Remedica
FOR A HEALTHIER WORLD

Newsletter 26

Contents

Welcome note

Welcome to the 26th issue of our Newsletter where we present our associates in Antigua & Barbuda, our Financial Manager and our product Finarem®.

Under Environmental Issues we report on the problem of acid rain and in the ABC of Pharmacy we continue with a description of the European Medicines Agency. In Corporate Social Responsibility we give details of our donation to the people of Serbia who have been severely affected by floods, the awarding of the Pattihis Family Scholarship 2014-2015, the support of Telethon 2014, the sponsorship of the Paddling for Children fund-raiser and the students' awards.

In Remedica News we announce the selection of Remedica as a "National Champion" in The European Business Awards, and its approval by the Japan Health Authorities. This section also reveals that the leading business publication of Cyprus, "IN BUSINESS" magazine, has published an article in which Remedica is referred to as a "titan" of Cyprus industry and the issue also includes an interview with Remedica's Managing Director, Mr. Emilios Savvides. In addition the visit by India's High Commissioner in Cyprus to Remedica is reported.

Finally, we take a glimpse at the ancient world of Cyprus.

Remedica Worldwide:

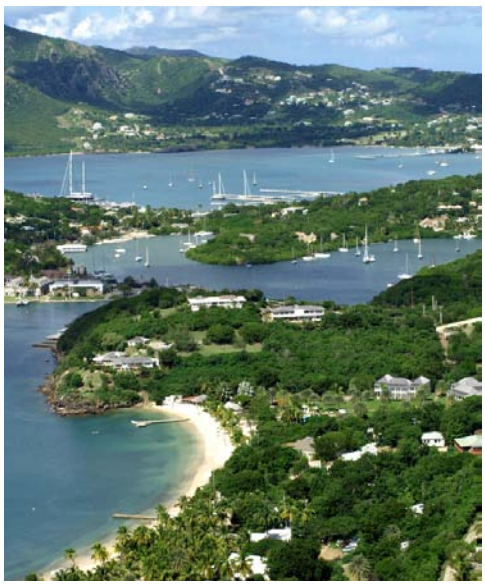
CARIBBEAN PHARMACEUTICALS SUPPLIES LTD. (Antigua & Barbuda)

Caribbean Pharmaceutical Supplies Ltd. is located on the Caribbean twin island state of Antigua & Barbuda which has a combined landmass of 170 sq. miles and a tropical climate all year round. The population is predominantly of African descent (95%), while other ethnic groups make up the remaining 5% of the population which presently stands at approximately 89,000. The official language is English and the system of government is based on a parliamentary democracy; Antigua & Barbuda is an independent sovereign state within the British Commonwealth. The official currency is the East Caribbean Dollar, which is shared with other members of the East Caribbean Currency Union, is pegged to the US dollar at EC $2.7169 = US $ 1.00. GDP (2010 est.) $ 1.433 billion/Per Capita GDP (2010) $16,500. Antigua & Barbuda's main industry is tourism, which accounts for more than 75% of the country's foreign exchange.

Caribbean Pharmaceutical Supplies Ltd. was established in 1986. Although the company's core business is primarily ethical and over-the-counter pharmaceuticals it is supported by a wide range of health and beauty aid products which the company offers to its clients.

Caribbean Pharmaceutical Supplies' mission is "to contribute to the improved health of our society: utilizing the most affordable and efficient information systems to deliver quality healthcare products and customer service to our customers, a good working environment and competitive compensation for our employees and a reasonable return on investment to our shareholders; within a framework of sound ethical standards"

The company's overall vision is "to become the leading pharmaceutical distributor in the Leeward Islands; providing our customers with high quality products, at reasonable prices and on a timely



basis". The Leeward Islands include St. Kitts and Nevis, Montserrat, Dominica, St. Lucia, Grenada and St. Vincent.

To realize this vision all employees of Caribbean Pharmaceutical Supplies are considered sales persons, however the company has two dedicated sales representatives who make the daily sales calls to the various distribution channels such as Pharmacies, Supermarkets, Doctor's offices and Hospitals. In addition the company employs a registered Pharmacist to advise on technical issues. The company has an overall staff complement of twelve.

