NAO
National Audit Office
MALTA

Performance Audit: The recruitment process within the Malta Medicines Authority

November 2020

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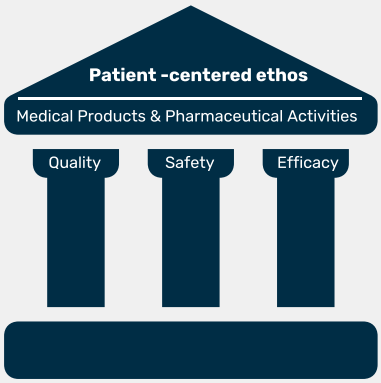
List of Abbreviations

BEMA	Benchmarking of European Medicines Agencies
BPR	Business Process Reengineering
CEO	Chief Executive Officer
EU	European Union
HR	Human Resources
ISO	International Organisation for Standardisation
ISSAI	International Standards of Supreme Audit Institutions
IT	Information Technology
JAP	Joint Audit Programme
KPIs	Key Performance Indicators
MFIN	Ministry responsible for Finance
MMA	Malta Medicines Authority
NAO	National Audit Office
OPM	Office of the Prime Minister
QMS	Quality Management System
SMART	Specific, Measurable, Achievable, Relevant, Time-Oriented
SOP	Standard Operating Procedure

The recruitment process within the Malta Medicines Authority

The Malta Medicines Authority

Aims to: "Protect and enhance public health through the regulation of medicinal products and pharmaceutical activities"



- People
- Quality
- Integrity
- Innovation

Changes influencing MMA's remit

New EU requirements

+

Updating of existing directives

+

Developments of the national pharmaceutical industry

=

Broadened MMA's remit

Changes from 2012 to 2019

	2012	2019
	36 employees	88 employees
	€1.1 million	€3.4 million
	(€194,768)	€1.1 million

MMA's output in units of activities

Directorate	2012	2019
Licensing	5,440	9,600
Inspectorate and Enforcement	317	537
Post-Licensing	174	614
Medicines Intelligence and Access	NIL	202
CEO's Office	Not Available	754
Quality Management Systems	77	152
Advanced Scientific Initiatives	Not Applicable	5,838
Scientific and Regulatory	Not Applicable	170

Business plans

- adopt best practice criteria
- reflect actual financial performance
- are supported by HR plans

Recruitment

- Generally accepted practices
- Compliance with recruitment policy
- Correlation between number of employees and level of activity

Executive Summary

Since 2012, the Malta Medicines Authority (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. Given the substantial increase in the Authority's payroll, this audit sought to determine the extent to which the increase in human resources reflected the Authority's requirements and constituted cost-effectiveness. This entailed reviewing the practices adopted by the MMA to strengthen its technical and administrative capabilities. This audit focused on the procedures adopted by the MMA. However, the scope of this audit did not extend to reviewing the interviewing boards' reports to verify interview scores allocated.

This Report concluded that this remodelling exercise complied with the Authority's strategic directive, and has placed MMA on a sound foundation to fulfil its vision as a centre of excellence. This transformation necessitated action at various levels, namely administrative and financial as well as technical.

The Authority's staff complement increased from 36 in 2012 to 88 as at end 2019. Similarly, its payroll rose from €1.1 million to €3.4 million during the same period. These circumstances reflected the broadening of the scope of the MMA's remit which in turn translated into a significant rise in the Authority's workload. Furthermore, various technical audit reports confirmed that the Authority has high quality systems in place to ascertain a highly qualitative output.

From a financial perspective, the Authority is now a self-sustaining entity. In part, this is due to the revenue generated through the increase in the MMA's activities over time as well as the revision of chargeable fees for some of the services provided. Since 2016, the Authority registered an annual surplus of over €1 million.

MMA's recruitment process followed generally accepted practices. To this end, the Authority has its policies which outline the procedures to be adopted on the recruitment of personnel. The audit based this assertion on a review of the 18 calls for application in 2019, which resulted in the recruitment of 33 employees.

Over the past years, the Malta Medicines Authority's role and internal organisation have evolved to reflect the changing circumstances within the pharmaceutical industry. The Business Process Re-engineering (BPR) exercise at the MMA generally embraced best practices in its implementation, particularly in circumstances where the Authority needed to strengthen its administrative and technical capacity.

Chapter 1

Chapter 1: Terms of reference

1.1 Introduction

1.1.1. Over the past years, the Malta Medicines Authority's (MMA) role and organigramme have evolved to reflect the changing circumstances within the pharmaceutical industry. The remodelling of the MMA's operational practices and processes required an increase in the Authority's staff complement from 36 as at end 2012 to 88 as at end 2019. Given the substantial increase in the Authority's payroll, this audit sought to determine the extent to which the increase in human resources reflects the Authority's requirements. This entailed reviewing the practices adopted by the MMA to strengthen its technical and administrative capabilities. This audit focused on the procedures adopted by the MMA. However, the scope of this audit did not extend to reviewing the interviewing boards' reports to verify interview scores allocated.

