THE LIFE SCIENCES LAW REVIEW

ELEVENTH EDITION

Editor
Peter Bogaert

THE LAWREVIEWS

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PREFACE

The eleventh edition of *The Life Sciences Law Review* covers a total of 24 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged so as to describe requirements throughout the life cycle of a regulated product, from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

The past year showed a transition from the covid-19 pandemic to more normal health conditions, but also an enhanced awareness of new challenges. During the two preceding years, manufacturers of healthcare products, together with healthcare professionals and services, focused on the development and testing of vaccines, other drugs, biologics, diagnostics and personal protective equipment. This was done on an expedited basis, and regulatory agencies have reviewed marketing applications with unprecedented speed and efficiency. Manufacturers and international organisations have also worked closely together in an effort to ensure equitable access to vaccines and other important healthcare products in low- and middle-income countries, but much work remains to be done. Regulators are now making preparations for later emergencies and are also drawing lessons from the experience gained during the pandemic for the development and assessment of new health products in important therapeutic areas. Efforts to support effective and equitable access to key products at a more international level also continue.

Given the constant challenges and quick developments, it is vitally important that lawyers who advise companies in the life sciences sector and the business executives whom they serve have a working knowledge of the regulations and policies that govern drugs, biologics and medical devices. It is equally important to keep up to date with developments in the regulatory systems that govern access to the market, pricing and reimbursement, advertising and promotion, and numerous other matters that are essential to success. It is our hope that this year's publication will be especially helpful in this respect.

All of the chapters have been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this publication.

Peter Bogaert
Covington & Burling LLP
Brussels
February 2023

Chapter 13

MALTA

Ian Gauci and Terence Cassar[1]

I INTRODUCTION

The life sciences sector has a strong historical presence in Malta, with the sector being a key pillar in Malta's economy. The production of generic pharmaceuticals is the most well-established sector within the overall local life sciences sector, mainly owing to Malta's broad application of the *Bolar* patent exemption, which, locally, is applied to effectively permit generic companies to establish themselves in Malta to conduct development work, conduct testing and go through the administrative application phase while the respective subject matter is still protected by a patent.

A considerable number of medical device manufacturers also have a presence in Malta, while health tourism is on the rise along with health-related technology suppliers.

The competent authorities for medicines in Malta are the Medicines Authority and the Licensing Authority, both headed by the Superintendent of Public Health. On the other hand, the competent authority for medical devices is the Medicines Authority together with the Malta Competition and Consumer Affairs Authority (MCCAA).

In terms of the legislative basis for oversight and enforcement, the Medicines Act (Cap 458 of the Laws of Malta) provides the main legislative basis with regard to medicines, while the Product Safety Act (Cap 427 of the Laws of Malta) provides the main legislative basis with regard to medical devices. As an EU Member State, EU-level legislation also applies in Malta.

II THE REGULATORY REGIME

i Classification

The Maltese regulatory regime distinguishes between medicines, medical devices and other regulated products.

Medicines are regulated under the Medicines Act and are classified as any substance or combination of substances that are presented as having properties for treating or preventing diseases in humans, or that may be used in or administered to humans with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis.

Medical devices are captured under the Product Safety Act, although the specific classification and regulatory treatment thereof depends on whether the medical devices fall under specific subsidiary legislation under the Product Safety Act, being mainly the Medical

1 Ian Gauci is a managing partner and Terence Cassar is a partner at GTG.

Devices Regulations (SL 427.44 of the Laws of Malta), the In-Vitro Diagnostic Medical Devices Regulations (SL 427.16 of the Laws of Malta) and the Active Implantable Medical Devices Regulations (SL 427.10 of the Laws of Malta). Certain types of software can be considered a medical device.

Similarly, general consumer products tend to be regulated via generic or specific legislation under the Product Safety Act, for example the Cosmetic Products Regulations (SL 427.58 of the Laws of Malta) with regard to cosmetic products.

Conversely, food is separately regulated under the Food Safety Act (Chapter 449 of the Laws of Malta).

Responsibility to classify 'borderline products' lies with the Borderline Classification Committee, within the Medicines Authority.

ii Non-clinical studies

The Animal Welfare Act (Chapter 439 of the Laws of Malta) regulates medical testing or experiments on animals with good laboratory practices requirements deriving from EU Directives being transposed into Maltese Law mainly via Legal Notice 371 of 2004.

In Malta, it is unlawful to carry out an animal experiment unless the way in which the experiment is to be conducted has been determined by a person whose qualifications satisfy the requirements under the Animal Welfare Act.