Caribbean Pharmaceutical Supplies prides itself on being partnered with Remedica since 1999. This partnership has grown from strength to strength over the years and as such the pharmaceuticals supplied by Remedica are well respected for their quality within the local market.

While Antigua and Barbuda does not have a pharmaceutical manufacturing industry, the pharmaceutical market offers many opportunities even though it is very competitive. To date the national health scheme known as The Medical Benefits Scheme has been the biggest client for the Remedica product lines and this is mainly due to the fact that the government provides 90% of the health care. In spite of this, the company has aggressively built relations with private pharmacy outlets to ensure that there is a permanent presence of Remedica products throughout the private market. ■

Our Products: Finarem®

1mg, film coated tablets

Finarem® film coated tablets contain the active substance finasteride which belongs to the class of testosterone-5-alpha reductase inhibitors.

The product is indicated for the treatment of men with male pattern hair loss (androgenetic alopecia) to increase hair growth and prevent further hair loss.
Finarem® is **not** indicated for use in women or children and adolescents.

Finasteride inhibits the process responsible for miniaturisation of the scalp hair follicles and by this means can lead to reversal of the balding process.

Finasteride is a competitive and specific inhibitor of type II 5α-reductase. It has no affinity for the androgen receptor and has no androgenic, anti-androgenic, oestrogenic, anti-oestrogenic, or progestational effects. Inhibition of this enzyme blocks the peripheral conversion of testosterone to the androgen DHT, resulting in significant decreases in serum and tissue DHT concentrations. Finasteride produces a rapid reduction in serum DHT concentration, producing significant suppression within 24 hours of commencement of therapy.

Hair follicles contain type II 5α-reductase. In men with male pattern hair loss, the hair follicles become miniaturised in the balding scalp and DHT levels rise. Administration of finasteride decreases scalp and serum DHT concentrations in this condition. Interestingly, men with a genetic deficiency of type II 5α-reductase do not suffer from male pattern hair loss.

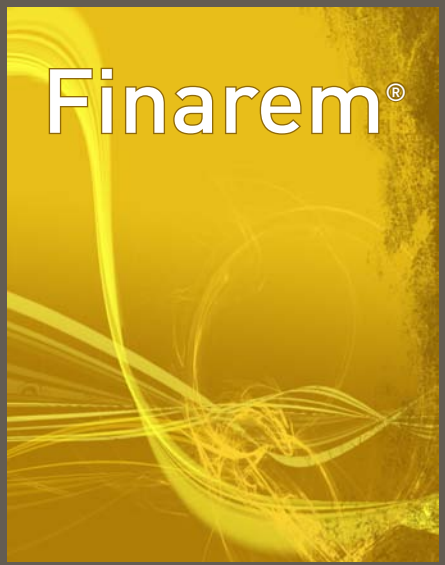
The recommended dosage is one 1mg tablet daily which may be taken with or without food. Perhaps unfortunately there is no evidence that increasing the dose produces an increase in effect.

Efficacy and duration of treatment should continuously be assessed by the treating physician. Generally, three to six months of once daily treatment are required before evidence of stabilisation of hair loss can be expected. Continuous use is recommended to sustain benefit. If treatment is stopped, the beneficial effects begin to reverse by six months and return to baseline by 9 to 12 months.

No dosage adjustment is required in patients with renal insufficiency.

Finarem® is available as 1mg Film-Coated Tablets.

References:
Summary of Product Characteristics of Finarem® Tablets. ■



Remedica News

1) Remedica: one of Europe's leading companies. (photo 1)
Remedica has been selected as a "National Champion" in The European Business Awards; a prestigious competition supported by businesses leaders, academics, media and political representatives from across Europe. Specifically, the company now moves into the next phase of the competition which will produce the top 100 companies in Europe, with Remedica pursuing the Import / Export Award. This award recognises organisations that can demonstrate a continuously positive trend in the export/import or re-export of goods, the expansion of coverage in existing or new markets and, through the introduction of creative and innovative operational processes, show robustness in managing and developing international trade and maintaining and improving market position in the face of competition. The European Business Awards, now in its 8th year, is engaged with over 24,000 businesses from 33 European countries this year and 709 companies from across Europe have been selected for the next phase.

