

## Well-Qualified Human Resources are readily available for this growing industry

### Human resource competencies

Malta already enjoys a reputation for high standards of education at all levels. Over 10,000 students now attend the University and include some 450 pharmacy and chemistry undergraduates. Both are 5-year courses and need no adjustments to be recognised qualifications throughout the EU. Analytical Chemistry and Industrial Pharmacy modules are being incorporated to address the needs of the expanding healthcare industry. A post-graduate University course for Qualified Person (QP) is shortly due to be launched. The Malta College of Arts, Science and Technology (MCAST), in collaboration with the industry and the Malta Laboratories Association, has introduced a Higher National Diploma (HND) course for Laboratory Technicians. The Employment and Training Corporation (ETC) runs evening and day release courses for assistant laboratory technicians and a course for chemical operators specifically for unemployed youths. All courses are, and will be, enhanced by lectures delivered where appropriate by specialists employed in the industry.

Malta's salaries and wages are not as low as in some of the new EU member states. However, fluency in English, high quality reliable and flexible workmanship and social costs contained at 10% of gross wages more than compensate for the wage differentials.

## Additional Infrastructure Support for the Industry

- Production premises to each company's specific requirements are made readily available. These are designed, constructed and located in a controlled environment thus enabling occupants to easily acquire a GMP licence as well as approval from the FDA, the MHRA and other regulatory authorities;
- High quality, competitively priced local suppliers of fine chemicals as well as plastic, carton and blister packaging;
- Malta has well-equipped and professionally staffed Laboratory facilities for outsourced testing services;
- Unlimited water services can be made available to desired quality standards;
- Waste management services are regular and efficient;
- Excellent air as well as sea passenger and freight connections within Central European time zone.



## Malta's EU Membership brings added benefits to the Pharma Industry

GMP audits conducted by the Malta Medicines' Regulatory Unit are acceptable throughout the EU. The industry will benefit from harmonisation of Summary of Product Characteristics (SmPCs) between EU countries so that a common SmPC exists for all generic applications, and also benefit from the Mutual Recognition Procedures for bioequivalence studies.

Moreover Malta has adopted the inward processing relief (IPR) procedure on imports. IPR provides relief from duties in order to promote exports from the European Community thus assisting community processors to compete on an equal footing in the world market. Duty is relieved on imports on non-EC goods, which are processed in the Community and re-exported. Processing can be anything from re-packing or sorting goods to the most complicated manufacturing. Relief can also be obtained on IPR goods received from another approved trader in Malta or another Member State. Official Journal of the European Community under Council Regulation (EEC) No. 2913/92