Animal experiments cannot be carried out:

a for a purpose that may be achieved by means other than animal experiments, or by means of an experiment using fewer animals or entailing less distress than the experiment in question;

b for a purpose the importance of which does not justify animal distress; or

c for such purposes as may be prescribed.

Animal experiments need to be carried out using animals bred in a licensed breeding establishment with a view to their use in experiments.

iii Clinical trials

Clinical trials on humans are regulated by the Clinical Trials Regulations (SL 458.43 of the Laws of Malta), which transposes Directive 2001/20/EC into Maltese law.

The legislation safeguards the testing of medical products from an ethical perspective, and an ethics committee is set up, which oversees the trials on aspects such as protocol, the suitability of staff, regulations of clinical trials on minors and other areas. This legislation also sets out regulations for the conduct of a trial, contingency plans in case of adverse or serious adverse reactions and other provisions.

Conversely, the well-being of the (human) trial subjects is ensured by the Good Clinical Practice and Requirements Regulations (SL 458.47 of the Laws of Malta), which enforce good practice and procedures that are to be adopted during the trial.

The Medicines Authority has also issued guidelines outlining how a clinical trial ought to proceed.

iv Named-patient and compassionate use procedures

Medicinal products marketed in Malta must hold a marketing authorisation to be placed in the Maltese market, either issued by the Maltese Medicines Authority or issued by the European Commission.

National marketing authorisations are issued by the Licensing Authority in terms of the Medicines (Marketing Authorisation) Regulations (SL 458.34 of the Laws of Malta).

During the covid-19 pandemic, conditional marketing authorisation was given to emerging covid-19 vaccines (based on the guidelines of the European Medicines Agency) given the time-restrained circumstances.

With regard to the distribution of medical devices, an authorised representative anywhere in the EU is required to place medical devices on the Maltese market, in line with relevant placing on the market rules at EU level for medical devices. The Medical Device Unit within the Malta Medicines Authority carries out the registration of local economic operators, carries out the listing of medical devices placed on the local market and operates a reporting system for medical device-related incident reports.

v Pre-market clearance

A marketing authorisation is required in Malta to be able to place medical products on the Maltese market. An entity wishing to apply for a marketing authorisation can do so through one of four procedures provided for at EU level, namely: parallel importation, the centralised procedure, European procedures and national procedures.

With regard to national procedures, an application for a marketing authorisation must be submitted to the Licensing Authority that meets the requirements and standards as set out in the Medicines (Marketing Authorisation) Regulations (SL 458.34). These include but are not limited to:

a the verification of good manufacturing practice by the company;
b a valid document outlining the risk–benefit balance of the product; and
c a brief description of the company's pharmacovigilance system.

Other legislation that the market authorisation must comply with includes the Medicinal Products (Labelling and Packaging) Regulations (SL 458.33), the Pharmacovigilance Regulations (SL 458.35) and the Wholesale Distribution of Medicinal Product Regulations (SL 458.37).

With regard to medical devices, the Medical Device Unit within the Medicines Authority manages a registration to place medical devices, with conformity assessments from a conformity assessment body being required, among other things. Specific local legislation is also relevant, particularly the Medical Devices and In-Vitro Diagnostic Medical Devices Provision on the Maltese Market Regulations (SL 458.59).

vi Regulatory incentives

Malta's regulatory incentives in the life sciences sector tend to be well known in the industry, principally as Malta applies one of the broadest interpretations and applications of the *Bolar* exemption to patent protection, which has resulted in Malta becoming a jurisdiction of choice for various generic pharmaceutical companies.

In Malta, patent holders cannot stop third parties who are using the patented subject matter for purely experimental or scientific research, or when the act is done for purposes related to the development and presentation of information regarding the production, use or sale of medicinal or pharmaceutical products. This effectively means, in practice, that generic pharmaceutical companies can conduct all research and development work and testing and go through the respective administrative marketing authorisation phase while a third-party patent is in force.

Key regulatory incentives in Malta also include an efficient taxation regime for life sciences operators, whereby, apart from a generically applicable net effective corporate tax rate of 5 per cent that typically applies, a tax exemption for certain royalties derived from qualifying intellectual property is in place along with a patent box regime that provides for a deduction in relation to qualifying income derived from qualifying intellectual property.

Furthermore, patent term extensions are effectively possible through supplementary protection certificates obtained from the local Maltese IP office. These serve as an extension to a patent right and apply to pharmaceutical or plant protection products that are authorised by the respective authorities, and aim to offset the lost time in patent protection term (which has a local maximum term of 20 years) resulting from the compulsory lengthy testing and clinical trials that such products need to undergo prior to obtaining regulatory approvals. A special protection certificate can extend a patent right for a maximum period of five years.

vii Post-approval controls

A marketing authorisation holder is granted a marketing authorisation for five years from approval; however, the marketing authorisation is subject to revocation by the Licensing Authority should the product not abide by the regulations as originally set in the marketing authorisation, such as having a harmful risk–benefit balance or the product being harmful to consumers.