2) Remedica approved by Japan Health Authorities. (photo 2)
Remedica has recently passed a GMP inspection from the health authorities of Japan (PMDA) which opens the way for the company to enter this market. The inspectors carried out a thorough inspection of Remedica's new oncology factory as well as its entire quality system and concluded that the company is in compliance with the standards of Good Manufacturing Practice (GMP) as enforced by the Japanese authorities, which is a pre-requisite for the registration of products.

3) Remedica: a "titan" of Cyprus industry. (photo 3)
In a recent article, the leading business publication of Cyprus, "IN BUSINESS" magazine, referred to Remedica as a "titan" of Cyprus industry and published an interview with Remedica's Managing Director Mr. Emilios Savvides who, after describing the organisation's history from its founding in 1960 to the present time and its world-wide activities and technical operations, emphasised the sector's contribution to the Cyprus economy and made a special reference to the company's R&D activities and the innovations that it has implemented.

4) Visit from India's High Commissioner. (photo 4)
In the context of trade and economic relations between India and Cyprus, India's High Commissioner in Cyprus Mr. Ravi Bangar visited Remedica. Further development of commercial activities with India was among the issues discussed by Remedica's Managing Director Mr. Emilios Savvides and India's High Commissioner. Mr. Bangar was pleased to take the opportunity to visit Remedica's modern facilities. ■

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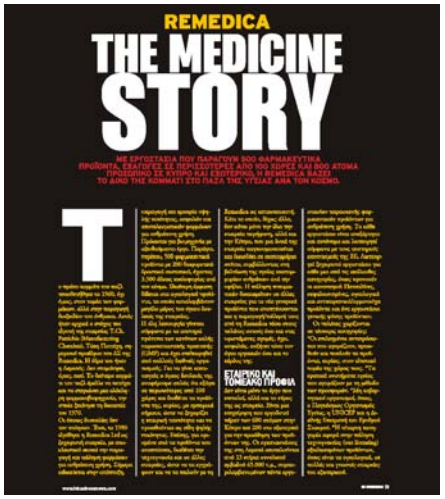
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Environmental Issues:
Acid Rain.

Acid rain refers to the rainfall which consists of water of low pH, meaning that it is more acidic than common rain. The acidity that turns normal into acid rain is formed due to the presence of pollutants in the atmosphere and specifically due to sulphuric dioxide and nitric oxides. Once on the ground, the acid rain causes significant effects to both natural and built environment.

According to the European Environment Agency, the term acid rain has been used since 1858 to describe the rain which was more acidic than normal. However, it was not until the late 1960s that the magnitude of the issue was appreciated and calls were made for it to be addressed. It should be noted that, Wright and Nebel reported that it was the Swedish scientist Svante Oden who first documented the acidification of lakes in Scandinavia and concluded that the pollutants were originating from other parts of Europe. Since then, studies have suggested that most of the industrialised parts of the world were experiencing rain that was 10 to 1,000 times more acidic than normal.

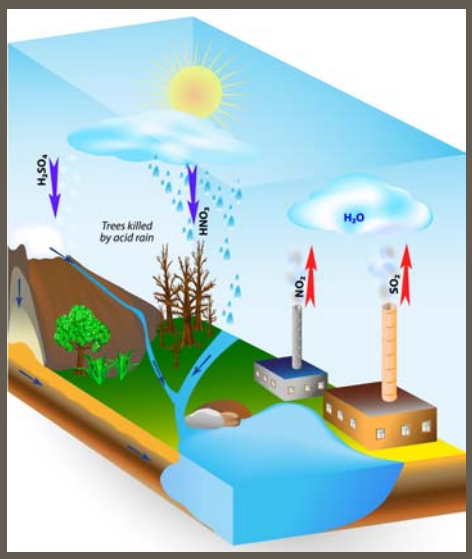
Anthropogenic emissions of sulphuric acid and nitric acid in the atmosphere which form the acid rain originate from the burning of fossil fuels. Once in the lower atmosphere, the given acids are oxidised by hydroxyl radicals to form sulphuric and nitric oxides. These oxides dissolve in water vapour present in the atmosphere which a week later return to earth in the form of rain, or other types of deposition. Due to the fact that the given emissions are mostly concentrated in industrialised regions, acid rain is mainly considered as a local issue, although several studies have showed that the source of acid rain in many countries was pollutants that were produced in neighbouring countries and moved by the climatic conditions.

