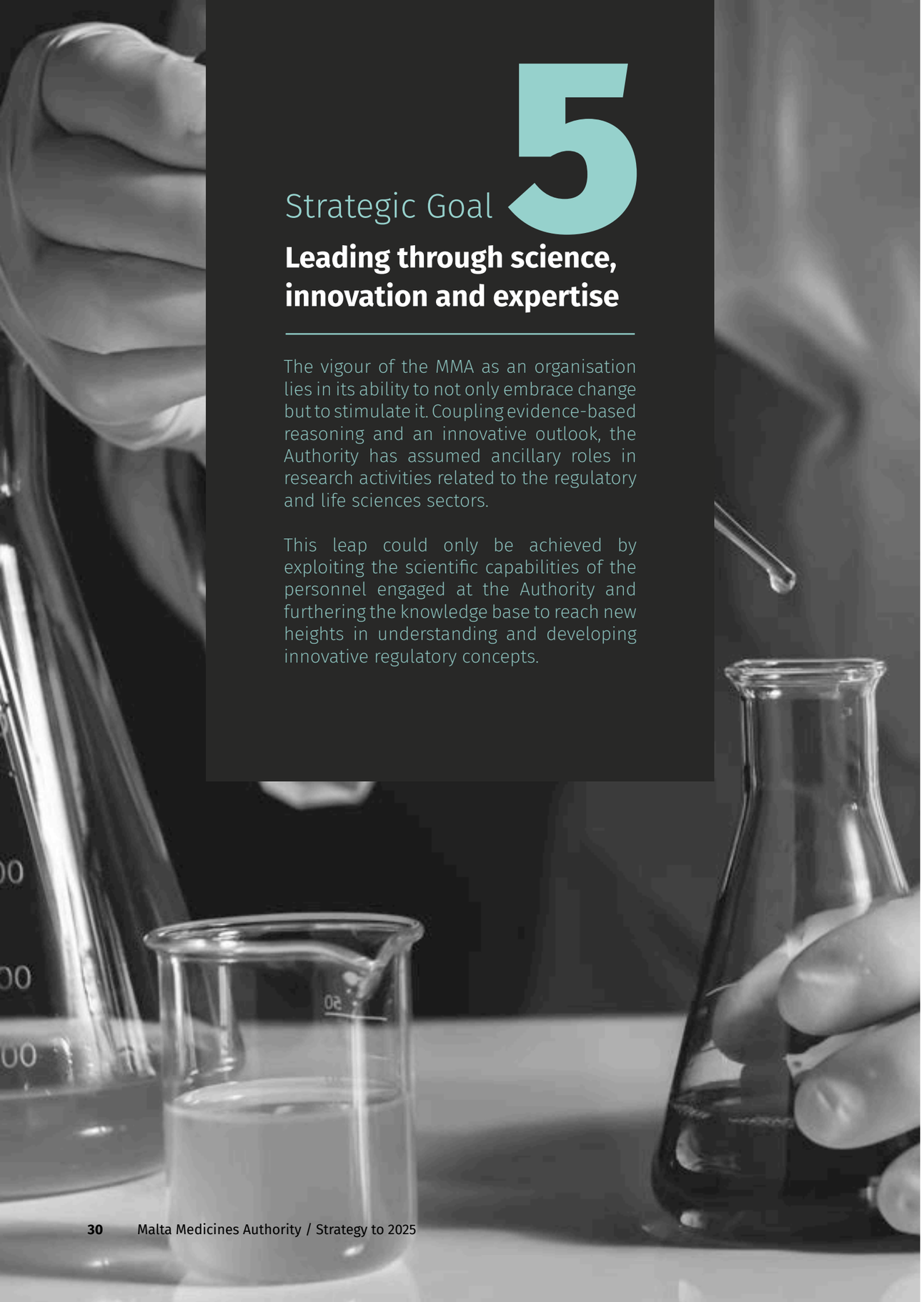
• Uphold and build on the achievements of the quality management system of the MMA through capacity building and compliance to the quality standard ISO 9001:2015.