An application can be submitted to renew a marketing authorisation and must be completed at least three months before the authorisation expires. The renewal evaluation includes submission of reports for quality, safety and efficacy of the product, periodical safety updates, evaluation of data on suspected adverse reactions (if any) and details of pharmacovigilance. The holder must also provide information on all variations (if any) of the product released, ranging from the date of the marketing authorisation approval until nine months prior to its expiry.

Transfer of ownership of the marketing authorisation holder requires the approval of the Medicines Authority.

viii Manufacturing controls

Manufacturing plants and facilities are required to possess a Category E permit (the industrial use permit) authorised by the Maltese Planning Authority as per the Development Planning (Use Classes) Order (SL 552.13). Medicine manufacturing plants must also adhere to the Good Manufacturing Practice in Respect of Medicinal Products and Active Substances for Human Use Regulations (SL 458.42), which transposes EU Directives 2017/1572 and 2011/62/EU into Maltese Law.

A specialised manufacturing licence is issued by the Licensing Authority to permit the manufacturing, assembly and modification of any medicinal products. To apply for such a licence, the manufacturer must provide the name of the medicinal products, any evidence ensuring that the manufacturing facility is adequate for producing the respective medicinal products, a list of the equipment and control facilities to be used and the necessary pharmaceutical forms, along with other information such as the name and address and other details of the manufacturers and the manufacturing sites to be used.

ix Advertising and promotion

The advertising and promotion of medicinal products in Malta is regulated by the Medicinal Products (Advertising) Regulations (SL 458.32). This law sets out clear rules for the general advertising of medicinal products, such as that the purpose of advertising medicinal products should be to promote and encourage the product but to not mislead the consumer about the benefits or properties of the product.

The medicinal product being advertised needs to hold a valid marketing authorisation. Furthermore, the Medicinal Products (Advertising) Regulations set out rules that exclude certain materials from advertising and any prescription medicines as they cannot be sold over the counter.

No substances that fall under the First Schedule to the Dangerous Drugs Ordinance (Cap 101 of the Laws of Malta) and the Third Schedule to the Medical and Kindred Professions Ordinance (Cap 31 of the Laws of Malta) may be advertised or distributed, with the exception of vaccination campaigns approved by the Licensing Authority.

Local broadcasting legislation, specifically the Requirements as to Standards and Practice on Programmes Involving the Participation of Certain Health Professionals in the Broadcasting Media and Requirements as to Advertisements, Methods of Advertising and Directions Applicable to Medicinal Products and Treatment (SL 350.30), restricts greatly the use of healthcare professionals in broadcasting medicinal advertisements by ensuring careful consideration of the legal and ethical implications that this would have.

There are currently limited if any dedicated laws regarding the advertisement of medical devices, but generic advertising rules on consumer products would apply.

x Distributors and wholesalers

The distribution and wholesale of medicinal products is regulated by the Wholesale Distribution and Brokering of Medicinal Products and Active Substances Regulations (SL 458.37). The seller of the medicinal product in question is required to possess a licence authorised by the Licensing Authority to be able to import or export the product. To apply for such a licence, the medicinal product needs to already hold a marketing authorisation.

The registration for a distribution and wholesale licence needs to include details such as the basic personal information of the seller applying for the licence (such as the corporate name, address, etc.), the active substances to be distributed, and a brief description of the premises housing the active substances and the technical equipment used for the distribution (importing or exporting) of the product.

The Licensing Authority may hold inspections of the distribution premises to ascertain that the seller of the medicinal product is adhering to the conditions imposed by their licence. A breach of the conditions may give reason for the Licensing Authority to revoke the licence.

On the other hand, the distribution of medical devices tends to be generically regulated under the Product Safety Act as well as relevant EU legislation.

xi Classification of products

The criteria as to whether a medicinal product is prescription-only or may be sold over the counter are whether the products:

a are likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision;

b are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health;

c contain substances or preparations, the activity and any adverse reactions of which require further investigation; or
d are normally prescribed by a doctor to be administered parenterally.

Medicinal products are classified as requiring a prescription or otherwise as part of the marketing authorisation process in terms of the Medicines (Marketing Authorisation) Regulations.