Acid rain not only has detrimental effects on aquatic systems and forests but also on buildings and monuments. According to Wright and Nebel, the alteration of natural pH levels of lakes and rivers has resulted in the decline in the numbers of fish and other aquatic organisms. This is mainly due to the fact that these organisms have adapted to certain pH conditions which, when changed, diminish the quality of the eggs and the offspring's health. In addition, as the pH levels lower due to acidic deposition, full developed aquatic organisms will eventually not be able to survive or reproduce.

Acid rain is also damaging to forests mainly due to the destabilisation of the chemical compounds and nutrients within the soil which are vital for the trees growth, health and immunity towards insects and diseases. Low levels of pH in soil could result to the entire destruction of a forest. In addition to its impacts on the natural environment, acid rain affects monuments and structures mainly due to the fact that water with a low pH is capable accelerating the natural erosion of building materials such as limestone and marble.

In order for the acid rain phenomenon to be tackled, in 1979 the European Community and North American States adopted the Convention on the Long Range Transport of Air Pollution. This Convention called for a reduction in air pollutants that could produce acid rain along with ground level ozone formation. According to the Institute of Environmental Management and Assessment, since 1970 there has been an 84% decline in sulphur dioxide emissions and a 37% decline nitrogen oxides emissions in the UK.

Although acid rain is no longer considered to be at the top of the agenda of current environmental issues, its decisive management has illustrated the ability of mankind to effectively address national and international environmental issues. ■



Corporate Social Responsibility:
Remedica Cares

1) Remedica donates pharmaceuticals to the flood victims of Serbia. (photo 1)
Two tons of food and pharmaceutical aid worth €55,000 were delivered to the flood victims of Serbia by the Cyprus Red Cross (CRC) and Remedica respectively. In a ceremony at the CRC central offices, its General Manager Takis Nephytou and Remedica's Marketing Manager Andreas Hatzipanayis delivered the aid to the Deputy Chief of mission of the Embassy, Ivana Golubovic Duboka, who expressed her "deep appreciation for the initiative and action undertaken by the Cyprus Red Cross and Remedica in order to collect and deliver humanitarian aid for Serbia" mentioning that "the Region as a whole was severely hit by the disaster and that in these tough times Serbia needs support from all!"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2) Pattihis Family Scholarship 2014 - 2015 awarded. (photo 2)
The Pattihis Family Scholarship for a Master's degree in Management at the Department of Management Science and Innovation at University College London (UCL) has generated interest from a number of countries and from applicants in a variety of educational fields and, for the academic year 2014-2015, was awarded to Andreas Hadjigeorgiou. Andreas is a graduate in Civil and Environmental Engineering from the Faculty of Engineering of the University of Cyprus, and also holds a Master's degree in Engineering Project Management from the University of Manchester, Faculty of Mechanical, Aerospace and Civil Engineering. During the summer holidays in between his studies he worked in various companies and, until recently, held the post of Civil Engineer in charge of several residential projects in Limassol with a local construction company. We wish him every success in his studies.


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Andreas Hadjigeorgiou (left), Martinos Demosthenous, HR Manager - Remedica

3) Telethon 2014 charity concert. (photo 3)
In the context of this year's fund-raising event, Telethon 2014, the Cyprus Institute of Neurology and Genetics, in collaboration with the Cyprus Muscular Dystrophy Association, organised a charity concert at the Presidential Palace. The event was under the auspices of the President of the Cyprus Republic, Mr. Nicos Anastasiades and his wife, Andri Anastasiades. Remedica supported the fund-raising efforts by purchasing tickets which it then gave to members of its staff who had expressed a wish to attend.

