

Newsletter 13

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Welcome note

Dear Readers

Welcome to the 13th issue of our Newsletter where we present our associates in Barbados, the Manager of our Microbiology Department and our product Fungifex. We continue our report on new European Union legislation on the marking of pharmaceutical products; we define the term Active Pharmaceutical Ingredient and report on the condition Multiple Sclerosis. In our Corporate Social Responsibility section the main focus is on activities to support Multiple Sclerosis sufferers and in Our News we have a number of interesting items but we also sadly report the untimely loss of two former colleagues. Finally, we take a glimpse at the beautiful town of Polis Chrysochous together with its tourist suburb Latchi.



Charalambos Pattihiis,
Group Managing Director

Remedica worldwide

SBI DISTRIBUTION INC., Barbados



SBI Distribution Inc. part of the BS&T, Neal & Massy Group, is a modern import distribution company that provides 100% nationwide distribution of dry food, general merchandise, health & beauty care products, pharmaceuticals, wines & spirits, produce, chilled and frozen foods and agricultural chemicals to a variety of customers.

SBI has a total storage capacity of 17,000 square meters, the largest in the island. The company employs 290 staff and has annual sales in excess of \$183 Million (BDS) or US\$91.5 Million.

The SBI Distribution fleet includes 8 delivery trucks, 10 van sales vehicles and 8 containers, supplemented by contracts with 32 independent truckers. The pharmaceutical department is one of the youngest in the company only having been established 7 years ago. The department has seven dedicated staff and average annual sales are US\$4.5 million which represents 15% - 20% of total company turnover.

Barbados is an island in the North Atlantic Ocean, northeast of Venezuela with 431 km² total land area. The island has an estimated population of 286,705 people, with around 80,000 living in or around Bridgetown, the largest city and the country's capital. Barbados has been an independent country since 30 November 1966. It functions as a constitutional monarchy and parliamentary democracy, modeled on the British Westminster system, with Elizabeth II, Queen of Barbados, as head of state represented locally by the Governor-General, Clifford Husbands and the Prime Minister Freundel Stuart as the head of the government.

Remedica is a significant business partner to SBI having been one of the first companies to allow SBI exclusive rights to distribute its pharmaceutical products on the island. SBI's strong business relationships across the English speaking Caribbean allows it to export to all the neighbouring islands making full use of its main competitive advantages which are the use of technology, swift delivery, solid financial support and customer service.

SBI Distribution Inc. has invested heavily in many aspects of the business including a Warehouse Management System (WMS), Monitoring and Evaluation Software, Server Software and Hardware, Electronic Order Processing and many other systems.

Remedica and SBI are confident about the future based on their excellent and fruitful cooperation to date, as well as on the unique expertise that SBI offer, allowing them to service the markets of the wider geographical area with great efficiency. ■



Remedica people

In this edition we wish to introduce the Head of the Microbiology section, Mr Manasith Pithak.

Manasith Pithak, the Head of the Microbiology Section of Remedica's Quality Control Department was born in Laos and in 1986 went to Germany to study. He completed a PhD in Microbiology at the Friedrich Schiller University in Jena (Germany) where he also met his future wife. After their marriage they moved to Cyprus and in 1999 he was granted Cypriot citizenship. They now have two young children.

Manasith joined Remedica as an analyst in the microbiology laboratory in 1996 and by the year 2000 had been promoted to Head of the Microbiology Section.

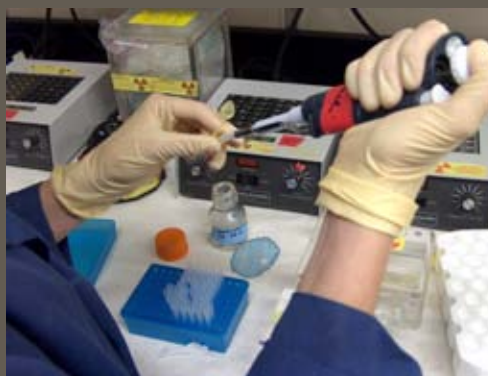
Over years he has attended seminars in Cyprus and abroad regarding Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Water Systems, Environmental Monitoring and other aspects of microbiological analysis related to the pharmaceutical industry. ■



The ABC of Pharmacy:

Active Pharmaceutical Ingredient

The component in a medicinal product which produces a pharmacological response used to be known as the drug: sadly it became popular to use this term to describe illicit substances which were abused. In the world of medicinal products the term has been replaced by the more acceptable, active pharmaceutical ingredient (API). The properties of the API had to be included in the application for the licence for a medicinal product but if this API was purchased from another manufacturer then the latter could hold a



file which had been approved by the relevant licensing authority and this file would be referenced in the application. It used to be known as the Drug Master File (DMF): once again, in order to avoid the use of the term drug it is now known as the Active Substance Master File (ASMF).