1.1.2. The main aim of the Malta Medicines Authority is to "protect and enhance public health through the regulation of medicinal products and pharmaceutical activities". The MMA's role entails the assurance of safety of medicinal products available on the market – that is, from the licensing up to the consumption of the product. Within this context, the MMA adopts a patient-centred ethos which seeks to embrace the principles of quality, safety and efficacy of products through continuous capacity building, innovation and integrity.

1.1.3. The MMA's strategy, covering the period 2016 to 2020, is driven by changes in the pharmaceutical environment, namely European Union (EU) and national legislative changes. The MMA's strategic goals for this period were:

- optimising regulatory systems;
- ensuring that users of medicinal products are better informed;
- ensuring better access to medicinal products; and
- supporting innovation and organisational development.

1.1.4. The MMA is headed by a Chairperson / Chief Executive Officer (CEO) and comprises five core directorates, namely Licensing, Post-Licensing, Scientific and Regulatory Operations, Inspectorate and Enforcement as well as Advance Scientific Initiatives. The Authority has been a self-financing entity since 2015 and generated a surplus of €1.1 million in 2019.

1.2 Audit focus

1.2.1. Against this backdrop, this performance audit sought to evaluate the extent to which the threefold increase in the MMA's staff compliment reflected the Authority's needs as set out

in its strategic framework. This review's objectives consider the audit criteria developed to assess the cost-effectiveness of the increase in the Authority's human resources. In this regard, the audit objectives sought to determine the impact on the Authority's staffing levels on the basis of:

- Changes in the MMA's mandate and work practices;
- the compilation of a needs analysis to support the increase in the Authority's staffing capacity;
- comprehensive business planning; and
- the Authority's recruitment policies and generally accepted practices.

1.3 Audit methodology

1.3.1. The attainment of the aforementioned objectives entailed a number of methodological approaches, namely:

a. **Adherence to ISSAIs** – The audit was carried out in accordance with the Standard for Performance Auditing, International Standards of Supreme Audit Institutions (ISSAI) 3000.

b. **Documentation review** – This included a thorough analysis of strategies, audits and other studies carried out. As the audits were carried out by reputable companies, this Office relied on the technical findings presented in these documents.

c. **Semi-structured interviews** – These interviews enabled this Office to understand the work of the Malta Medicines Authority.

d. **Data analysis** – This approach was required to determine how the workload of the Malta Medicines Authority increased over the years.

e. **Financial analysis** – This Office noted the change in revenue of the Malta Medicines Authority over the years and tried to determine the correlation between the increase in workload and the revenue generated.

1.3.2 All issues and conclusions presented in this Report, unless otherwise indicated, reflect the situation up to the end of 2019.

1.4 Report structure

1.4.1. Following this Introductory Chapter, the Report proceeds to discuss the following:

- Chapter 2 outlines the key factors which contributed to a re-modelled Malta Medicine Authority. The discussion therein mainly relates to the changes in the Authority's objectives, workload and finances.
- Chapter 3 discusses whether the Authority has compiled comprehensive business plans to reflect its strategic framework. The focus relates to supporting documentation prepared by the Authority to determine its staffing levels.
- Chapter 4 analyses the extent to which the Malta Medicines Authority has carried out its recruitment in accordance to its internal policies and generally accepted practices.

1.4.2. The overall conclusions and recommendations related to this performance audit are presented in this Report's Executive Summary on page 5.

Chapter 2

A re-modelled Medicines Authority

2.1 Introduction

2.1.1. Since 2012, the Malta Medicines Authority (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. This re-modelling exercise reflects the Authority's strategic objectives whereby at 2012, its vision was to continue to keep abreast with developments of pharmaceutical activities on the local market so that it can meet all new developments, whereas in 2019, it sought to become a centre of excellence in advancing effective and innovative regulation and promoting quality and scientific rigour. To this end, the MMA has increased its technical and administrative resources from 36 to 88 as at end 2019. From a financial perspective, in 2012, the Authority was receiving a Government's subvention amounting to €110,000. As at 2015, the Authority became a self-financing entity and in 2019, even registered a surplus of €1.1 million.

2.1.2. This Chapter discusses the changes within MMA during the period under review, that is 2012 to 2019. The objectives of this restructuring were to increase the efficiency of the processes, provide a quality service to all stakeholders, reduce bureaucracy and create opportunities for employees. Within this context, the ensuing discussion will focus on:

a. The effect on the MMA's remit through legislative developments;
b. the impact of strategic developments on MMA's organisation, operations and processes;
c. measuring the Authority's performance in terms of Key Performance Indicators (KPIs);
d. the relationship between the number of employees employed and workload; and
e. the relationship between the Authority's revenue and expenses.

2.2 MMA's legislative remit broadened in substance and scope

2.2.1. As at 2012, MMA's remit was regulated by the Medicines Act. This Act reflected European Union (EU) directives which were in force at the time. The main legislative obligations on the Medicines Authority, at the time, were to authorise the placing on the market of medicines, and to keep abreast with developments of pharmaceutical activities on the local market so that it can meet all new developments. Additionally, MMA's regulatory function extended to include inspectorate requirements relating to the manufacturing of injectable medicinal products and third country inspections.