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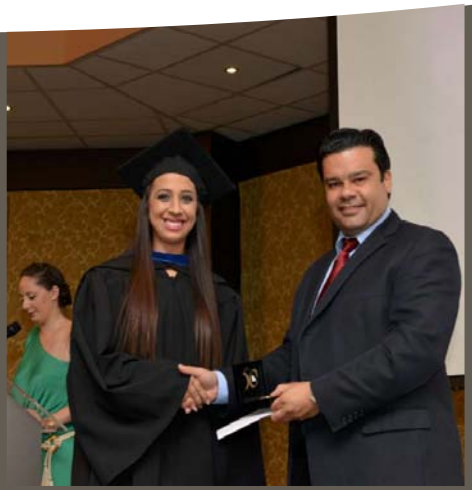
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4) Paddling For Life, Paddling For Children. (photo 4)
In order to raise financial support for the Center for Preventive Paediatrics, Costas Symeonides covered a distance of 400 kilometers, from Kastelorizo, Greece to Limassol, Cyprus on a Stand-Up Paddle (SUP). The Center for Preventive Paediatrics is a pioneering non-profit organisation in the implementation of universal prenatal and neonatal screening programs. All programs are offered free of charge to the population of Cyprus. Remedica contributed to this effort with financial support.

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5) Student Awards. (photo 5, 6)
As part of its social contribution and its efforts to promote health and education in Cyprus, the company presented awards and monetary prizes to the top students on the Medical Representative course. The recipients were Mrs. Stallo Patta of KES College and Mrs. Fekka Andria of The Cyprus College. ■

The ABC of Pharmacy:
European Medicines Agency (EMA)

The European Union (EU) was established with the signing of a treaty by the 6 founding member states (Belgium, Germany, France, Italy, Luxembourg, and the Netherlands) which effectively put their heavy industries under common management in 1951. By this initiative it was hoped that none of the Member States would be able to make weapons of war for use against one another. This fulfilled one of the guiding principles in the creation of a peaceful, united and prosperous Europe. In 1973 three more countries (Denmark, Ireland and the United Kingdom) joined the union which was then known as the European Economic Community or, more usually, the Common Market. The European Parliament came into being in 1979 and the euro was adopted as a common currency on 1st January 1999, but not by all of the member states. The admission of new Member States has continued since 1973 and it now comprises 28 countries.

The EU began to set up agencies (specialised administrative bodies with a legal identity and governed by a management board) in the 1970s, the first group of which was concerned with the implementation of social policies. The second tranche was initiated towards the end of 1980s and included the European Agency for the Evaluation of Medicinal Products (EMEA) which was established in 1993. The EMEA, which changed its name to the European Medicines Agency (EMA) in 2009, was physically located in Canary Wharf in London in 1995 with funding from the EU, the pharmaceutical industry and the individual Member States (MS). This was part of a policy of distributing the Agencies around Member States and it has often been alleged that the UK would have preferred to have hosted the European Bank; with the benefit of hindsight this decision may worked to the advantage of the UK.

The agency is charged with the responsibility for the issue of Marketing Authorisations (MAs) for human and veterinary medical products and devices, the collection of information on adverse drug reactions and the coordination of inspection of any premises involved in the manufacture, packaging, storage and distribution of medicines. The ability of the European Commission to regulate the conditions under which medicines are manufactured, distributed or used is totally dependent upon the scientific advice that the EMA has to actively provide. It can therefore, to all intents and purposes, be considered to be a Regulatory Authority. The EMA has two committees that can recommend MAs, the Committee for Proprietary Medicinal Products (CPMP) and the Committee for Veterinary Medicinal Products (CVMP) both of which were in existence before the creation of the EMA and their functions were essentially unchanged. The main change to the application process was the introduction of a Common Technical Document (CTD) in 2003 which is harmonised with the documents used by the USA and Japan.

An application will be considered via the centralised procedure (CP) if it is submitted directly to the EMA which then appoints two MS to carry out the assessment. However, the application is sent to all the other MS who can submit comments that may be incorporated in the report sent to the applicant which must be done within 210 days of receipt of the application. If, usually after a process of interaction and negotiation between the EMA and the applicant, a product is considered satisfactory then a MA is issued and this allows the product to be marketed in all EU states plus Iceland, Liechtenstein and Norway as members of the European Free Trade Association. This means that the product has a potential customer base of 495 million people and the EMA is responsible for a third of the new products brought to the world market each year. It appears paradoxical therefore that despite employing more than 400 staff, the EMA has no assessors and has to rely upon those employed by the agencies in each EU State to carry out this work for them.