Throughout the world there are many companies that specialise in the manufacture of chemicals who produce APIs and so, for example, many of the paracetamol tablets which are marketed will contain an API made by the same chemical manufacturer. Although the products which are produced by each pharmaceutical manufacturer will be packaged differently they have to be subjected to stringent tests which ensure that each product will have the same therapeutic effect. ■

Our Products-Fungifex 250mg Tablets

Fungifex 250 tablets contain the antifungal compound Terbinafine Hydrochloride. Terbinafine is an allylamine which exhibits a broad spectrum of antifungal activity. At low concentrations Terbinafine is fungicidal against dermatophytes, moulds and some dimorphic fungi.

The primary site of action of terbinafine is the fungal membrane where it works by interfering specifically with sterol biosynthesis resulting in fungal death. Terbinafine also acts by inhibiting squalene epoxide in the fungal cell membrane. When given orally, the drug concentrates in the skin at sufficiently high levels to exert fungicidal activity.

Fungifex 250 is indicated for the treatment of:-

- Infections of the skin and nails caused by *Trichophyton sp*, *Microsporum canis* and *Epidermophyton floccosum*.
- Ringworm (*tinea corporis*, *tinea cruris* and *tinea pedis*) where oral therapy is considered appropriate due to the site, severity or extent of the infection.
- Onychomycosis.

Ringworm is a fungal infection of the skin, scalp or nails and Terbinafine has been shown to be more effective than Griseofulvin in its treatment.

Onychomycosis is a common fungal infection of the nail that can be caused by dermatophytes, non-dermatophyte moulds and yeasts. Terbinafine is the most frequently prescribed oral antifungal agent for such conditions and its efficacy and safety in

dermatophyte toenail onychomycosis in adults has been established in many studies. Additionally terbinafine has been reported to be superior to both itraconazole and fluconazole in comparative studies in the treatment of dermatophyte toenail onychomycosis.

Terbinafine has also been used to treat onychomycosis effectively and safely in special patient populations such as children, the elderly and diabetics. ■



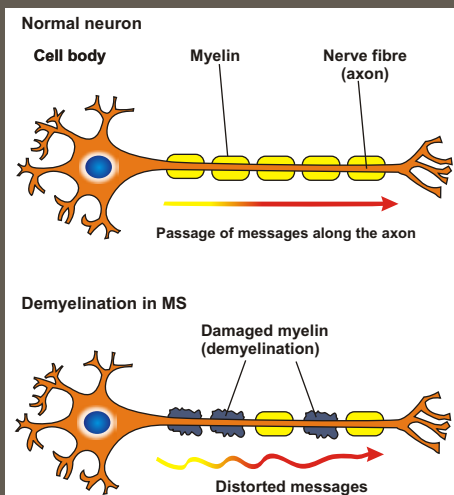
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Health matters: Multiple Sclerosis

Multiple sclerosis (MS) was first recognised in 1868 by Jean-Martin Charcot and usually occurs in young adults among which it is the most common disease of the central nervous system (CNS). The occurrence is more frequent in females and it has been estimated that there are 1.2 million sufferers worldwide.

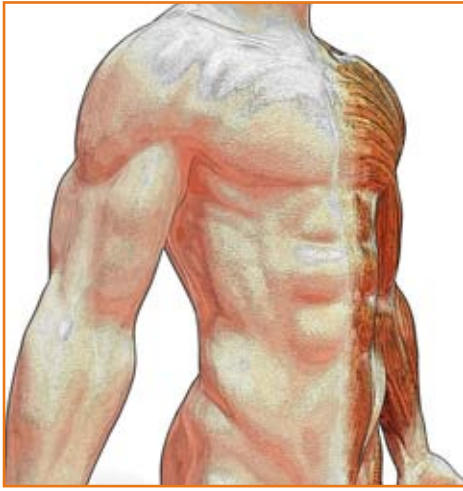
The cause of this chronic inflammatory disease is damage to the fatty sheath of myelin surrounding the nerve cells (neurons which contain axons (nerve fibres)) of the brain and spinal cord which comprise the central nervous system. The myelin sheath forms an insulating layer rather like the plastic coating of electrical cable and when this is damaged (usually referred to as demyelination) then the electrical signals are disrupted so communication between the brain and other parts of the body such as muscles is disturbed. Because the extent and the degree of scarring (the term sclerosis means hardening) can affect any part of the CNS then the symptoms which present can vary from patient to patient. Since a certain degree of repair can occur