2.2.2. Over the past seven years, MMA's legislative remit expanded to encompass other regulatory and technical functions. The main driver of these changes, generally, related to the introduction of new EU requirements and updates to existing directives. This entailed the

transpositions of these provisions into national legislation. Moreover, national legislation was updated to incorporate developments within the local pharmaceutical sector. Table 1 shows the main legislative changes.

Table 1: Main legislative changes

EU/National legislation	New/amendment	Year introduced on a national level	Type of Legislation	2012	2019
				Activity	Activity
	Amendment	2013	Pharmacovigilance	174	614
	New	2015	Drug Dependence (Treatment not Imprisonment) Act	NIL	5,838
	New	2018	Production of Cannabis for Medicinal and Research purposes Act	NIL	
	Amendment	2020	Medical Devices	NIL	NIL

2.2.3. Table 1 clearly shows that over a number of years, MMA's legislative remit broadened in substance and scope. In turn, these changes triggered strategic developments relating to the Authority's organisation, operations and processes.

2.3 MMA's strategic development resulted in a steady increase of activity over time

2.3.1. The MMA's strategic developments were influenced by a number of drivers namely legislative changes and the national and international pharmaceutical industry, including technological as well as product developments. The period under review experienced three major strategic developments. A common trend within the three strategic phases is to ensure the quality, safety and efficacy of all medicinal products on the local market and to support availability and access to medicines.

Strategic developments were geared to transform MMA into a centre of excellence

2.3.2. The 2010 – 2012 strategy specifically aimed to provide information to users on medicines, increase awareness of the MMA's available resources and promote use of trusted sources of information. Moreover, it aimed to increase awareness, knowledge and trust in the medicines lifecycle and provide information on the regulation of medicines and pharmaceutical activities. It also aimed to inform, educate and empower healthcare professionals and consumers in the choice of medicines.

2.3.3. The 2013 – 2015 strategy particularly focused on access to medicines, patient protection, addressing public health needs as well as the sustainability, good governance and efficiency of the Authority. In addition, the strategy focused on the development of the Authority's capacity to cater for new and emerging sciences.

2.3.4. The 2016 – 2020 strategy sought to optimise the Authority's regulatory system, enable better informed users, further improve access to medicinal products and the Authority's support to innovation and development. The MMA emphasised these objectives through its vision to be a centre of excellence in advancing effective and innovative regulation and promoting quality and scientific rigour in the work it does. This implied that the Authority aimed to be the best in class regulator for the benefit of patients and stakeholders. Moreover, MMA endeavoured to be an internationally recognised efficient entity and promoter of people development and sustainable growth.

The Authority's workload and activities increased continuously over time

2.3.5. These three strategic development phases brought about an increasing workload and activities for the Authority. For practicality sake, despite its inherent limitations, Table 2 portrays a simplified overview of the Authority's output during the period under review. The information provided through this Table assumes that all activities require the same effort, time and resources. Whilst acknowledging this methodological limitation, it is reiterated that this Table is only intended to provide a general idea of the increase in the Authority's workload over time.

Table 2: MMA's annual output (2012 - 2019)[1]

Directorate	2012	2013	2014	2015	2016	2017	2018	2019
	Volumes	Volumes	Volumes	Volumes	Volumes	Volumes	Volumes	Volumes
Licensing	5,440	6,012	6,849	7,341	7,409	7,940	8,940	9,600
Inspectorate and Enforcement	317	417	401	335	471	458	514	537
Post-Licensing	174	233	235	264	355	421	497	614
Medicines Intelligence and Access	NIL	NIL	55	173	113	159	344	202
Office of the CEO - Coordination of meetings	Not Available [2]	132	209	191	308	426	733	754
Quality Management Systems	77	116	231	97	113	134	145	152
Advanced Scientific Initiatives	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	577	5,838
Scientific and Regulatory Operations	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	48	170

[1] This Table excludes the output of the Medical Device Support Office in 2019. The Malta Medicines Authority became the National Competent Authority for medical devices on 4 August 2020. Thus, the Authority was shadowing and actively participating but could not legally take responsibility for medical devices in 2019. Table 2 also excludes the workload of the administrative arm of the Authority.

[2] A new Chairperson was appointed in 2013. MMA does not have data pertaining to the activities held by the previous Office holder.

2.3.6. Unequivocally, Table 2 shows the increase in the Authority's workload and activities. To this end, the Authority's strategic documents recognised the need to support the increasing workload and activities by strengthening its technical and administrative branches. Moreover, subsequent strategic documents strengthened the Authority's independence by becoming a financially self-sustaining entity. The ensuing Section discusses how the Authority attained the strategic objectives in terms of pre-determined Key Performance Indicators (KPIs).

2.4 The Authority generally attained high scores with regards to pre-determined KPIs

2.4.1. The Authority's monitoring of its pre-determined KPIs assumes four main approaches. These include KPIs established in relation to the International Organisation for Standardisation (ISO) 9001, the Joint Audit Programme (JAP), the Benchmarking of European Medicines Agencies (BEMA) and a pharmacovigilance audit report to the European Commission. The monitoring of these KPIs covered the period 2012 to 2019. Given that the audit of these KPIs was undertaken by reputable entities and adopted the appropriate methodologies, the National Audit Office (NAO) accepted these results and did not perform further substantive testing.