• Effect reforms to the communications and risk management policies to reflect current practices and advancements in quality requirements.

• Follow-up on internal and external audit recommendations and seek the Authority's certification and re-certification in new and established quality standards, respectively.

Strategic goal targeted outcomes
An adequate working environment for employees, including premises which provide the right ergonomics.
Improved ICT infrastructure which keeps pace with the digital transformation and having efficient approaches to tackle day-to-day troubleshooting.
Global networking to maintain strong ties with international partners.
Consolidation of the MMA quality management system.

Strategic goal performance indicators
Implementation of the MMA quality objectives, key performance indicators and corporate budgetary/simplification measures.
Employ triangulation techniques in regulatory data management to achieve the links in the data-information-knowledge-wisdom hierarchy in support of corporate decision-making.
A new collective agreement for employees of the MMA.
Systems for financial governance and management that secure and build on currently established practices.
Number of bilateral and multilateral agreements, including the monitoring of actions emanating from the agreed commitments pledged by the concerned parties.
Optimal performance in external audits related to the BEMA, JAP and ISO 9001:2015, and streamlined internal operations in preparation for ISO 27001:2013 certification.
State-of-the-art teleconferencing facilities and equipment.



Strategic Goal 5

Leading through science, innovation and expertise

The vigour of the MMA as an organisation lies in its ability to not only embrace change but to stimulate it. Coupling evidence-based reasoning and an innovative outlook, the Authority has assumed ancillary roles in research activities related to the regulatory and life sciences sectors.

This leap could only be achieved by exploiting the scientific capabilities of the personnel engaged at the Authority and furthering the knowledge base to reach new heights in understanding and developing innovative regulatory concepts.

5.1 Strategic Objective
To intensify the research arm by leveraging on collaborations

5.2 Strategic Objective
To instil a professional acumen in tomorrow's pharmaceutical leaders

5.3 Strategic Objective
To venture further into the Authority's innovative regulatory activities

Strategic Objective 5.1:

To intensify the research arm by leveraging on collaborations

- Continue to support the collaboration between the MMA and academic and professional bodies on multiple research and learning initiatives.

- Identify local and foreign funding opportunities for research and liaise with relevant parties in the process of acquiring the necessary funds needed to bridge to more advanced research plans.

Strategic Objective 5.2:

To instil a professional acumen in tomorrow's pharmaceutical leaders

- Obtain official recognition of the Academy for Patient-centred Excellence and Innovation in Regulatory Sciences as an educational institution offering high-level training regimes.

- Consider the introduction of digital programmes delivered through a virtual learning environment.

- Encourage candidates to engage in the MMA International Fellowship Programme to overcome skills mismatches in the pharmaceutical work sectors.

- Provide the necessary support structures for the Authority's employees to pursue higher academic levels as a catalyst to career development.

Strategic Objective 5.3:

To venture further into the Authority's innovative regulatory activities

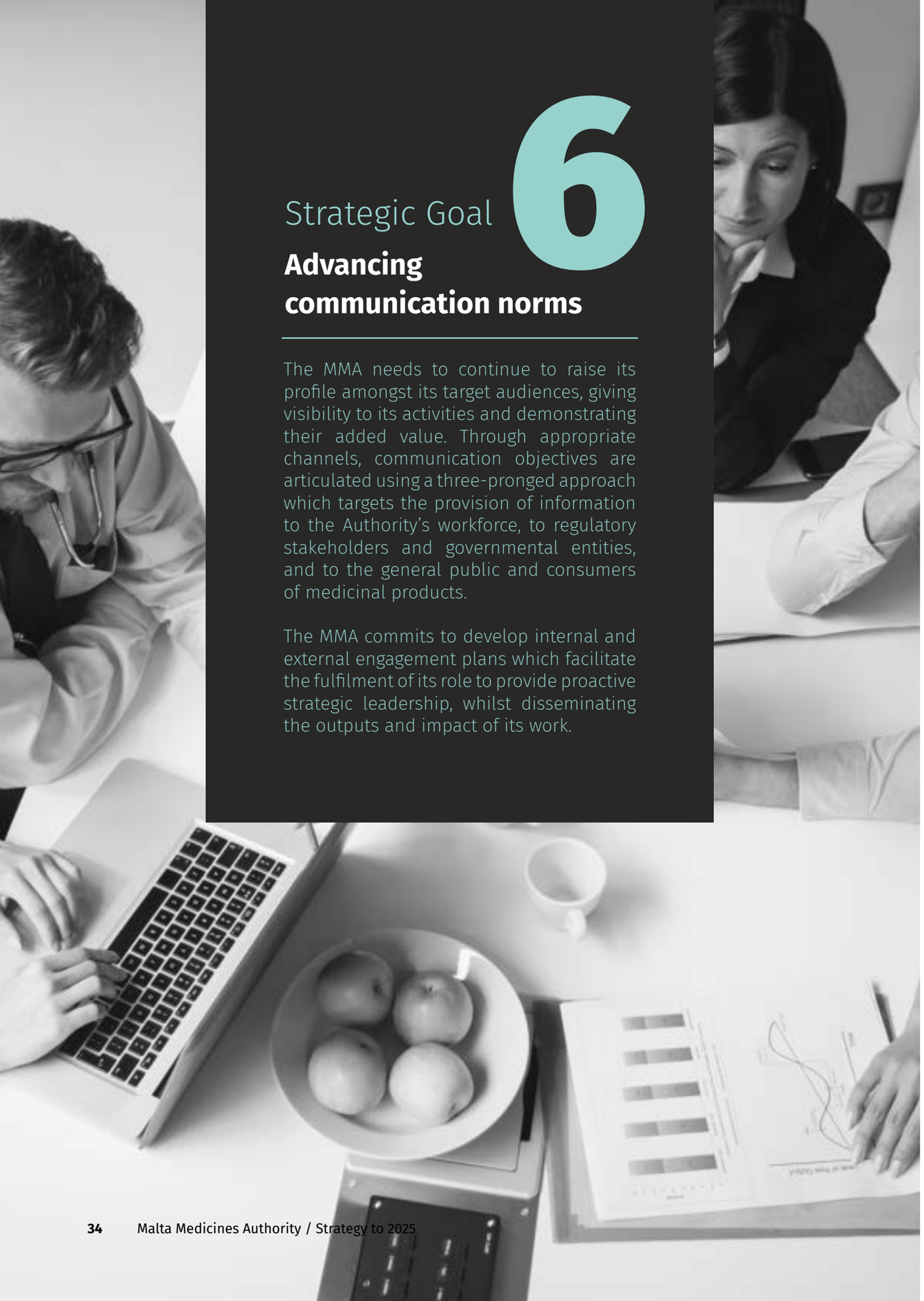
- Expand on the area of cannabis for medicinal and research purposes by investing in capacity growth for personnel and activities related to the regulation of cannabis-based products.

- Actively engage in fora aimed towards harmonisation and consolidate dialogue with stakeholders and relevant bodies to construe emerging developments and corresponding guidance with regards to medicinal cannabis.

- Perform horizon scanning in collaboration with Malta Enterprise to identify potential fields that could further proliferate the pharmaceutical industry, and hence the notion of pharmaceutical tourism, in Malta.

Strategic goal targeted outcomes
Registration of the Academy as an educational institution and development of accredited courses.
Maintain and build on the momentum achieved in the area of medicinal cannabis.
Explore innovative areas of pharmaceutical regulation which could attract interest by international pharmaceutical stakeholders.

