

Newsletter 14

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Welcome note

Dear Readers,

Welcome to the 14th issue of our Newsletter in which we present our associates in Albania, the Manager of our Engineering Department and our products Losar & Losar Plus. We report on pharmacovigilance, define the term "excipient", and present simple but effective advice in the event of heart attacks. In our Eco-friendly tips, and following the destruction of the main power plant in Cyprus, we inaugurate a series of articles on renewable energy sources, beginning with solar power. In our Corporate Social Responsibility section we report on the award presented to Remedica by the Cyprus Red Cross, a school visit, our established Summer blood donation session, a Conference on Corporate Social Responsibility (CSR), and Remedica's prize giving to the top graduate of the Medical Representative course at a local college. In Our News we focus on the power cuts faced after the destruction of the island's main power station. Finally, we take a glimpse at the beautiful municipality of Agia Napa.



Charalampos Pattihi,
Group Managing Director

Remedica worldwide

TRIMED PHARMACEUTICALS COMPANY, Albania



Albania, officially known as the Republic of Albania, is a country in Southeast Europe, in the region known as the Balkans. It is bordered by Montenegro to the northwest, Kosovo to the northeast, the former Yugoslav Republic of Macedonia (FYROM) to the east and Greece to the south and southeast. Albania is a member of the UN, NATO, the Organisation for Security and Co-operation in Europe, the Council of Europe, the World Trade Organisation, the Organisation of the Islamic Conference and one of the founding members of the Union for the Mediterranean. Albania has been a potential candidate for accession to the European Union since January 2003, and it formally applied for EU membership on 28 April 2009.

Albania is a parliamentary democracy with a transition economy. The Albanian capital, Tirana, is home to approximately 600,000 of the country's 3,000,000 people. Free-market reforms have opened the country to foreign investment, especially in the development of energy and transportation infrastructure. (wikipedia.org)

Remedica has exported its products to Albania since 1994 through Trimed Pharmaceuticals Company. The company was founded by three partners, Mr. Shani Peposhi and his two children. "TRIMED" is a company with a long and successful record in the import, distribution and sales of pharmaceuticals. The founders have had excellent careers and experience in the management and direction of important pharmaceutical enterprises in the country.

The Albanian pharmaceutical market is mainly prescription-driven. Therefore good access and

relationships with the medical practitioners represents a key factor in their success. There is a team of medical representatives which is responsible for the promotion and distribution of Remedica's products. They have based their strategy on an efficient and simple organisational structure. There is full coverage and a direct supply to all the pharmacies in Tirana, which represents almost 50% of the market in the whole country and to another 35 cities which covers the remainder. They have qualified employees (pharmacists, doctors, managers and medical representatives), a well-established infrastructure (modern warehouse, 24/7 delivery, ordering system using GPRS etc.) and appropriate experience to apply excellent marketing, promotional and distribution methods which easily and expeditiously satisfy the drug registration process. Finally, it must be mentioned that their expertise in detailed market analysis provides sound information for planning supplies and sales. ■



Remedica people

In this edition we present our Head of Engineering Department, Mr. Panayiotis Konstantinou.

After receiving a mechanical engineering degree from Greece, he continued his studies in UK and received his postgraduate degree from the University of Salford.

He began his career as a mechanical engineer at Remedica in 1998.

Till 2005 he went through several positions such as engineering manager, health and safety officer, calibration and validation engineer, personnel manager, trainer and assistant production manager.

In 2005 it was necessary for him to leave Remedica in order to run a family owned business but after 5 years he returned to his current position and thus continue his career.

Throughout his time at Remedica he has attended many seminars on pharmaceutical engineering, GMP, GEP, production and personnel management: he has also gained a diploma in business administration.

He is a member of Remedica's strategic team and a registered member of the Scientific and Technical Chamber of Cyprus (ETEK).

He is also a member of both the Cyprus Mechanical Engineers Association and the International Society for Pharmaceutical Engineering (ISPE).

He is married with 2 children. ■



The ABC of Pharmacy: Excipient

An excipient is a pharmacologically inactive substance which is included in the composition of a medicinal product in order to enable the release of the API in an appropriate manner so that it can exert its intended effect on the body.

Excipients form an essential part of the formulation since it is impossible to make a dosage form which is comprised solely of the active pharmaceutical ingredient (API).