in the early stages then relapses are common and can, paradoxically, make the diagnosis more difficult. There are three different subtypes of the disease which have been identified. These can vary from patients experiencing long periods of being symptom free (remission) with short periods (hours to days) when the symptoms appear: about 80% of sufferers have this form of the disease for which the long term prognosis is good although it may be worse for those who develop symptoms later in life.

In about half of these patients, MS may develop into a progressive form of the disease when the periods of remission become shorter and the severity of the symptoms increases.

Although the changes can occur at any time, a period of between 5 and 20 years is not uncommon. About 15% of sufferers may have the primary progressive form of the disease where there is no remission following display of the initial symptoms which gradually and continually worsen.



Almost any neurological symptom can be indicative on MS: these include lack of sensation or tingling, muscle weakness and spasticity, inability to maintain balance or coordinate movements and loss of sight. Memory loss and mood changes can also occur. The prognosis of the disease depends upon its type, the age and gender of the patient and the severity of the symptoms. Most are expected to survive for about 30 years after diagnosis which means that the life expectancy of a patient with MS is only 5-10 years less than non-sufferers.

Since it is believed that MS is an autoimmune disease (the body literally fails to recognise its own cells and therefore attacks them) for which there is no known cure, the main treatment involves the use of immunosuppressive agents. Steroids such as methylprednisolone in high doses can be used to treat acute attacks. Relapsing, remitting MS can be treated with interferons (β -1a and β -1b), mitoxantrone, glatiramer and natalizumab. All suffer from the disadvantage that they have to be administered by injection and a small improvement on disability and a reduction in relapses are the best results that can be expected. Examples of other agents that have been used but have been found to be ineffective are cyclophosphamide and cladribine.

Palliative care in response to symptoms is an important aspect of treatment and this burden often falls on family and friends. An interesting development is the recent approval of a cannabinoid-containing oral spray for the relief of spasticity in MS.

There are several organisations worldwide that raise funds and offer advice and support to sufferers. Remedica Ltd is one such organisation and is the official sponsor of the Cyprus Multiple Sclerosis Association, even though the company has no specific medicines that can be used in MS. Within this context, Remedica takes part in various charity and fund-raising events, press conferences and TV shows aiming to enhance public awareness as well as making a considerable financial contribution to the Association. ■



Corporate Social Responsibility Remedica cares

1) In the context of Remedica's support to people with substance-dependencies, the company donated computers to the rehabilitation scheme "Ayia Skepi" in Cyprus.

(photo 1)

This is a small community, whose inhabitants have a common programme of activities and interests who are in need of help to become free of their drug addiction. The computers were presented to a representative of the community by Remedica's Human Resources Manager, Mr. Martinos Demosthenous.

2) Multiple Sclerosis Activities: (photo 2, 3, 4, 5)

In 2010 Remedica celebrated its 50th anniversary and laid the foundations for the official sponsorship of the Cyprus Multiple Sclerosis Association and a multifaceted cooperation with its members. As Remedica's support for the Association has brought positive results, the company's social contribution was continued for another year aiming for greater awareness and education of both the public and MS patients on

this condition but also towards the financial aid of the Association and subsequently its members. Remedica Volunteers, a group formed to contribute in various ways towards the creation of a better, more sensitive society that cares about its fellow human beings, was present in this whole effort. In the context of events held to mark the World MS Day, the following took place:

(a) Press Conference, attended by the Ministers of Labour & Social Security, and Communication & Works, the Director General of the Ministry of Health, the President of the Cyprus Multiple Sclerosis Association and Remedica's Marketing Manager. All speakers stressed the need for employers to support MS patients so that they may continue to actively contribute in the productive sector. This year a lot of emphasis was given to the issue of employment of MS patients whilst the slogan of the World MS Federation was "Employers make small and inexpensive modifications to the work place. Keep MS patients active."