2.4.2. Generally, the reports referred to in the preceding paragraph provide a positive assessment with respect to the Authority's performance. This is illustrated by the conclusion of the reports pertaining to each of the four entities reviewing the Authority's KPIs as indicated below.

2.4.3. In 2013, 2014 and 2017, the Standards and Metrology Institute Certification Services within the Malta Competition and Consumer Affairs Authority, assessed the MMA's Quality Management System (QMS) to verify its effectiveness and compliance to the requirements of standard ISO 9001, to the organisation's policies and to the legal requirements supporting the framework of the products and services provided.

2.4.4. The audit reports concluded that there was objective evidence showing that the MMA's QMS is implemented and maintained effectively and that the processes during the audits were found to be effective.

2.4.5. The audit reports did not identify any minor or major non-conformities. In 2013, the Institute only made two observations pertaining to, firstly, the review of the documents and records control system, and secondly, to a lack of follow-up on Online Customer survey. However, these were subsequently addressed by MMA.

2.4.6. In 2016, the MMA was audited by the Dutch Competent Authority. The overall conclusion of the inspectors was that the quality system of the Medicines Agency of Malta does meet the EU standards and that the relevant EU legislation has been implemented into national laws.

2.4.7. This Report looked at a number of components, which were sub-divided into further sub-components, and assessed whether the requirements were fulfilled, partially fulfilled or not completely fulfilled. In the majority of cases, the requirements were fulfilled. The few exceptions are portrayed in Table 3. It is to be noted that all concerns outlined below were adequately handled by the MMA, as the report in itself outlines.

Table 3: Outstanding issues and identification of areas for improvement

Indicator	Concern	Proposed corrective action
Indicator 24: A process for designation of inspectors exists	Inspectors' identity cards are not signed, do not have an expiry date and it is not indicated by who they are authorised	Inspectors' identity cards have now been updated with the recommendations
Indicator 32: A training programme for inspectors is established and records are maintained	Inspectors are not qualified for inspecting steriles, biologicals	MMA trained its inspectors on steriles in 2015-2017. To mitigate immediate need for steriles inspections the MMA renewed a contract with the Italian Competent Authority for such inspections
Indicator 36: A procedure details the requirements for pre-inspection activities, and is followed	Although it is common practice to request an updated Site Master File from the inspectee, this is not included in the Standard Operating Procedure (SOP)	Site Master File was actually being requested under SOP IN 005 on the conduct of inspections
Indicator 44: Critical stages and parameters of manufacturing processes are assessed	Observing inspector was unable to verify that a number of aspects were covered during inspection (requirements of the Marketing Authorisation or Clinical Trial Authorisation)	SOP to be updated to include that, as part of batch release review, inspection checks will also ascertain that certificates tally with the specifications of the marketing authorisations or Clinical Trials Authorisations for IMPs
Indicator 60: The regulatory authority has access to laboratories capable of conducting necessary analyses for the purpose of official testing	There is no frequency defined for auditing the MHRA contract lab by Malta	Onsite audit planned for 2017
SOP updated to include frequency of auditing at least once every five years or three years, depending on the type of lab		
Indicator 74: KPI for overall GMP regulatory compliance programme is established and available	KPIs defined for each inspector. However, targets have not always been set	KPIs were updated

Indicator	Concern	Proposed corrective action
Indicator 77: Quality audit plans and records are available	The traceability of the planning process of the internal audits should be improved	Processes with the highest risk will be audited more than once in 5 years. Processes with lowest risk will be audited once every 5 years. SOP updated to reflect this
Indicator 78: Management reviews ensure the performance of the quality management system on an annual basis	KPIs not considered to be Specific, Measurable, Achievable, Relevant, Time-Oriented (SMART)	Update carried out in the Management Review to clarify the Annual Management Review Reports should include SMART data analysis for KPIs. SOP updated

2.4.8. Additionally, MMA was also assessed as part of the Benchmarking Exercise of European Medicines Agencies (BEMA). The BEMA III and BEMA IV reports assessed the performance of the MMA against a number of KPIs, which are summarised in Table 4. The scores provided are average scores of the various sub-indicators listed under the main KPIs. Overall, it can be noted that the MMA registered an improvement in its performance over the years.