They can be used to add essential bulk to a formulation of a low dose API, to slow its release and thus produce a medicine which can be taken less frequently or for pharmaco-technological purposes that include ensuring good flow of the powder



so that dosage forms with consistent weight are produced, preventing sticking of the powder on the compression tooling, coating of a tablet to mask the bitter taste or even for colour-coding reasons to make distinction from other medicines easier.

The quality of excipients is as rigorously controlled as the API by the monographs included in pharmacopoeias. ■



Our Products-Losar 12.5, 25, 50, 100 FC Tablets

Losar contains the active ingredient losartan which belongs to a group of medicines known as angiotensin II receptor antagonists.

Angiotensin II is a substance produced in the body which binds to receptors in blood vessels, causing them to constrict or tighten which produces an increase in blood pressure. Losartan prevents the binding of angiotensin II to the receptors, allowing the blood vessels to relax which in turn lowers the blood pressure. As a consequence, losartan has been found to slow the decrease of kidney function in type 2 diabetic patients with high blood pressure.

Losar is used :

- to treat high blood pressure (hypertension) in adults, children and teenagers between the age of 16 and 18.
- to protect the kidney in hypertensive type 2 diabetic patients.
- to treat patients with chronic heart failure when therapy with specific medicines

called angiotensin-converting-enzyme (ACE) inhibitors which are often used to lower high blood pressure are not considered suitable for the particular patient.

- in patients with high blood pressure accompanied by thickening of the wall of the left ventricle.

Losar Plus 50/12.5, 100/25 FC Tablets

Losar Plus is a combination of the angiotensin II receptor antagonist losartan and the diuretic hydrochlorothiazide.

In Losar Plus the components losartan and hydrochlorothiazide have been shown to have an additive effect such that they reduce blood pressure to a greater degree than either component alone. Furthermore, as a result of the diuretic action of hydrochlorothiazide, plasma renin activity, aldosterone secretion and angiotensin II levels increase, whilst serum potassium levels fall. Administration of losartan blocks all the physiologically relevant actions of angiotensin II and through inhibition of aldosterone could tend to attenuate the

potassium loss associated with the diuretic.

Losar Plus is therefore indicated for the treatment of hypertension in patients whose blood pressure has not been adequately controlled on hydrochlorothiazide or losartan monotherapy.

A further potential advantage of Losar and Losar Plus is that they are considered to exhibit fewer side effects than angiotensin converting enzyme inhibitors. ■



Health matters: Heart Attacks: Simple measures that can be applied on the spot

This simple technique can be used in people of all ages and it may help to save a life so it is worth reading and being committed to memory.

The following tips are useful in the event of a heart attack:

1) If you are not in bed, do not lie down.

2) Keep a supply of aspirin by your bedside: the majority of people (about 60%) who had a heart attack whilst asleep, did not wake up.

However, if the chest pain does wake you then immediately dissolve two aspirins in your mouth and swallow them with some water. Aspirin helps to prevent blood clots and maintains the flow of blood through a partially blocked artery. When taken after a heart attack, Aspirin



may reduce the risk of death by 25%.

3) CALL 112 (or the equivalent emergency number in your country)

Do NOT lie down.

4) If you live alone unlock the front door, phone a neighbour or a family member who lives close-by and say "heart attack". If members of your family are at home tell them about the situation. In both cases mention that you have taken 2 aspirins.

5) Take a seat on a chair or sofa near the front door, and wait for help - do NOT lie down. ■



Eco-friendly tips: Solar electricity production

After the recent explosion near the main power station of the electricity provider in Cyprus which destroyed most of its infrastructure and caused extensive power cuts island-wide (see relevant article in the Remedica News section), and the explosion at Fukushima, Japan that destroyed a large power station, this article is particularly apposite, not only to Cyprus and Japan, but to most countries throughout the world.

Solar electricity production involves, as its name suggests, the harnessing of solar energy in order to produce electricity. This can be achieved either by the use of photovoltaic cells or technologies that concentrate solar power. Solar power provides clean electricity without the need to burn fossil fuels and it is considered to make a significant contribution in the control of climate change and the reduction of air pollution.