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(b) Charity tea with a cultural part and auction of art works donated by established artists as well as personal effects of Cyprus politicians. The event was under the auspices of the Cyprus President's wife Mrs. Elsi Christofia and was attended also by Members of Parliament, volunteers, friends and members of the Cyprus MS Association.

3) "International Year of Chemistry - 2011".

As part of the activities by the Chemistry Department of the Cyprus University to support 2011 being nominated "International Year of Chemistry", it organised a public event on the 6th April where Mrs. Maria Roussou, Remedica's Quality Control Manager, gave a presentation to pupils of more than 150 local schools on Quality Control Laboratories and the prospects of cooperation between chemists and the pharmaceutical industry.



4) As part of its support to non-profit organisations, Remedica purchased for all its staff Easter Candles from 3 different associations: the Day Centre for People with Special Needs (Prosvasi), the Theotokos Foundation and the Cyprus Association of Cancer Patients and Friends.



5) "Cyprus University Careers Day". (photo 6)

Mrs. Maria Roussou and Mr. Martinos Demosthenous, Remedica's Quality Control Manager and Human Resources Manager respectively, attended the "Cyprus University Careers Day" during which students had the opportunity to be informed by the company representatives about employment opportunities, benefits and career prospects at Remedica, as well as on post-graduate courses that are suited to the pharmaceutical industry.

6) Earth hour:

In an attempt to contribute to world action for the reduction of climatic change, Remedica reminded its staff to switch off all lights at home for an hour on the 28th March. This is a symbolic indication to world leaders that ordinary people care about the environment and especially about the potential catastrophic consequences of climatic changes.



7) As part of Remedica's social role in the promotion of educational activities in schools, it organised visits to its premises by pupils from the St. Neophyte Lyceum (Paphos), The Kykkou Lyceum (Paphos) and the American Academy of Limassol. (photo 7, 8)



8) Pan-Cyprian "door-to-door collection" by the local Red Cross: (photo 9)

This annual charity collection was held in order to raise funds for the various programmes and missions of the Cyprus Red Cross, both locally and abroad. Once again, Remedica contributed to these efforts by offering financial aid. ■

Remedica News

1) Women's day at Remedica Ltd. (photo 1)

Remedica's management recognises the valuable contribution of its female employees towards the company's success and the important role of working wife / mother that many have to balance in order to pursue a career. In recognition of these achievements, the company posted colour advertisements in the local press featuring its female managers thus sending out the message that Remedica not only offers equal opportunities for advancement to women but the management but also takes pride in their achievements and career advancement.



2) Remedica participates in the 5th International Limassol-GSO Marathon. (photo 2)

Remedica participated in the 5th Limassol International Marathon GSO held on the 20th February with a corporate entry (a new venture for this year) and contributed to the raising of a substantial sum of money that will be distributed to a range of charities. Remedica's volunteers also helped man several posts along the way. In total 1625 runners took to the starting line and thousands more either took part in the pupils' event, the charity march or attended as enthusiastic spectators. Among them were about one thousand overseas visitors who came to Cyprus specifically for this event. Apart from its charity goals, the event aims to promote the spirit of sport, active social participation and volunteerism.



3) 5% VAT on pharmaceuticals. (photo 3)

As of the 10th January, Remedica is obliged to charge 5% VAT on the sale of its pharmaceutical products in Cyprus following the implementation of an EU Directive into local law. The law naturally covers all pharmaceutical products on sale in Cyprus irrespective of country of origin or manufacturing company.



4) During the 7th IMH annual conference on Sales and Customer Service, Remedica's Marketing Manager, Mr. Andreas Hadjipanayis presented the company's Key Account Management (KAM). (photo 4)

Remedica's contribution as a leader in KAM and Customer Relationship Management (CRM) was particularly significant as it was the only pharmaceutical company that made such a presentation in this conference. The event was attended by Managerial and other key personnel from sales, marketing, CRM managers, business analysts, strategic planners, account managers, from all the sectors of the Cyprus economy.