Table 4: BEMA III and BEMA IV

KPIs	BEMA III	BEMA IV
Strategy and planning (objectives, targets, resources, performance, management)	3.75	4.8
Leadership and culture	4	4.5
Stakeholders (communication, transparency, contribution to network and national health system, raising awareness on reporting)	3.8	4.2
Quality management (quality system, improvement, internal audits (not in BEMA III))	4.25	5
Risk management (risk management system, conflicts of interest)	3.8	4
Crisis management (agency infrastructure, staff, risks to public and animal health)	3.75	4.25
Human resources management (recruitment, learning, development)	4	4.5
Operations management (capacity, risked based regulation, assignment of regulatory work, timelines)	3.6	4
Information management (IT facilities, information resources, data transfers, protection of information (In BEMA III, under KPI 5))	3.3	4.125
Interfaces (management of interactions between disciplines, assessors and inspectors)	4.17	4
Scientific decision-making (quality and consistency of assessment, opinion-making by assessors and inspectors, decision-making by the Agency)	4.25	4
Impact/effectiveness of regulation (clinical trials, regulatory and scientific advice, authorisation, pharmacovigilance/safety decisions, inspections)	4.25	3.5
Pharmacovigilance (audits)	4.5	N/a
Inspection (system for risk-based GXP inspections)	4	Included in KPI 12

2.4.9. Finally, the MMA sent a number of reports to the European Commission on pharmacovigilance audits carried out by the Medicines Authority in Malta. The reports covered the following periods: 2013-2015, 2015-2017 and 2019. In these reports, the MMA did not report any critical or major findings.

2.5 Generally, the MMA increased its number of employees based on the prevailing workload

2.5.1. During the period 2012 to 2019, as referred to in Table 2, using a simplistic calculation method, the MMA doubled its workload, namely due to a broader scope and substance. Some Directorates / Units have even more than tripled their workload, while others were recently set up. Similarly, this Office noted that during the same period the MMA has also increased its workforce by nearly three times.

2.5.2. A correlation between the two variables shows that there is nearly a perfect relationship between the two – a co-efficient of 0.95. Further analyses of these two variables per Directorate and Unit show that generally, in all Directorates and Units, there is a positive relationship, with a correlation co-efficient equal or greater than 0.7. Only two exceptions resulted, but these results are deemed unreliable due to the limited number of events to be considered for the correlation exercise.

2.5.3. The aforementioned situation shows that MMA's Human Resources (HR) plan reflects the envisaged workload of the entity. The ensuing Chapters will delve in more detail regarding the Authority's HR plan and recruitment.

2.6 MMA is now a financially self-sustaining Authority

2.6.1. Up to 2014, MMA was still receiving a minor subvention ranging from €70,000 to €110,000 annually. As at end 2019, the Authority's audited financial statements showed a surplus of €1.1 million. This financial turnaround materialised despite the significant increase in the Authority's payroll. The main factors contributing to this surplus relate to a significant increase in revenue generated through increased activities over time. This has by far offset the payroll increases during the period under review. Table 5 refers.

Table 5: Audited income and expenditure of the Malta Medicines Authority

	2012	2019	Variance
Income			
Fees			
Licensing Activities - under national obligation	666,009	2,496,570	1,830,561
Licensing - Reference Member State Activities		808,378	808,378
Cooperation agreement with MEB		15,600	15,600
Scientific Advice (SAWP)		164,227	164,227
Inspectorate Activities - under national obligation	90,482	95,351	4,869
Inspectorate Overseas Inspections		374,719	374,719
Post-Licensing Activities excluding DHPCs	652	21,266	20,614
Post-Licensing Direct Healthcare Professional		18,400	18,400
Centralised Procedures		533,105	533,105
Advanced Scientific Initiatives - Cannabis		145,935	145,935
Advanced Scientific Initiatives - Research, Training & Innovation		109,479	109,479
Reference Member State Activities and Centralised Procedures	403,346		(403,346)
Pharmacies		37,028	37,028
Fines and Penalties	11,647	-	(11,647)
	1,172,136	**4,820,058**	**3,647,922**
			-
EMEA Linguistic Translations	**45,357**	**50,940**	**5,583**
Government Subvention	**110,000**	**-**	**(110,000)**
Other income	**50,000**	**715,262**	**665,262**
			-
TOTAL INCOME	**1,377,493**	**5,586,260**	**4,208,767**
	2012	**2019**	**Variance**
Expenses			
Staff Cost	1,144,764	3,401,163	2,256,399
Other Operating Expenses	278,252	785,925	507,673
Contractual Services	102,648	170,398	67,750
Administrative Expenses	45,990	94,662	48,672
Financial Expenses	607	9,843	9,236
Finance Cost	-	18,521	18,521
Total Expenses	**1,572,261**	**4,480,512**	**2,908,251**
Surplus / (Loss)	**(194,768)**	**1,105,748**	**1,300,516**

2.6.2. Table 5 shows that over the period under review, revenue increased threefold. This rise is mainly due to the fees collected by the Authority for services rendered. Mostly, this increase reflects the broadening of MMA's activities. In some cases, however, revenue was affected through the increase of chargeable fees. Examples in this regard relate to the annual maintenance fee for Malta being a Reference Member State and product authorisation fees in terms of Article 10(4) of Directive 2001/83/EC.

2.6.3. Over time, the substantial increase in the Authority's revenue has covered the significant rise in staff related costs. In accordance with the MMA's strategic framework, the managerial, technical and administrative staff complement increased by 52 persons. During the period under review, the average annual salary costs of the MMA increased from €30,917 to €36,851, denoting an increase of over 19 per cent.

