Remedica
FOR A HEALTHIER WORLD

Newsletter 30

Contents

Welcome note

Welcome to the 30th issue of our Newsletter where we present our associates in Kenya, our Planning Officer and our product Tenoviral® (Tenofovir).

In our Environmental Issues we report on the issue of hazardous waste, in Health Matters we republish a previous article on allergies and in the ABC of Pharmacy we explain the terms "batch" and "batch release".

In Corporate Social Responsibility we have the awarding of the Pattihis Family Scholarship, our summer blood donation, our financial aid to the Karaiskakeion Foundation, our humanitarian aid in the form of pharmaceuticals to the people of Madagascar and an award to the top student of a local college.

In Remedica News we report on our successful collaboration in research and laboratory testing with the Cyprus University of Technology and include an interview of mine in the online newspaper of the Limassol Chamber of Commerce and Industry.

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

Charalambos Pattihis
Group CEO

Remedica Worldwide:
TWOKAY CHEMICALS LTD - Kenya

Kenya is a country in Africa and a founding member of the East African Community (EAC). Its capital and largest city is Nairobi. It is located on the equator with the Indian Ocean lying to the south-east and is bordered by Tanzania to the south, Uganda to the west, South Sudan to the north-west, Ethiopia to the north and Somalia to the north-east.

According to IMS Health Kenya has made great efforts in controlling diseases such as Malaria, TB, Cholera, as well as taking the necessary steps to actively fight the HIV/AIDS pandemic. Similar efforts have been made in controlling communicable diseases such as poliomyelitis, neonatal tetanus and measles. Kenya has committed to spending 15% of its national budget on healthcare amid plans to transform itself into a middle income nation by 2030.

The Healthcare Industry in Kenya has experienced substantial development in the last few years. It is estimated that pharmaceutical sales in Kenya have a value of $659m, with a forecasted compound annual growth rate (CAGR) of 17% by 2019.

Twokay Chemicals Ltd, located in the country's capital Nairobi is a leading importer and distributor of Pharmaceuticals, Surgical Dressing and Hospital Disposable supplies. The company was established in 1992 and today employs a skilled team of 16 people.

The company has been the agent for Remedica Ltd in Kenya since 1995 and currently markets more than 20 products. The products are distributed throughout all the major towns in Kenya and have been well received by health professionals. It is also important to note that some of the major NGOs located in Kenya continue to show a clear preference for Remedica products.

Mr. Kaushik Shah is the Managing Director and Pharmacist in Charge of the company. Mr. Shah qualified as a pharmacist from Chelsea College, University of London. Mr. Bhavik Shah is also a director of the company and holds degrees in Pharmaceutical Sciences and Chemistry from the UK. Both of them lead a hard working team of 14 people.

Despite the stiff competition in the Kenyan market, Remedica has gained the trust of health professionals and patients for its quality, safe and efficacious products which are available throughout the country.

Last but not least, Twokay Chemicals Ltd has adopted Good Distribution Practice (GDP) following WHO guidelines. ■

The ABC of Pharmacy:
Batch and batch release.

Batch

According to the EU pharmaceutical Glossary[1], a batch is defined as “A defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous”. The Glossary further notes that “To complete certain stages of manufacture, it may be necessary to divide a batch into a number of sub batches, which are later brought together to form a final homogeneous batch. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterised by its intended homogeneity.”

Also for control of the finished product, the following definition has been given in Annex 1 of Directive 2001/83/EC as amended by Directive 2003/63/EC: 'For the control of the finished product, a batch of a proprietary medicinal product comprises all the units of a pharmaceutical form which are made from the same initial mass of material and have undergone a single series of manufacturing operations or a single sterilisation operation or, in the case of a continuous production process, all the units manufactured in a given period of time'.

Batch Release

When a pharmaceutical company applies for a product licence or, to give it its proper name, a Marketing Authorisation (MA) for any new medicinal product, it is required to include details of who will be responsible for certifying that the finished product complies with the details given in the authorisation and that the product has been manufactured in full compliance with the European Guidelines of Good Manufacturing Practices (GMP) before it can be released onto the market. The aspects that must be assessed for the certification are the quality of the active ingredients, the manufacturing and packaging process, storage and handling of any intermediate products, packaging materials, stability and the laboratory tests carried on the product in order to ensure that it complies with product specifications.