5) One of our longest-serving colleagues, Mrs Christa Vasiliadou retired recently after 20 years of service. (photo 5)

A farewell party was held in her honour at the company canteen where she was presented with an honorary plaque. We wish her all the best and many well-deserved years of happy and healthy retirement.



Obituaries

1) Mr. Dinos Kittis, formerly a non-executive director of Remedica has died at the age of 73 in a hospital where he was recently taken after suffering serious health problems. Mr. Kittis was also Finance Minister in 1985 and Minister of Commerce & Industry in 1980. In addition to his Directorship at Remedica, Mr. Kittis also served as President of the Cyprus Tourism Organisation and President of the Cyprus Association of Directors.

2) Alexandra Perikleous, who had retired from Remedica some years ago, having served with the company for 23 years, died at the age of 65. ■

Regulations: Vignette sticker

In this issue we continue our report on new European Union legislation with regards to EUROPEAN PACK CODING GUIDELINES and specifically Article 62 of EUROPEAN *DIRECTIVE 2001/83/EC* on CODIFICATION AND TRACEABILITY ON PACKING AND LABELS FOR MEDICINAL PRODUCTS FOR HUMAN USE by examining the requirement for a vignette also known as bollini.

This takes the form of a label (sticker) that must be affixed to the secondary package in order to provide information for health systems. The vignette has to be a double layered white sticker with two stubs, in other words it is actually two or more copies of two or more separate labels on the same carrier.

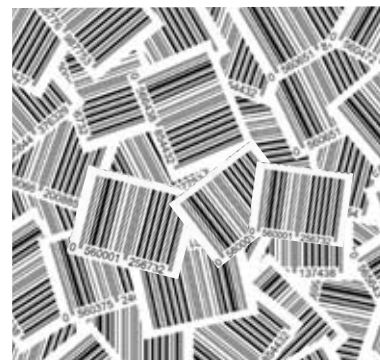
The top one contains a bar code made of 22 numbers that includes the EAN 7 code. An EAN 13 code is written with human-readable digits just below the barcode.

Each vignette will carry a unique serial number and adheres to the specification where this field is a variable length (up to 20 digits) alphanumeric field followed by a Group Separator GS character (to delimit it from the next field unless it is the last field). This serial number will be unique to the product code so that each serial number "range" will be unique to each product code type. (i.e. not per batch or per product code-batch). The alphanumeric range will include the digits 0-9 inc. and the letters of the western alphabet less the letters l, j, i, o, q and u. The letters are case-insensitive and no use of character accents etc. is allowed. This gives a range of 30 different alphanumeric character-options that can be used if required. Some countries have already requested that a serial number for each pack be included in addition to the national product code.

The size of the vignette will be in accordance with country-specific requirements and has to be defined. The text on the vignette will be in a font and size that are in accordance with country-specific requirements or GS1 recommendations depending on local requirements.

The pre-printed vignette sticker used for reimbursements should contain the reimbursement rate and the price as well.

Some countries have imposed special requirements like the printing of the vignette by the state authorities, reporting of how many have been used and which serial numbers, whether any have been damaged in which case their serial numbers have to be reported on special forms and any that have not been used have to be returned to the authorities. ■



Eco-friendly tips: House thermal insulation

Household energy loss is considered to be a major factor of the European Union's efforts to achieve reductions in energy consumption and to protect the environment. According to the European Action Plan for Energy Efficiency, the biggest energy savings are to be made in residential and commercial buildings with saving potentials at 27% and 30% respectively which would not only help to achieve these goals but reduce household costs whilst at the same time protecting the environment from unwanted greenhouse gases and air pollutants.

At the household level the reduction of heating losses can be achieved by implementing a number of home improvements in households which are inefficient. The plans of the residence should be examined and reviewed in order to identify all walls between air-conditioned and unconditioned spaces. If walls are identified as not being constructed from insulated materials, bulk wall insulation should be installed wherever this is feasible. In addition foam sheathing should also be installed in order to reduce heat loss from non-insulated walls. Furthermore windows should be replaced with double glazed ones in order to reduce the heat transfer through them.

Draughts are a major source of heat loss so air leaks through small openings around doors and window frames should be sealed. In addition air leaks could occur at openings or cracks at the point where two walls meet, or where the wall meets the ceiling. The bathroom is another place where air leaks are likely to be present and gaps in bathroom lofts and openings behind bath tubs or shower units should be sealed. Furthermore gaps around electrical outlets and switch boxes and plumbing connections should be also sealed. It should be noted that the air escaping through gaps will also carry moisture which has the potential to rot the walls or wooden fixtures.