2.6.4. Another significant expense which also seeks to fulfil the Authority's strategic direction relates to training. Moreover, training costs increased by almost 14 times from €9,139 in 2012 to €126,082 in 2019. During this period, the number of hours for professional development increased from 1,287 to 3,217.

2.7 Conclusions

2.7.1. Since 2012, the Malta Medicines Authority (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. This Chapter has shown that this remodelling exercise complied with the Authority's strategic directive and has placed MMA on a sound foundation to fulfil its vision as a centre of excellence. This transformation necessitated action at various levels, namely administrative, financial, as well as technical.

2.7.2. The Authority has increased its technical workforce threefold over the past years. This increase was also reflected in the significant increase on the Authority's activities. Furthermore, various technical audit reports confirmed that the Authority has high quality systems in place to ascertain a similarly qualitative output.

2.7.3. From a financial perspective, the Authority is now a self-sustaining entity. In part, this is due to the broadening and increase in the MMA's activities over time. In other cases, this was due to the revision of fees due. The foregoing confirms that the BPR exercise at the MMA generally embraced best practices in its implementation, particularly in circumstances where the Authority needed to strengthen its administrative and technical capacity.

2.7.4. The next Chapter discusses the Authority's business planning processes.

Chapter 3

Business Planning

3.1 Introduction

3.1.1. Malta Medicines Authority's (MMA's) operations are appropriately supported by annual business plans which outline the Authority's initiatives for the respective periods. Business planning, in terms of financial and human resources enable organisations to create their goals and outline the approaches that will be used to attain the predetermined targets.

3.1.2. In this regard, this Chapter discusses:

a. the annual business plans prepared by MMA; and
b. MMA's business plans in terms of the number of staff engaged by the Authority.

3.2 MMA prepares its business plans on a yearly basis

3.2.1. The MMA carries out a yearly business plan, outlining the Authority's projected revenues and expenditures. This exercise considers the MMA's strategy as well as the measures referred to in the annual national budget speech delivered by the Honourable Minister for Finance. In addition, MMA identifies the administrative processes that need to be simplified to reduce bureaucracy to improve the Authority's cost-effectiveness. To this end, the MMA prepares detailed documentation, including an implementation action plan, whereby a programme is compiled to outline the Authority's actions on a quarterly basis.

The business plans prepared by MMA are considered to be robust

3.2.2. This performance audit evaluated the robustness of the MMA's business planning against a set of criteria reflecting best practices. Table 6 refers.

Table 6: Evaluating the MMA's Business Plans against best practice criteria

Criteria	MMA's business plans
Executive Summary	Yes
Market Analysis	Yes
Company Description	Yes
Organisation and Management	Yes
Marketing and Sales Strategy	Yes
Service and/or Product Line	Yes
Funding requirements	Yes
Financial evaluation	Yes

3.2.3. The best practices criteria portrayed in Table 6, is self-explanatory and highlights the various inputs to comprehensive business planning. MMA generally fulfilled the best practices criteria in relation to its business planning. The business planning review focused on the period 2017 to 2019.

3.2.4. MMA uses the standard templates provided by Ministry responsible for Finance (MFIN) and Office of the Prime Minister (OPM) to present its annual business plans. The Authority's business plan documentation also highlights the person responsible for leading a specific project / measure. Hence, these plans instil a sense of ownership while at the same time increasing accountability for worked performed.

3.2.5. The business plan documentation, however, does not refer to the cost of specific measures as these are presented in an aggregated manner. To this end, the national budgetary measures, the simplification plans and the business plans do not highlight the cost of implementing a specific measure. Such circumstances prohibit comprehensive monitoring of financial performance of specific initiatives.

MMA is generating more profits than that anticipated by its business plans

3.2.6. MMA has been a self-financing authority since 2015. As already outlined, it carries out yearly business plans, highlighting its aggregated projected income and expenditure. An analysis of the projected aggregated budget against actual performance during the period 2017 to 2019, shows that there was always a positive variance between the two variables. Table 7 refers.

Table 7: Variance between projected and actual income as well as expenditure (2017 – 2019)

Year	Income			Expenditure			Surplus (Deficit)		
	Projected (€)	Actual (€)	Variance (€)	Projected (€)	Actual (€)	Variance (€)	Projected (€)	Actual (€)	Variance (€)
2017	3,038,673	3,914,162	875,489	3,116,996	2,557,701	(559,295)	(78,323)	1,356,461	1,434,784
2018	3,023,919	4,201,469	1,177,550	3,023,414	2,959,887	(63,527)	504	1,241,582	1,241,078
2019	4,124,814	5,586,260	1,461,446	4,105,538	4,480,512	374,974	19,276	1,105,748	1,086,472

3.2.7. Table 7 shows that MMA adopts a conservative approach when establishing its financial projections. The variance between income and expenditure shows that in three instances the Authority underestimated the annual surplus by more than €1 million.

3.2.8. Table 7 also shows that the new measures introduced in the business plans are being absorbed and/or rendering the necessary financial return. A case in point relates to the introduction of measures intended to reduce bureaucracy and increase administrative and operational efficiency. These measures are commonly known as 'simplification' measures.