If the product is manufactured on just one site in a member state of the EU then the requirements are relatively straightforward since the company only needs to appoint one 'Qualified Person' (QP) who will be responsible for the release of the batch having assured themselves that it is of the required standard. The QP will rely upon his/her personal knowledge of all the facilities and procedures used and the systems in place to ensure the quality of the product. He/she is able to delegate certain tasks to other employees (some of whom may be QPs in their own right) but he takes personal responsibility for the final certification and any subsequent consequences. Once a product is approved for release, it can be marketed in any member state of the EU (as long as this is permitted by the MA) or exported.

When various stages of the manufacture are carried out on different sites within the same company, a QP must be available at each site and the company must identify the QP who will take personal responsibility for the final batch release. His/her decision may, in part, be based upon the evidence and records provided by the QP responsible for any individual stage. It is also permissible for a manufacturer to contract out an intermediate production stage to another authorised manufacturer. In this case the QP in the contracting company takes personal responsibility for the release of the product based on the evidence provided by the QP in the contracted company. A similar arrangement is allowed to be put in place when the holder of a MA purchases a finished product from another licensed manufacturer which has not been certified against his own MA but here the QP of the purchasing company must either take responsibility for all manufacturing stages or rely upon the confirmation of the vendor QP. These arrangements are permitted because all the sites involved will have been awarded Manufacturing Licences (ML) and will therefore be operating in accordance with the EU rules and guidance governing Good Manufacturing Practices.

In the instances when more than one site or legal entity is involved in the manufacture of a medicinal product the specific arrangements must be documented either in the form of a standard operating procedure (if within the same company) or a formal contract (when different companies are involved). Where the responsible QP relies upon the evidence of another QP then this should be recorded in a document that includes an accurate description of those aspects which have been confirmed. A QP has the same obligations in respect to his/her duties whether he/she is responsible for either an intermediate stage or the certification of the final product.

If a medicinal product is imported into the EU then the importer's QP must certify each batch before it is released for sale in any member state. Obviously, this will involve laboratory testing of the product but this can be carried out in a different member state to the one where the importation is occurring. The most straightforward situation relates to the importation of a whole batch of a product since the QP only has to ascertain that the product was manufactured using an approved process and that it has been transported appropriately: of course, all the laboratory test results must be satisfactory. If only part of a batch is being imported, then the QP must

ensure that it is indeed part of the same batch and that it has been transported under the same conditions as previously. If this is the case and the other part was also imported into the EU, then the QP can take into account the testing and certification of the first part of the batch. If this is not the case, then each batch must be considered independently. Finally if a batch is imported in several portions for sale under the same MA, then the QP who dealt with the certification of the first batch normally accepts responsibility for all the batches. If any samples need to be taken in the exporting country then these must be shipped either with the exported batch or under similar conditions which will need to be monitored.

For products manufactured in the EU, the QP who certifies a batch is responsible for arranging the storage of sufficient reference samples of the product so as to be able to carry out at least 2 tests for a period of up to one year after the expiry date of the batch. The samples must be securely stored under the conditions set out in the MA and at the site in the EU where they were manufactured. The finished product should be stored in the final packaging, including any inserts, and bear the batch number and expiry date. For imported products an authorised manufacturer located in the EU, preferably at the location where the laboratory testing was conducted should store the samples.

The QP must have access to and be able to trace the stored samples at any time so it is important that the details of the storage arrangements are appropriately documented. These samples are used if at any time during the shelf life of the batch, a query is raised in respect of the quality, stability or labelling/packaging. If as a result of a complaint, a batch is found to be deficient in any way then the QP is responsible for its recall which means that he must be able to trace every batch that has been issued. Consequently, the importance of comprehensive and reliable records cannot be overemphasised: the inability to trace just a few samples could be fatal but, thankfully, due to the high standards to which EU pharmaceutical companies work, this is very, very rarely, if indeed ever, the case. ■

1 = http://ec.europa.eu/health/files/eudralex/vol-4/pdfs-en/glos4en200408_en.pdf

Remedica News

1) 6th conference of University – Industry Liaison Offices of Cyprus' universities. (photo 1)
In the context of the Liaison Offices' Conference, the Marketing Manager of Remedica, Andreas Hadjipanayis and the Assistant Professor at the Cyprus University of Technology, Dr. Dimitris Tsialtas presented their successful collaboration in research. The goal of the conference was to highlight success stories of successful collaborations between Business / Industry and Universities and the mutual benefits for both parties.