All medicines may be found on the Medicines Authority's Medicines Database, with prescription medicines being listed as 'POM' (meaning 'prescription-only medicines') while non-prescription medicines are listed as 'OTC' (meaning 'over the counter').

Prescription medicines are then further classified into the following subcategories:
a medicinal products on medical prescription for renewable or non-renewable delivery;
b medicinal products subject to special medical prescription; and
c medicinal products on 'restricted' medical prescription, reserved for use in certain specialised areas.

xii Imports and exports

Importation and exportation of medicinal products is regulated by the Manufacture and Importation of Medicinal Products for Human Use Regulations (SL 458.36).

An importation licence is required to import medicinal products into Malta, which may be issued by the Medicines Authority based upon correct documentation, adequate premises for manufacturing or importing the medicinal product, and other factors.

The Customs Authority along with the Commissioner for Revenue and the Licensing Authority have the discretion to impose any further specific ad hoc importation rules that may be necessary on a case-by-case basis. Fares, duties and tariffs related to importation are regulated by the Import Duties Act (Cap 337 of the Laws of Malta).

There is a special parallel import licence that can be applied for to grant importation from a Member State of the EU or of the European Economic Area (EEA). This is regulated by the Parallel Importation of Medicinal Products Law (SL 458.40).

Generic import and export control rules apply with regard to medical devices.

xiii Controlled substances

Controlled substances such as narcotics and psychotropics are mainly regulated by the Dangerous Drugs Ordinance (Cap 101 of the Laws of Malta) as well as the Medical and Kindred Professions Ordinance (Cap 31 of the Laws of Malta).

Any importation, exportation or commercial sale of controlled substances requires approval by the Chief Government Medical Officer.

xiv Enforcement

Various ad hoc penalties and offences apply under the Medicines Act, without prejudice to liability under other laws, depending on the specific violation of the Act.

In certain cases, a special procedure may apply where, notwithstanding any other law providing for the trial of offences, a special procedure may be adopted whereby the Licensing Authority gives notice in writing to such offending person, describing the offence of which the person is accused, indicating the steps to be taken to remedy the offence and the penalty that he or she is required to pay in respect of that offence.

The Medicines Act grants the right of entry to authorised officers by the Licensing Authority (in writing) to carry out random or repeated inspections at any premises to

establish whether a contravention occurred or is to occur against any provision of the Act. These officers may inspect any substance, medicinal product, machinery and other related items in the production of medicinal products as well as any records and related documents of the marketing authorisation holder. The authorised officers may also take photos and samples to be tested by the Licensing Authority.

Violation of the provisions of the Medicines Act may also lead to criminal proceedings under the Criminal Code.

Enforcement with regard to medical devices is regulated generically in terms of consumer product legislation. However, the Medical Devices and In-Vitro Diagnostic Medical Devices Provision on the Maltese Market Regulations also provide for a specific contravention for devices falling thereunder whereby a fine of not less than €12,000 and not exceeding €120,000 or imprisonment for a term not exceeding two years, or both, applies.

III PRICING AND REIMBURSEMENT

There is no generic law in Malta that regulates the pricing of products on the Maltese market, including of medical devices. Medicines are, however, an exception as their prices are adjusted and balanced by the MCCAA together with the Medicines Authority, which jointly negotiate with importers to settle on fixed prices for the products. The pricing is also determined by referring to the pricing used by EU and EEA states.

The Directorate for Pharmaceutical Affairs is tasked with ensuring the fair pricing of government-dispensed medicinal products. The pricing for marketing authorisation holders to place their products within the Government Health Services is controlled by the Availability of Medicinal Products Within the Government Health Services Regulations (SL 458.31). External pricing is then used as reference when reimbursing medicines in the Government Health Services.

When sold, the pricing of any product, including medicines and medical devices, must abide by the Consumer Affairs Act (Price Indication) Regulations (SL 378.09).

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

A Medicines Review Board is established under the Medicines Act to hear appeals filed by applicants for a marketing authorisation regarding any decision taken by the Medicines Authority on the safety, efficacy, quality and other factors of the medicinal product of the applicant.

Decisions of the Medicines Review Board are subject to a right for appeal in the Court of Appeal. The appeal must be made on a point of law, as a Judicial Review of an Administrative Action. Where criminal charges are involved, the case is then taken to the Criminal Court. Once decided, the case can also be appealed in the Court of Criminal Appeal.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYERS

The pricing of medicinal products is fixed and agreed upon by the MCCAA along with the companies that import, export and market the medicines. It is prohibited for prices of medicines to be altered unless this is approved by the MCCAA and the Medicines Authority.