3.3 Business plans are generally supported by HR plans

3.3.1. The MMA's business plans are generally supported by Human Resources (HR) plans. To this end, each of the five Directorates assesses its current HR capacity and project its personnel requirements for the forthcoming year. The Authority consolidates each Directorate's plan in one HR plan. The Authority's Human Resources Management Documentation is ISO 9001 certified.

3.3.2. MMA sought to maintain an up-to-date HR plan. To this end, during 2019, the Authority amended its HR plan four times. All revisions within the HR plan were endorsed by the Authority's Chairman.

3.3.3. A review of the 2019 plans revealed the following:

- During the course of the 2019 HR plan, MMA envisaged that it would need an additional 10 personnel more than projected in the original HR plan for that year. The original plan shows that MMA would be recruiting 30 employees.
- Nonetheless, the Authority only recruited 18 persons out of the 40 envisaged in the 2019 HR plan. Four of these persons were recruited to replace staff who terminated their employment with the Authority.
- In accordance with the Authority's internal policies, all recruitment carried out by MMA was subject to MFIN approval.
- MMA always had funds available to finance the additional recruitment.

3.3.4. MMA contends that the changes in the HR plan are due to, amongst others, changing circumstances in the pharmaceutical industry and increase in third country inspections. These factors require the Authority to modify its HR plan. Moreover, these factors provide an opportunity for the Authority to generate funds and sustain a self-financing Authority.

3.4 Conclusion

3.4.1. The MMA's business planning process is based on solid foundations since it caters comprehensively for both the Authority's finances and human resource requirements. Furthermore, Human Resource Management Documentation is not only subject to the Authority's internal policies but is also ISO 9001-certified.

3.4.2. Nonetheless, a review of the 2019 business planning process revealed that the Authority is adopting an over-prudent approach to its financial and HR projections. Within this context there was a positive variance of €1.1 million between projected and actual financial balances. In the same vein, HR recruitment did not match projected figures by 12 employees. This comment is not intended to diminish the best practices adopted by the Authority in its business planning process but merely to highlight that the opportunity exists for more accurate projections.

Chapter 4

Recruitment process

4.1 Introduction

4.1.1. The Malta Medicines Authority's (MMA's) recruitment process follows generally accepted practices. To this end, the Authority has its policies which outline the procedures to be adopted with regards to the recruitment of personnel. This assertion is based on a review of the 18 calls published in 2019 which resulted in the recruitment of 36 employees.

4.1.2. This Chapter discusses the extent to which the MMA adheres to its recruitment policies. The scope of this audit, however, did not extend to reviewing the interviewing boards' reports with the objective of verifying whether the person recruited was the best applicant for the post.

4.1.3. The discussion within this Chapter includes:

- The MMA's recruitment policy; and
- Compliance aspects relating to key phases of the recruitment process.

4.2 MMA's recruitment policy follows generally accepted practices

4.2.1. Since 2012, the Authority updated its recruitment policy three times. The changes mainly related to the publication of a new Public Sector Recruitment Manual, approvals relating to delegation of recruitments and changes in the line Ministry recruitment policy. The recruitment policy is endorsed by the Chairman/Chief Executive Officer (CEO) and all Directors employed by the Authority.

4.2.2. The policy identifies the principal roles and the following key stages within the recruitment process:

- **Needs Analysis** – Directors and Managers are responsible to provide input in the formulation of the Plan to cater for a fully flexible system.
- **MFIN clearance** – MMA seeks financial approval to recruit employees from MFIN.
- **Publication of the call for applications** – The call is advertised on the Medicines Authority website, in the Malta Government Gazette and in any other local newspaper as deemed necessary.
- **Selection process**:
  - A Selection Board is appointed which is composed of a minimum of three persons,

namely the chairperson of the board and two other members, one of whom is nominated by the line Permanent Secretary. Board members are to submit a declaration regarding any potential conflict of interest.

- The duties of the Selection Board are the following: declaration of eligibility of candidates, overseeing the recruitment process, preparing a comprehensive report which establishes the criteria and sub-criteria for the ranking of applicants and includes a schedule indicating the marks obtained by each candidate.

- **Publication of results** – once the Selection Board report is approved, the results are displayed on the official notice board of the Authority for a minimum period of 10 working days.

4.3 MMA fully complied with its own recruitment policy

4.3.1. This audit entailed determining the extent to which MMA complied with its recruitment policy. This review evaluated documentation maintained by the Authority with respect to the key stages of the recruitment process, as discussed in the preceding Section. This involved a two-tiered approach pertaining to the 11 internal and seven external calls of application. Firstly, MMA submitted a declaration relating to the availability of documentation as requested by the NAO. The second phase of this exercise included a physical review of this 2019 related documentation. Table 8 refers.

Table 8: Compliance testing of key recruitment stages with MMA's policy (2019)

Stage	Score out of 18 calls
Listed in the HR Plan?	18
Was the call approved by MFIN and / or line Ministry in view of funds availability?	18
Was a Selection Board appointed?	18
Was the call published?	18
Did the Selection Board submit a report based on the criteria established in the recruitment policy?	18
Were the results published?	18

4.3.2. Table 8 illustrates MMA's full compliance with its recruitment policies with respect to the key stages of this process. Appendix I explains in more detail the results of this review.