2) Interview of Remedica's CEO in the online newspaper of the Limassol Chamber of Commerce and industry. (photo 2)
The online newspaper of the Limassol Chamber of Commerce and industry recently interviewed Remedica's CEO, Mr Charalambos Pattihis, who is also the Chamber's Vice President of Industry. Mr. Pattihis, when asked about the state of the local industry, responded that *"almost the whole industrial sector of Cyprus was negatively impacted by the recent economic crisis but also by other, chronic factors"* and cited figures showing the downward trend of the Cyprus industry as well as important factors where Cyprus is lagging behind the European Union average. He also made reference to a proposal for a New Industrial Policy, which is under preparation, and which aims to comply with the objectives of the European Union, so that the industry's contribution to GDP will be at least 20%. This, he stressed *"will mean a simultaneous reduction of unemployment since, by definition, an industrial company employs more people than an equivalent company that simply imports similar products"*.
Finally, his message was clear: *"it is only with systematic, smart and team work that will exit the economic pit that we found ourselves in"*. ■

Environmental Issues:
Hazardous waste

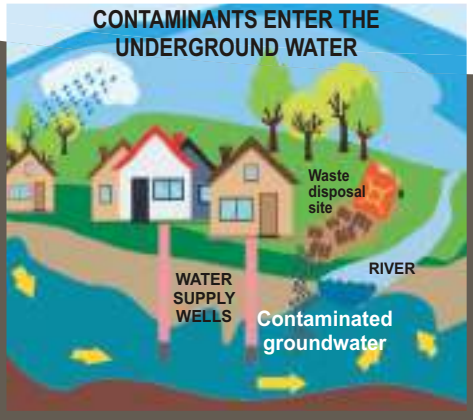
According to the US Environmental Protection Agency, a hazardous waste is a waste with a chemical composition or other properties that make it capable of causing illness, death, or some other harm to humans and other life forms when mismanaged or released into the environment.

Hazardous waste production occurs as a by-product of industrial, mining, construction, agricultural and transport activities. These include contaminated soil, batteries, electrical and electronic equipment; pesticides waste mineral oils, waste fuel and toxic and corrosive chemicals. In addition, hazardous waste is also produced by household and municipal activities. Hazardous waste produced by households, includes batteries and electronic and electrical equipment, such as monitors, mobile phones, computers, fridges etc., which are usually incorrectly disposed of, rather than taken to the appropriate sites specialising in their safe disposal.

Uncontrolled hazardous waste disposal imposes a major risk, which greatly contributes to the impairment of environmental and human health. Due to unsafe disposal practices, natural resources, such as water and arable land are being contaminated by chemical agents. Consequently, hazardous chemicals enter the food chain and end up in humans themselves.

For example, contaminants enter the underground water, which is then used for irrigation in agriculture. Therefore, contaminants are being accumulated in agricultural plants and crops. When these crops are consumed by humans, the contaminants are then accumulated in the human body. Due to the fact that the majority of contaminants are not metabolised by the human body, the given agents also end up accumulating in human organs and when this accumulation of many chemical agents exceeds a certain level of tolerance, health impairment and subsequent illness become inevitable.

According to Eurostat, the total amount of hazardous waste produced in the EU reached 100.6 million tons in 2012. Moreover, the average per capita amount of hazardous waste produced in the EU by all economic sectors, was 200kg. Household contribution to this figure was limited to 7kg per capita. It should be noted that during the reference year, the amount of hazardous waste produced in Cyprus was 31 thousand tons. The average per capita amount of hazardous waste produced in Cyprus was 36 kg, of which 20 kg were produced by households.



In order for this issue to be tackled in a European scale, the EU has implemented the Waste Framework Directive which imposes specific regulations and practices for the classification, management and safe disposal of hazardous waste. According to Eurostat the given Directive stipulates that hazardous waste must be recorded, identified and kept separated from other types of hazardous and non-hazardous waste.

Therefore hazardous waste producers are responsible for the safe management, control and disposal of their by-products so that contaminants would not be released to the environment and reach humans via the food chain or via any other means. Moreover, the Waste Framework Directive specifies that certain hazardous waste such as electronic and electrical equipment, batteries and fuel wastes would be collected and reused or recycled by competent parties.