Bribery is a crime in Malta under the Criminal Code (Chapter 9 of the Laws of Malta) in a generic fashion; thus, no company or person may bribe healthcare professionals for an unfair advantage on the market, such as false exaggerated advertising of a product.

The Public Administration Act (Chapter 595 of the Laws of Malta) further provides that a gift can be accepted if it is a 'token in nature', as it could otherwise be constituted as an act of bribery.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

A person who infringes the Medicines Act is liable to dedicated liability under the Medicines Act, and this without prejudice to any other liability under any other law. The dedicated liability applicable depends on the type of violation and can comprise fines of up to €116,468 or two years' imprisonment, or both.

With regard to medical devices, these are subject to the generic consumer liability rules deriving from the Consumer Affairs Act. Liability without fault is provided for; therefore, while the injured consumer would need to prove the damage, defect and causal relationship between the defect and the damage, the injured person does not need to prove the negligence or fault of the producer or importer in such consumer cases.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

There are no competition rules that are specific to the life sciences sector in terms of the Competition Act (Chapter 379 of the Laws of Malta), nor any enforcement actions to date that are particularly noteworthy.

ii Transactional issues

The transfer of ownership of a marketing authorisation holder requires the approval of the Medicines Authority. Further, foreign direct investment approval from Malta's National Office for Foreign Direct Investment Screening may be required in transactions involving non-EU persons or entities.

VIII CURRENT DEVELOPMENTS

Current developments in the Maltese life sciences sector mainly revolve around the regulation of cannabis.

In 2018, Malta enacted the Production of Cannabis for Medicinal and Research Purposes Act, which provides legislative measures that allow the production of cannabis for medicinal and research purposes. This law was followed by an amendment to the Drug Dependence Act, which allowed the prescribing of medical preparations of cannabis.

An ad hoc licensing process for the manufacture of medical cannabis was created, and this manufacturing is becoming a nascent industry in Malta.

Furthermore, in 2021 the Authority for the Responsible Use of Cannabis (Chapter 628 of the Laws of Malta) established an authority bearing the same name along with the concept of cannabis associations being not-for-profit associations from where cannabis can be purchased by a member.

Changes to the law introduced in 2021 effectively legalise the private consumption, carrying and private and personal growing of cannabis (up to certain limits) for recreational purposes, with Malta becoming the first EU Member State to do so.

Despite the legislative changes catering for such developments being in place for some time locally, to date no licences have been issued to cannabis associations by the Authority for the Responsible Use of Cannabis, and it is reported that the Authority is still working on establishing the details of the regulatory framework and monitoring system for when applications are available.

Appendix 1

ABOUT THE AUTHORS

IAN GAUCI

GTG

Dr Ian Gauci is the managing partner of GTG and oversees the business development of the firm, as well the technology, media and telecommunications practice and the legal futures, innovation, life sciences and legal-tech sectors. He has over 20 years of legal experience and is considered a local legal market leader.

Dr Ian Gauci has advised various companies in the pharma and medical device industries, particularly on the overlap between health and technology. Dr Gauci has also been active in advising on intellectual property and regulatory matters and in advising entities tendering their services to the Maltese government in relation to the 'Pharmacy of Your Choice' schemes and in advising manufacturers of medical cannabis looking to relocate to Malta. He is particularly focused on the application of distributed ledger technology to the health sector and has been key in authoring of legislation in respect of distributed ledger technology.

Dr Gauci has been key adviser on various local legislation and co-authored, among others, the Maltese Electronic Communications Framework and the Maltese Digital Innovation Laws, and lectured on legal futures and technology at the University of Malta.

He is also a regular international speaker on legal matters and contributor to various legal publications.

TERENCE CASSAR

GTG

Dr Terence Cassar is the partner responsible for the intellectual property, data protection and privacy, technology, media and telecommunications practices within the firm.

In the life sciences sector, Dr Cassar provides representation and advice particularly to businesses operating in the pharma, biotech, medtech, healthtech, medical cannabis and medical device and consumer products industries. He mainly focuses on regulatory matters and clearances, pharma and medical device regulation, intellectual property litigation, registration, franchising and licensing, data protection compliance and litigation as well as commercial transactions and deals.

He has advised on the establishment and operation of various health-related software suppliers, online pharmacies, manufacturers of medical devices and technology, as well as pharma manufacturers, distributors and IP companies and is particularly known for having led multiple high-profile mergers and acquisitions as well as for having negotiated and advised on major transactions and licensing deals.

Dr Cassar was admitted to the Maltese Bar in 2016 and holds a doctor of laws from the University of Malta and an LLM in internet law and policy from the University of Strathclyde. He is also a visiting lecturer and examiner at the University of Malta.

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