4.3.3. Upon NAO's enquiry, MMA confirmed that it has not received any complaints or contestations from applicants concerning the processes and the results about the 18 calls in 2019.

4.3.4. An issue elicited by this review relates to the abnormal length, by MMA's own standards, of the recruitment process. A case in point relates to the last call for application in 2019 related to the internal call for Head Medicines Intelligence and Access. The vacancy for

this call was published on 14 October 2019, with the interview being held on 30 June 2020. Results were published on 16 July 2020 and the date of commencement was 28 July 2020. On average, internal and external application in 2019 were completely processed in 62 and 132 days respectively.

4.4 Conclusion

4.4.1. MMA's recruitment process adheres to the Authority's policies which embrace generally accepted practices. This audit is generally satisfied with the Authority's recruitment procedures and processes. This statement is evidenced by the array of documentation maintained by the Authority. The only contention raised in this Chapter relates to the prolonged process concerning one of the 18 calls for applications which deviated from the Authority's own performance relating to the other calls.

Appendix I: Compliance testing of key recruitment stages with MMA's policy (2019)

Vacancy	Was this vacancy listed in the HR Plan? (Y/N)	Was the vacancy approved by MFIN and / or line Ministry in view of funds availability? (Y/N)	Was the vacancy published? (Y/N)	Was a selection board appointed (Y/N)	Did the selection board submit a report based on the criteria established in the recruitment policy (Y/N)	Were all the results published? (Y/N)
Junior Operations Support Workers	Yes	Yes	Yes	Yes	Yes	Yes
Medicines Inspectors	Yes	Yes	Yes	Yes	Yes	Yes
Senior Pharmacists	Yes (additional Headcount approval sought)	Yes	Yes	Yes	Yes	Yes
Junior Operations Support Workers	Yes	Yes	Yes	Yes	Yes	Yes
Senior Pharmacists	Yes (additional Headcount approval sought)	Yes	Yes	Yes	Yes	Yes
Documentation Officers	Yes	Yes	Yes	Yes	Yes	Yes
Pharmacists	Yes (additional Headcount approval sought)	Yes	Yes	Yes	Yes	Yes
Operations Support Worker	Yes	Yes	Yes	Yes	Yes	Yes
Manager (People Management)	Yes	Yes	Yes	Yes	Yes	Yes
Manager (Finance)	Yes	Yes	Yes	Yes	Yes	Yes
Manager (Administration and Procurement Affairs)	Yes	Yes	Yes	Yes	Yes	Yes
Head (Operations and Data Interpretation)	Yes	Yes	Yes	Yes	Yes	Yes
Head (Pharmacovigilance)	Yes	Yes	Yes	Yes	Yes	Yes
Case Executive	Yes	Yes	Yes	Yes	Yes	Yes
Pharmaceutical Officers	Yes	Yes	Yes	Yes	Yes	Yes
Head (Research, Scientific Affairs and Innovation)	Yes	Yes	Yes	Yes	Yes	Yes
Head (Educational Planning and Academic Development)	Yes	Yes	Yes	Yes	Yes	Yes
Head (Medicines Intelligence and Access)	Yes	Yes	Yes	Yes	Yes	Yes

2019-2020 (to date) Reports issued by NAO

NAO Work and Activities Report

April 2020	Annual Report and Financial Statements 2019

NAO Audit Reports

November 2019	Report by the Auditor General on the Workings of Local Government 2018
November 2019	Performance Audit: An analysis of issues concerning the Cooperative Movement in Malta
December 2019	Report by the Auditor General on the Public Accounts 2018
December 2019	An investigation of contracts awarded by the Ministry for Home Affairs and National Security to Infinite Fusion Technologies Ltd
January 2020	Performance Audit: Community Care for Older Persons
February 2020	Performance Audit: Assessing the Public Transport Contract and Transport Malta's visibility on the service
March 2020	Information Technology Audit: ICT across Local Councils
March 2020	The disposal of the site formerly occupied by the Institute of Tourism Studies
April 2020	A review of the ethical framework guiding public employees
April 2020	Addendum Investigation: The Mater Dei Hospital Project
May 2020	Performance Audit: Tackling Child Abuse
May 2020	Annual Report and Financial Statements of the National Audit Office 2019
June 2020	Follow-up Reports by the National Audit Office - 2020 Volume I
June 2020	Performance Audit: A Follow-Up on the 2016 Analysis on OHSA's Operations - A Case Study on the Construction Industry
July 2020	An audit of matters relating to the concession awarded to Vitals Global Healthcare by Government Part 1 - A review of the tender process.
July 2020	An audit of matters relating to the concession awarded to Vitals Global Healthcare by Government Part 1 | A review of the tender process - Addendum
October 2020	Follow-up Reports by the National Audit Office - 2020 Volume II
November 2020	IT Report: Planning Authority