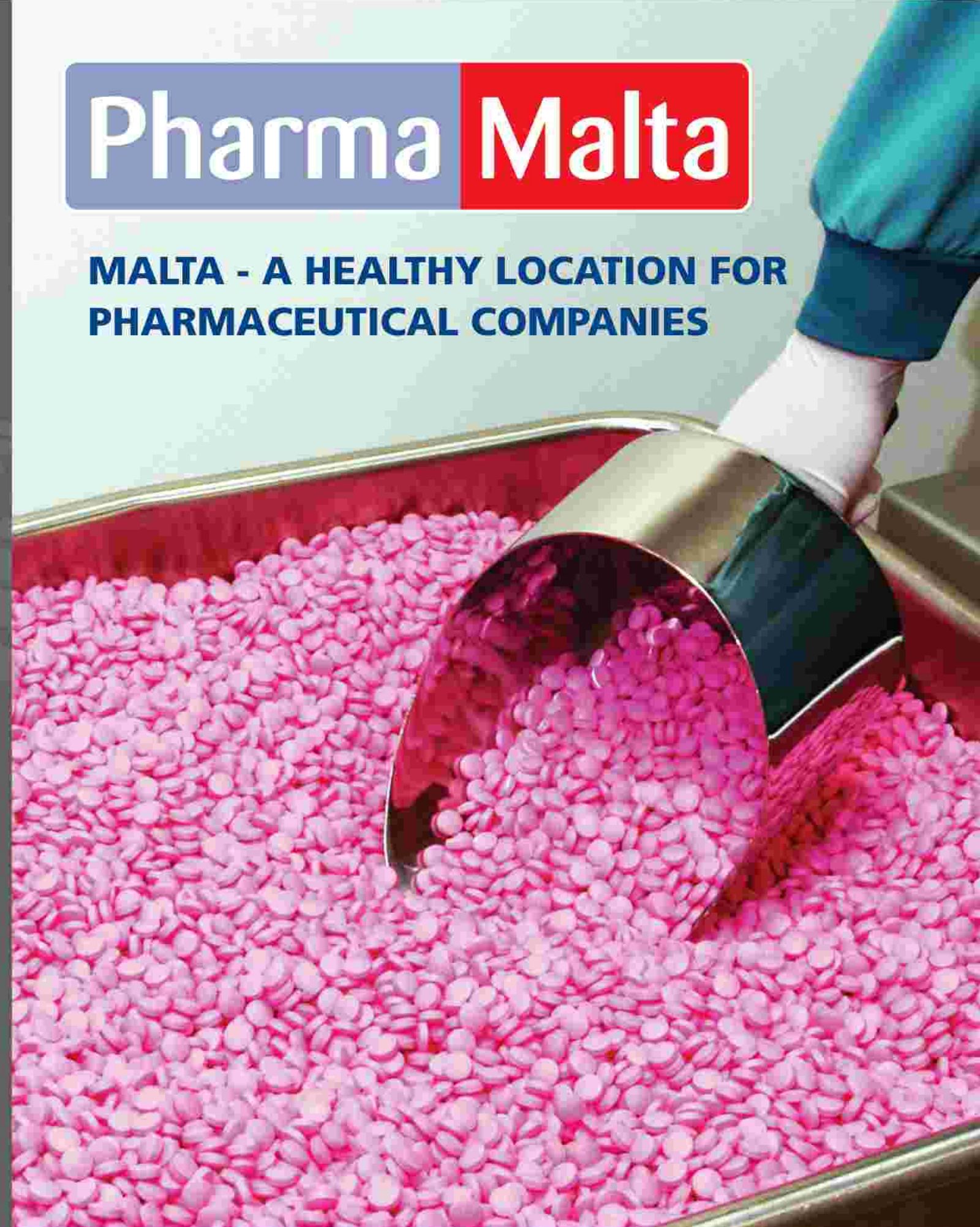
Locate to Malta and you can rely on a Malta Enterprise support team, well versed in the industry, providing all the necessary assistance to ensure ease of start-up and profitability thereafter.



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# Pharma Malta

## MALTA - A HEALTHY LOCATION FOR PHARMACEUTICAL COMPANIES



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The fastest growing industrial sector in Malta is the manufacture and assembly of generic pharmaceuticals

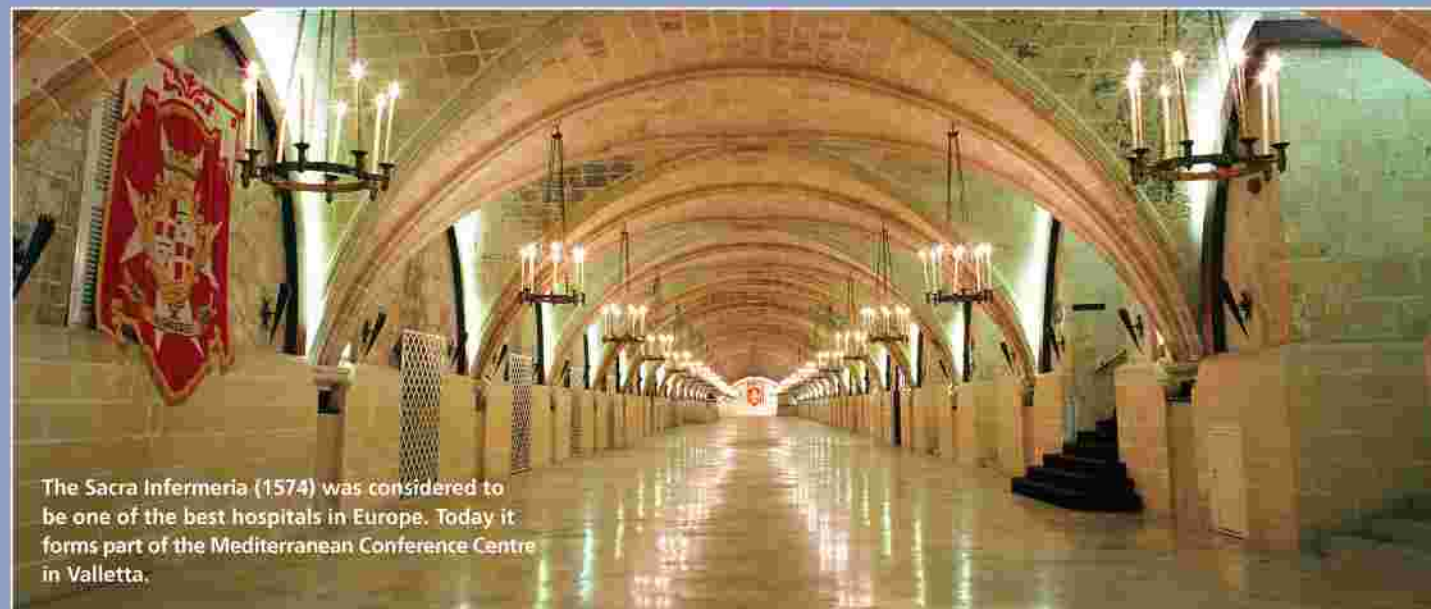
Malta's Patents legislation dates back to the 1960's and protects the interests of proprietors of a patent against third parties. (CAP. 417 of the Laws of Malta). The insignificant size of the domestic market, however has resulted in the registration of comparably few patents. Generic pharmaceutical manufacturers may therefore develop and produce in Malta a large number of medicines for launch on EU and other markets upon expiry of the patent protecting the innovative drug elsewhere. Since the novelty criteria allows no more than one year from the date of first filing to protect an innovation, the vast majority of patented medicines, medicinal ingredients and production processes will not have had their patents registered in Malta. The prohibition of retroactive patent registration provides a long-term window of opportunity benefiting generic pharmaceutical manufacturing companies locating in Malta. In this highly competitive industry, timing bestows a crucial advantage.