Although certain measures have been implemented by the EU in order to safeguard the environment and human health from hazardous waste, unsafe disposal practices have not been entirely eliminated. As a result, further actions are required towards the minimisation and safe disposal of hazardous waste both at a European and a global scale. ■

Corporate Social Responsibility:
Remedica Cares

1) Pattihis Family Scholarship 2015 - 2016 awarded. **(photo 1)**
The 2nd Pattihis Family Scholarship for a Master's degree in Management at the Department of Management Science and Innovation at University College London (UCL) for the academic year 2015-2016, was awarded to Panagiotis Moullotos. Panagiotis finished high school with distinction and went on to study Mechanical and Manufacturing Engineering at the University of Cyprus, from where he also obtained a Master's degree in Energy Technologies and Sustainable Design. He participated in many music competitions and has been a member of the school choir for 6 years and a member in a professional music band since 2011. He has played football in local teams for six years and also attended a number of seminars and conferences on scientific topics. We wish him every success in his studies.

2) Remedica's Blood donation. **(photo 2)**
"Millions of people owe their lives to people they will never meet". Using this message, Remedica organised a blood donation session where more than 50 employees made this altruistic gesture. The purpose of the blood donation was to boost the stocks of the blood bank of the Limassol General Hospital. Remedica organises yearly blood donations and encourages all its employees to participate.

3) Financial aid to the Karaiskakeio Foundation. **(photo 3)**
As part of its corporate social responsibility activities, Remedica has made a donation to the Karaiskakeio Foundation. During α charity gala dinner held at the residence of Mrs. Maria Rousou (foundation's volunteer in Limassol), under the auspices of the President of the Cyprus Republic Mr. Nicos Anastasiades, Remedica's Group CEO, Mr. Charalambos Pattihis presented the Foundation's President Dr. Popi Kanari with a cheque for €1,000. The Karaiskakeio Foundation is a charity organisation set up with the aim of organising and running a donor's bank of bone marrow in order to offer the hope of life to fellow human beings. It is worth pointing out that many of Remedica's employees, as well as making regular donations of blood, are also bone marrow donors.

4) Aid to the people of Madagascar.
As support to the people of Madagascar, Remedica donated humanitarian aid in the form of pharmaceutical products through the Cyprus Association for Famine Relief.

5) Student Award. **(photo 4)**
As part of Remedica's social contribution and its efforts to promote health and education in Cyprus, the company's Medical Representative, Mr. Anestis Georgiades, presented Andreas Constantinou, the graduate with the highest score of the Medical Representatives course of KES COLLEGE, with a monetary prize.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Remedica People

In this issue we present our Planning Officer, Mr. Fotos Constantinou.

This month we are presenting Mr. Fotos Constantinou, who has recently been promoted to Planning Officer. After completing his military service he was employed in Remedica as an operator and it was during this time that strong bonds with the company were first established. Working closely with the Coating Supervisor, he learnt the sugar-coating procedure which he practiced for almost 2 years.

His thirst for knowledge led him to participate in the Pancyprian exams where he successfully qualified for a place studying Industrial Management & Technology at the Piraeus University in Greece. With the blessing of both the company management, he left the company briefly in order to complete his studies, before returning to Remedica after 4.5 years with his university degree and gaining the position of Production Supervisor.

The knowledge and expertise he obtained during his employment in Remedica, having served in various sections of the production Department, are vital tools for his professional career. His personal goal is the creation of an optimal production schedule through the use of electronic systems with the ultimate goal of being the effective coordinator of the various departments that provide support and services to the Production Department through solid team work.

Health Matters: Allergy - definition, cause, prevention, treatment

(republished from Remedica Newsletter 6)

An allergy is an unexpected reaction of an individual to certain substances, which are harmless to other 'normal' subjects. These substances are called allergens and they come into contact with the body via inhalation, food intake or by contact with the skin. When an allergen enters the body it activates certain blood cells called leukocytes to release specific substances called antibodies. These antibodies attach to specific cells and cause lysis of the cell membrane releasing several substances (e.g. histamine) which act on target organs e.g. eyes, skin, lungs etc. This allergic reaction may not occur following the first exposure to the allergen, but after repeated exposures of a person to a specific allergen.

Amongst the most common allergens are dust mites, pollen, animal fur, birds' feathers, fungi, certain types of food and even various environmental factors (e.g. atmospheric pollutants, cigarette smoke, and humidity). Such allergens may cause a variety of illnesses such as asthma, conjunctivitis, eczema, dermatitis, food allergy and many others. In some very rare cases the consequences can be fatal.