In the case of households with gardens, deciduous trees should be planted in front of the house. In that way during the summer the tree will shade the house whilst in the winter when the tree would shed its leaves any sunshine may heat the property. In this way the household would be naturally warmed during the wintertime and be kept cool in the summertime without any cost. ■



A glimpse of Cyprus: Polis Chrysochous & Latchi

Polis, which in Greek means town, is one of the most beautiful areas of Cyprus and includes romantic sites, amongst them the one where, according to Greek mythology, Aphrodite, goddess of love and beauty, used to meet her lover Adonis. Polis is situated in the northwest of Cyprus, near the Akamas Peninsula with its renowned Baths of Aphrodite.

Polis Chrysochous Municipality was founded in 1882 and it is therefore one of the most ancient in Cyprus: it is the centre of the area which comprises 23 communities and has 3,500 inhabitants. Polis was known as Marion in ancient times and was one of the city-kingdoms founded by the Myceneans when they came to Cyprus. The kingdom was rich in gold and copper ore, mined chiefly in the Limni mines.

The whole Polis area has been bountifully blessed by nature and combines the beauties of mountain, sea and plain. Its seas are clean and warm, with extensive sandy beaches. The climate is healthy with mild winters and cool summer nights. The area is especially suited to people with special interests and enjoy participating in activities when on holiday. Polis is a perfect refuge for mental and physical relaxation and recreation. Those wishing to escape the stress and routine of daily life will find an ideal place to take rest and relaxation, in an environment of unparalleled beauty. It is a favourite spot for discerning visitors in search of a quality holiday in a friendly, sociable environment. The two beaches of Polis Chrysochous, the Municipal Beach located on the southwest of the town and the camping site on the west have been awarded European Blue Flags so, not surprisingly, both beaches are

very clean and provide a high standard of safety and security.

Latchi is one of the oldest ports in Cyprus, and was where travellers from Greece and other countries used to land in Cyprus in ancient times. Later, they used the port for the exportation of carobs and remains of the old carob warehouses are still visible although most of them have been converted into restaurants and fish taverns. Latchi port has been used by fisherman for many years and it is still famous for its fresh fish. The planned extension and embellishment of the existing port is now complete, and it is a centre of attraction all the year round. The development and upgrade of Latchi Harbour has provided modern facilities for boats for which there are 200 berths. The area surrounding the harbour has also been developed to make it more attractive with the addition of cycle ways, improved car parking, walkways and public conveniences. There are also plans to create a maritime / sea life museum utilising the currently disused store rooms formerly used by the Navy.

The seaside walkway has been extended from the municipal park at the beach as far as the camping site. This project, which was started after many years of red tape, includes lighting and seating and is one of the most pleasurable amenities in the area, promoting the environmental aspects of the locality to tourists and providing a pleasant area for exercise and relaxation. The walkway includes seating at strategic points with green oasis areas for the public to enjoy the beautiful scenery and unforgettable sunsets making the walk from Latchi to the Camping site a

memorable experience for everyone.

The area is ideal for sports enthusiasts, and cycling and hiking are a great ways to keep fit and explore the region. With warm crystal-clear seas, Polis is perfect for water sports such as paragliding, jet skiing, water skiing, banana boat riding and canoeing. Windsurfing, sailing and deep-water fishing can be enjoyed all the year round thanks to the gentle winds and mild weather.

The sandy beaches of Lara on the Akamas west coast are some of the last remaining Mediterranean nesting grounds for the green and loggerhead turtles, whose numbers have been markedly increased thanks to a successful conservation project on this site.

The Ayios Andronicos park, which is in the central area of Polis, adds a green area to the backdrop of the parade. In the park there are seating areas and historical and ecclesiastical monuments. The park is designed to offer a haven of peace in what is otherwise a busy part of the town where it is hoped that inhabitants and visitors will be encouraged to take time for thought or maybe read a book in quiet and lush surroundings.

The Polis area relies upon visitors for its economic survival and all the developments have borne this factor in mind. It has many places where visitors can stay and an excellent range of places to eat. A range of cultural entertainments and other events are organised throughout the year to supplement the extensive sports facilities of the area. ■