Malta's Patents and Designs legislation also incorporates the "Bolar" provisions which clearly define the circumstances in which the proprietors of a patent still have no right to prevent third parties from performing those acts which are otherwise protected under the Patent legislation.

The Malta Medicines Act of 2003 stipulates only a six-year data protection period from the date that the originator drug is first marketed.

European Union entry has served to further consolidate Malta's position by enabling generic pharmaceutical manufacturers operating on the island to easily promote their medicines on North African markets where there are established trading routes for onward delivery particularly to the Sub-Sahara region. Market authorisation granted by a regulatory authority in a EU member state should suffice to ensure market penetration to this continent, and to the fast growing markets in South America.

The growth of the industry would have been hampered had not the Government taken the initiative to ensure that the supporting infrastructure develops in tandem. Most significantly, from tertiary level downwards the educational system is adapting to the needs of the expanding sector. Additionally, with the status of English as Malta's second official language, local Maltese personnel are more than capable of easily handling scientific document writing and laboratory reports to the standards required by the industry. Annual labour costs at the technical and professional level average Euro 11,000 and Euro 18,000 respectively.



The Sacra Infermeria (1574) was considered to be one of the best hospitals in Europe. Today it forms part of the Mediterranean Conference Centre in Valletta.

## Malta's long tradition in this sector

Malta's reputation as a centre for healthcare dates back to 1574 when the Sacra Infermeria started to function under the Knights of St. John providing 900 beds for male patients - crusade soldiers. In 1676 a school of anatomy and surgery was set up in the same building. The British, who assumed Malta's governance in 1800, renamed the infirmary "Station Hospital", and used it as such until the end of the First World War. Indeed Malta's 200-year association with Great Britain enhanced the islands' distinct competencies in the healthcare sector. Today Malta's medical services rank amongst the best in Europe.

The Medical School within the University of Malta is one of the oldest within the Commonwealth. More than 500 students graduate every year in the medical, pharmaceutical and related fields. Many continue for further studies abroad, a significant proportion of whom have excelled and are now renowned as world-class specialists in their field. Currently the number of medical practitioners registered in Malta is around 1,150.



The newly built 'Mater Dei' Hospital 2004. Improved facilities for more than 800 beds and state-of-the-art equipment offer patients the very best in hospital care.



The Business Promotion Act ([www.maltaenterprise.com](http://www.maltaenterprise.com)) classifies this sector as one of priority for the country, thus enabling companies to qualify for the full package of incentives available. These include:

- Reduced rates of income tax (as low as 5%) on company's profits.
- Tax credits up to 50% on all qualifying expenditure on investments of a capital nature.
- Provision of industrial buildings finished to pharma requirements at competitive rates of rent.
- Low interest (less than 2%) loan financing.
- Loan guarantees.
- Financial assistance for training of employees up to 80% of costs involved.