An applicant can also obtain mutual recognition in each state by means of a decentralised procedure when the application is submitted to each MS at the same time. There are limitations on the type of product can be submitted by this route and some products have to use the CP (e.g. biotech and advanced therapies and new APIs for HIV and diabetes). An application can also be made to just one MS but, if approved, the MA which is issued will only permit the sale of the product in that state. Such an application can subsequently be submitted to any other MS either for individual approval or to all of them for mutual recognition, whichever the applicant considers it to be appropriate. However, just because it has been authorised by one state does not necessarily mean that it will be accepted by any or all of the others.

One of the most important roles carried out by the EMA is the coordination of the safety monitoring procedures which are conducted by all the EU Agencies (this is often referred to as pharmacovigilance). Because of its overarching function, the EMA can be alerted to any increased risk with any medicinal product marketed within the EU and if necessary cause its MA to be revoked. A major benefit to members of the EU is that the EMA acts as the contact point for agencies in all parts of the world and can thus share information and be forewarned of problems. It is therefore possible that on the rare occasions that a product is discovered to be harmful then a global ban could be implemented.

Another significant role fulfilled by the EMA is the production of Notes for Guidance (NfG) which it does after consultation with the agencies in MS and concerned industries. Because of the number of parties involved, the process can be a long one but their central issue ensures a harmonised approach by the various agencies. These guidelines do not have any standing in law but following the advice given should prevent the applicant from infringing other regulations. One exception is the 'Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products' compliance with which is mandatory (the commonest form of this condition is referred to as mad-cow disease and the restrictions put in place prevented any instance of the disease being transferred to humans via a medicinal product). The monographs in the European Pharmacopoeia set standardised specifications for medicines including the active ingredients, excipients and packaging. However, many of the monographs are based on NfGs and cross-referencing permits regular updating so that technological advances can be incorporated.

The EMA has also instituted procedures to deal with medicines or classes of medicines which are referred to them either by an individual Member State or the EC or the company which holds, or has applied for the grant of, a MA. Committees have been established by the EMA, which include scientific experts in their membership, and referrals can either be dealt with as a matter of urgency when there is a safety issue or as part of the regular business when concerns are raised about manufacturing or other quality related issues. Once more the prime purpose of this process is to ensure that the agencies maintain a harmonised approach to regulation.

Finally, the EMA also coordinates inspections of all aspects of the industries that are involved in the marketing of a medicinal product. The areas involved are: -
1. Good Manufacturing Practice
2. Good Laboratory Practice
3. Good Clinical Practice
4. Pharmacovigilance

Such inspections may be carried out by the inspectors appointed by the relevant member agency if the function is carried out in their state and an application has been made either to the EMA or any MS. It is also a requirement that facilities in countries outside the EU must be inspected if a company is involved in any part of the development or production of a medicinal product. The reports on all such inspections are made available to each MS thus preventing duplication.

In conclusion, the EMA, which is considered to be a major success of the EU organisation, is essentially the head of a federation of agencies to which it provides leadership through coordination and harmonisation whilst at the same time allowing each one to conduct its own business in an independent manner.

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Remedica people

In this issue we present our Financial Manager, Mr Michalis Cocconis.

After completing his studies in Accounting and Finance at the University of Manchester in the UK, Michalis returned to Cyprus where he worked as an auditor in the audit department of Deloitte where he was involved in the audit of various companies in the private sector as well as financial institutions. At the same time he attended courses and obtained the Chartered Accountancy Qualification.

After five years in the audit department, he was transferred to the Financial Advisory services department where as a manager he was involved in company valuation projects, feasibility studies and other related projects.

After he left Deloitte in 2009, he was hired by Remedica as Financial Controller.

Michalis is a member of the Institute of Chartered Accountants in England and Wales (ICAEW) and Institute of Certified Public Accountants Cyprus (ICPAC) and attends seminars related to financials on a regular basis.

A glimpse of Cyprus: The ancient world of Cyprus.