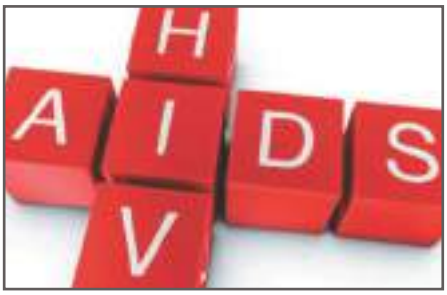
The best therapy is prevention, so avoiding contact with known allergens is mandatory, in order to prevent an allergic reaction. It should be noted that although a wide range of medicinal products are available, none cure the underlying allergy but mainly keep it under control, by preventing the occurrence of the symptoms. Allergy patients are thus enabled to lead a normal life.

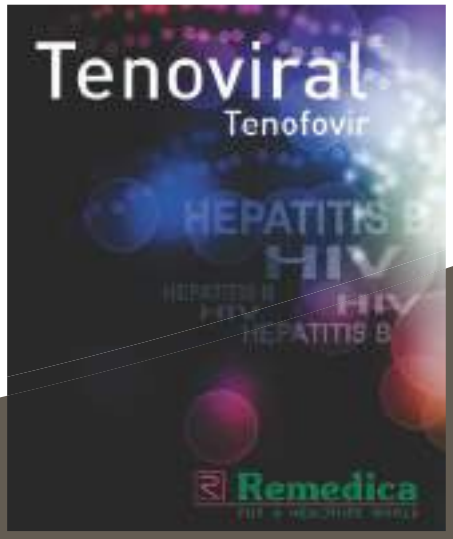
Remedica has the following products that may be used either at the onset of an allergic reaction or for chronic conditions.

- Remidine 10 (Loratadine 10mg: long-acting antagonist of the H-1 receptor with anticholinergic activity)
- Zirex 10 (Cetirizine 10mg: selective antagonist of the H-1 receptor with minimal action on other receptors).

Our Products:

Tenoviral® (Tenofovir)





Tenoviral® 245mg film-coated tablets contain the active substance tenofovir disoproxil.
The product is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults. It is also indicated for the treatment of HIV-1 infected adolescents aged 12 to < 18 years, with nucleotide reverse transcriptase inhibitors (NRTI) resistance or toxicities precluding the use of first line agents.

The choice of Tenoviral® to treat antiretroviral-experienced patients with HIV-1 infection should be based on individual viral resistance testing and/or treatment history of patients.
Tenoviral® 245mg film-coated tablets are also indicated for the treatment of chronic hepatitis B in adults with:
- Compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis.
- Evidence of lamivudine-resistant hepatitis B virus.
- Decompensated liver disease.
Tenoviral® 245mg film-coated tablets are indicated also for the treatment of chronic hepatitis B in adolescents 12 to < 18 years of age with:
- Compensated liver disease and evidence of active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis.

The active substance in Tenoviral®, tenofovir disoproxil, is a 'prodrug' that is converted into tenofovir in the body.

Tenofovir is a nucleotide reverse transcriptase inhibitor (NRTI). In the case of HIV infection, it blocks the activity of reverse transcriptase, an enzyme produced by HIV that allows it to infect cells and replicate itself producing more viruses.

Tenoviral®, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Tenoviral® does not cure HIV infection or AIDS, but it may delay the damage to the immune system and the development of infections and diseases associated with AIDS.

Tenofovir also interferes with the action of an enzyme produced by the hepatitis B virus called 'DNA polymerase', which is involved in the formation of viral DNA. Tenoviral® stops the virus making DNA and prevents it from multiplying and spreading. Therapy should be initiated by a physician experienced in the management of HIV infection and/or treatment of chronic hepatitis B.

The recommended dose of Tenoviral® for adults and adolescents aged 12 to < 18 years and weighing ≥ 35 kg for the treatment of HIV or for the treatment of chronic hepatitis B is 245 mg (one tablet) once daily taken orally with food.

The safety and efficacy of tenofovir disoproxil in HIV-1 infected children under 2 years of age have not been established as of yet. The safety and efficacy of tenofovir disoproxil in children with chronic hepatitis B aged 2 to <12 years or weighing < 35 kg have also not yet been established.

The optimal duration of the treatment is currently unknown.
Tenofovir is eliminated by renal excretion and the exposure to tenofovir increases in patients with renal dysfunction.

Tenoviral® is available in 245mg Film-Coated Tablets.

A glimpse of Cyprus: Ancient theatres of Cyprus.

As of date, four ancient theatres have been excavated throughout Cyprus: the "Ancient Theatre of Nea Paphos", the "Ancient Theatre of Kourion", the "Ancient Theatre of Salamis" and the "Ancient Theatre of Soli".