Strategic goal performance indicators
Number of scientific papers and publications by members of the Authority.
Number of ongoing research projects targeting diverse aspects of regulatory and life sciences.
Enrolment of employees in training initiatives offered by the Institute of Public Service (IPS) and the EU Network Training Centre (EU-NTC), amongst others.
Enhanced competence which enables the Authority to accelerate in the wide range of scientific assessments undertaken.



Strategic Goal 6

Advancing communication norms

The MMA needs to continue to raise its profile amongst its target audiences, giving visibility to its activities and demonstrating their added value. Through appropriate channels, communication objectives are articulated using a three-pronged approach which targets the provision of information to the Authority's workforce, to regulatory stakeholders and governmental entities, and to the general public and consumers of medicinal products.

The MMA commits to develop internal and external engagement plans which facilitate the fulfilment of its role to provide proactive strategic leadership, whilst disseminating the outputs and impact of its work.

6.1 Strategic Objective
To implement internal engagement initiatives

6.2 Strategic Objective
To uphold professional communication approaches with external stakeholders

6.3 Strategic Objective
To enhance public knowledge on the MMA and the appropriate use of medicines

Strategic Objective 6.1:

To implement internal engagement initiatives

· Raise awareness and interest on the MMA amongst employees, external experts and other associates within the organisation.

· Propagate timely and effective internal communications on new initiatives taken on by the Authority to ensure compliance and empower its members to become organisational advocates when connecting with peers and service users.

· Ensure coherent knowledge on the responsibilities of data processors and information asset owners regarding the rights of data subjects and *modus operandi* when processing personal data and responding to freedom of information (FOI) requests.

· Maintain clear internal reporting and approval lines that allow optimal operational management through convergence of actions and elimination of communication bottlenecks.

· Transform the intranet service into a high-quality repository and document exchange platform.

Strategic Objective 6.2:

To uphold professional communication approaches with external stakeholders

· Identify stakeholder needs through regular meetings and stakeholder satisfaction surveys and populate the MMA stakeholders' database with new contacts involved in the medicines and pharmaceutical regulation with whom the Authority builds dialogue and professional relations.

· Central coordination of media queries, press releases and other public-facing corporate communication material, in a transparent and accountable manner.

· Update the official website as required to ensure that it continues to function as one of the main pillars in the Authority's arsenal of communication tools.

· Adopt best practices from communication strategies implemented by the EMA, HMA and other EU and international organisations.

· Incorporate elements related to risk communications and the value of communications in big data, in the MMA work culture.

Strategic Objective 6.3:

To enhance public knowledge on the MMA and the appropriate use of medicines

· Organise campaigns, through social media or otherwise, and public seminars to increase awareness on the remit of the MMA and other themes of topical interest related to the safe and effective use of medicinal products.

· Continue to offer assistance to queries posed by the public through the MMA website and/or other communication platforms.

Strategic goal targeted outcomes
Align with and implement communication initiatives adopted by partners in the EMRN and international bodies such as theInternational Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organisation (WHO).
Engage more actively in print and broadcast media and scientific fora through commitments and involvement in activities such as panel discussions, seminars, workshops, and article-writing.

Strategic goal performance indicators
Continued publication of the internal newsletter on a quarterly basis to keep employees updated on initiatives, responsibilities and other relevant information.
Participation in pan-European and global social media campaigns.
Internal training of website content writers on the website content management system (wCMS).

IMPLEMENTATION OF THE STRATEGY

The task force within the Scientific and Regulatory Operations Directorate will oversee the implementation of the Strategy and its corresponding action plan.

Through annual reporting, this will be an ongoing process open for scrutiny by internal and external stakeholders, who will have the opportunity to measure the progress registered and provide constructive feedback towards the successful attainment of the MMA's strategic goals and objectives.

Appendix 1: Visual representation of the planning and development stages of the Malta Medicines Authority Strategy to 2025.