Situated at the crossroads of three continents, Cyprus has over the years been influenced by numerous and diverse cultures. The earliest known human activity on the island dates back to the 10th millennium BC. During the late Bronze Age, Cyprus experienced two waves of Greek settlement which were followed by the arrival of the Assyrians, Egyptians and Persians, before the island was seized by Alexander the Great in 333 BC. Subsequently, Cyprus was ruled by Ptolemaic Egypt, the Roman Empire, the Byzantines, the French Lusignan dynasty, the Venetians and the Ottomans. Imposing ancient ruins and archaeological sites of unparalleled beauty and value now lie silently in numerous locations around the island and testify to the rich cultural heritage of the country.

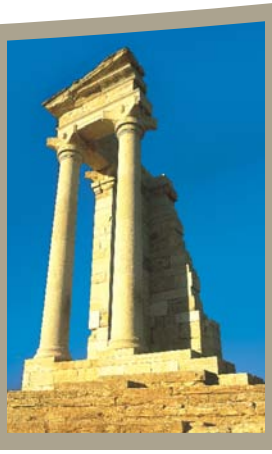
The earliest confirmed site of human activity on the island is Aetokremnos. A rock shelter on the southern coast of Cyprus, it gives evidence of the activity of hunter-gatherers in the region during 10,000 BC. However, among the earliest and most significant archaeological sites on the island is the Neolithic village of Choirokoitia. Listed as a UNESCO World Heritage Site, this remarkably well-preserved village constitutes one of the primary prehistoric sites found in the eastern Mediterranean. Discovered in 1934, Choirokoitia exposes an organised and functional society that was surrounded by a strong wall of stones for further protection. Among its primary features are the round buildings that lie within the walls and which include hearths used for cooking and heating, windows, benches, and piers that are believed to have supported an upper floor. Abandoned suddenly for unknown reasons at around 6,000 BC, Choirokoitia, as well as the settlement found at Kalavasos in the district of Larnaca, remain two of the most valuable representations of life during the Neolithic period in the region.

The archaeological site of the ancient city-kingdom of Kition is a remarkable example of the Bronze Age in Cyprus. Established in the 13th century BC on the southern coast of the island, Kition constituted a settlement of the Mycenaeans who hoped to exploit copper. Though the settlement soon faded, the remains of the ancient city-kingdom, which also comprise a striking Acropolis, are still visible. The settlement found at Alambra in the district of Nicosia, which features some of the earliest buildings of rectangular shape on the island, is another example of the Bronze Age in Cyprus, as is the ancient city-state of Salamis. Dating back to the 11th century BC, Salamis is located on the east coast of the island and boasts a temple dedicated to Zeus Salaminios, as well as a "cultural centre" established during the Roman period which features a gymnasium, a theatre, an amphitheatre, a stadium and public baths. The site of Salamis also includes the remains of a Hellenistic and Roman agora, the Byzantine remains of the basilica of Bishop Epiphanos, as well a large necropolis.

The prominent archaeological sites of Amathus and Kourion can be found in the region of Limassol. Human activity around the location of the ancient city-kingdom of Amathus dates back to 1,100 BC, while the present remains give evidence of a palace, a port used for trade, a site of worship and temples dedicated to the goddess Aphrodite and the god Apollo, as well as a special burial ground for infants. Among the most notable findings is an exceptionally well-preserved sarcophagus, which dates back to the 5th century BC and integrates Cypriot, Greek, and Oriental features. As opposed to Amathus, which is located on the east coast of Limassol, Kourion stretches over a wide area in the region of modern day Episkopi. Over the years, excavations have unearthed a large agora, public baths featuring cold, warm and hot spas, private houses dating back to the late Roman period, a number of mosaics, an early Christian basilica, the Sanctuary of Apollo and the remains of an enormous amphitheatre which originally held gladiator games. Also found on the area is the Roman Nymphaeum. Dedicated to the Nymphs, the Nymphaeum constitutes one of the most important monuments of its kind in the Mediterranean region.

In the region of Paphos, the Tombs of the Kings is another archaeological site of immense value. A UNESCO World Heritage Site, this large necropolis dates back to the 4th century BC and comprises a number of underground tombs carved out of solid rock. Though no kings were buried here, the sheer magnificence of these burial sites, many of which feature Doric columns and exquisite frescoed walls, establishes their unique historical and cultural value.

Sources:
www.cyprus-archaeology.org.uk
www.wikipedia.org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