"Ancient Theatre of Nea Paphos"

The last king of Paphos, Nikoklis, decided to move his kingdom to a new location further to the west of what is known today as the modern city of Paphos. This new location was given the name of "Nea Paphos" (New Paphos) and the city built on the site was fortified with strong defensive walls as was common in the architecture of all city-states and kingdoms of the era.To the north-east part of this location, is the Hellenistic-Roman theatre of Nea Paphos which dates back to the end of the 4th century BC, with a capacity of 8000 spectators. An Australian archaeological excavation team revealed architectural remains carved into the rock on the south slope of the hill known as "Fabrica". Interestingly enough it seems that the theatre of Paphos is closely linked with the architectural style of the ancient theatre of Alexandria in Egypt, whereby their characteristic semicircular shape is believed to constitute one of the elements which contributed in the evolution of the design of the theatres of the Classical Era. The theatre, functioned as a place for performances and entertainment. In 365 AD, it was destroyed by an earthquake and later on, it suffered great losses from stone-theft. The theatre has since been declared a World Heritage Monument of UNESCO.

"Ancient Theatre of Kourion (Curium)"

Kourion was an ancient city in the southwest coast of Cyprus. According to Herodotus, it was a colony of the Achaeans from Argos in the Peloponnese and one of the most rich and powerful kingdoms of Cyprus. Pasikratis, was the last king of ancient Kourion and was among the other Cypriot kings who helped Alexander the Great at the siege and capture of Tyre in 332 BC. On the hill above the bay of Episkopi, stands the ancient theatre of Kourion, one of the oldest theatres in Cyprus. It was built in two construction phases, during the late Classical or early Hellenistic period and during the Roman period. The initial phase dates around the 2nd century BC, however the theatre acquired its current dimensions in the 2nd century AD. The auditorium was built according to the Roman standards and had a capacity of 3500 spectators. The central part is based in the bedrock, while the wings are built on artificial embankments. The theatre was bounded at the south side with the façade of the stage building which was probably reaching the level of the stage wings. Nowadays, only its foundations are preserved. After its complete restoration, the ancient theatre of Kourion is one of the most important places of Cyprus where cultural events are held, attracting large crowds of people.

"Ancient Theatre of Salamina"

Salamina was an ancient city-state of Cyprus, located to the east coast, in the estuaries of the river Pedieos. According to archaeological discoveries, it was founded around 1100 BC by Teucer, the son of Telamon who came from the island of Salamina, hence his choice to give the city the name of his home island. When Menelaus became king of Salamis, he proclaimed it as the capital of Cyprus. It remained as the capital for 1000 years until it was replaced by Paphos. The magnificent ancient theatre of Salamis, is one of the "treasures" among other archaeological finds, discovered during archaeological excavations. It dates around to the 2nd century AD and is comparable with the ancient theatre of Epidaurus. It was built on the spot of an earlier Hellenistic theatre and is the largest ancient theatre in Cyprus with a capacity of 20000 spectators. The auditorium was based on an artificial embankment and the stage building was designed according to the Roman standards with seven rooms and an aisle with a façade on two levels. It was destroyed by an earthquake in the 4th century AD. Before the Turkish invasion, the theatre was completely restored and ancient drama performances took place there. The archaeological area of Salamis is considered to be one of the greatest of Cyprus along with Paphos and it has also been declared as a World Heritage Monument of UNESCO.

"Ancient Theatre of Soli"

Soli was an ancient city and an important kingdom to the northwest coast of Cyprus. It was colonized by the Achaeans around 1200 BC. The first king and founder of Soli according to tradition is considered to be Akamas, a hero of the Trojan War and son of Theseus. Herodotus, mentions that the city was named in honor of Solon a member of the king's court and the scholar who indicated the point of setting up the city and formed its first laws. The ancient theatre of Soli was excavated in 1929 by a Swedish archaeological mission. It is situated on the north slope of the hill near the sea and dates back to the late 2nd century or the early 3rd century AD. The auditorium, most of the seats and the semicircular orchestra area, were carved in the rock, while the rest is based on an artificial embankment. The main stage building had many rooms and a large underground passage which traversed the entire theatre. Extremely impressive, are the two snapshot gnomes, respectively representing an actor parodying a wandering Silenus and an actor with a masque. Both the ancient theatres of Soli and Salamis are found in the occupied area of Cyprus.

Πηγές:

http://www.visitcyprus.biz
https://diktyoellinwn.wordpress.com
www.hellenicaworld.com
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www.24h.com.cy