Photovoltaic cells have the ability to convert sunlight into electricity. In order to produce electricity, a continuous flow of electrons must occur through the cells and this is triggered by solar energy. Photovoltaic cells have been used extensively in calculators, watches, radios. More important applications are the production of energy and heat for domestic and industrial premises. Photovoltaic cells have been employed for extraterrestrial applications since the 1950s. Examples are found in the production of power for space probes, satellites, telescopes in orbit and even the International Space Station.

Currently, according to the European Commission solar power generated by photovoltaic cells is considered to be the fastest growing energy technology with an estimated turnover of around ten billion

Euros in 2007. The same source suggests that the worldwide installed capacity of this technology was estimated to be 9.5 GW by the end of 2007. The European share of that figure amounted to 4.5 GW.

Furthermore it is suggested that photovoltaic cells would play a vital role in the European electricity production. In particular the European Industrial Initiative estimates suggest that this technology's share of electricity production by 2020 would reach 12% of the European total.

Along with photovoltaic cells another technology using sunlight for electricity production is emerging known as concentrating solar power technologies. These technologies use mirrors to reflect and concentrate solar rays onto a point collector.

Then from the collector, which is usually on a tower, the sunlight is reflected onto a pipe located in the centre of the system through which an oil or other fluid with heat absorbing properties circulates. This heated liquid is in turn used to boil water in order to generate steam. Subsequently, the steam is used to drive a turbo generator which then produces electricity.

According to the European Commission, Spain is a world leader in the use of this type of technology having commissioned commercial solar concentrating plants with a combined capacity of 3GW.

Both technologies are positioned to play a vital role in energy production as the European Industrial Initiative requires them to provide 3% of all European electricity production by 2020. ■



Corporate Social Responsibility

Remedica cares

1) Remedica receives an award by Red Cross for its contribution. (photo 1)

At a formal dinner held at the house of the President of the Cyprus Red Cross, Remedica was awarded an honorary plaque for its continuous contribution to the efforts of the Red Cross.



2) Visit by Foley's School, Limassol. (photo 2)

The pupils of the lower sixth grade of Foley's School visited Remedica and after being informed about the company and its activities, they were given a tour of the laboratories where they had a chance to see the latest analytical technology used by Remedica. They were also able to discuss employment opportunities and career paths in the pharmaceutical industry in order to help students making better informed decisions about what to study after graduating from school.



3) Blood donation. (photo 3)

Remedica held a blood donation session in its premises where many employees volunteered for this altruistic gesture that saves many lives every year.



4) A very successful 4th Conference on Corporate Social Responsibility (CSR) was recently organised in Nicosia and Remedica was a sponsor. (photo 4, 5)

Distinguished speakers from Cyprus and abroad presented various Social Responsibility strategies based on the conference's topic "Incorporating CSR in companies' strategies." Remedica's Marketing Manager, Andreas Hadjipanayis, began his presentation with title "CSR. So what?" by showing a short part of the 6 minute impressive speech by Severn Suzuki a 12 year old Canadian girl who raised money with other children, to attend the Earth Summit in Rio de Janeiro and present environmental issues from



a youth perspective. Afterwards, he presented Remedica's strategy for CSR and environmental responsibility and emphasised the implementation of the International Labour Organisation's values from the company. In addition, it was mentioned that Remedica supports the 10 principles of the UN Global Compact in the areas of human rights, labour, the environment and anti-corruption.



5) Graduation ceremony of KES College. (photo 6)

During the graduation ceremony of KES College for the academic year 2010-2011, the top-ranking graduate of the Medical representative course was presented by Remedica's Marketing Manager, Andreas Hadjipanayis, with the Remedica bursary and a symbolic silver olive tree. In the context of Remedica's social contribution and efforts to promote education and health in Cyprus, the company offers this prize to the graduate obtaining the highest marks on the course. ■





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Remedica News

1) Explosion near the main power station. (photo 1, 2)

An explosion near the main power station of the one and only (state) electricity provider in Cyprus destroyed most of its infrastructure and caused extensive power cuts island-wide as the capacity was reduced to half. This resulted in rationing of electricity by means of controlled power cuts for certain periods during the day and these affected all business premises and households.

Remedica immediately began using its backup generators, including the one that had recently arrived for the warehouse of the new factory which is under construction, and ordered additional units so that it would be able to cover its entire demand. Fortunately a deal was quickly reached with the electricity provider for the continuous supply to industrial areas and hotels throughout the day without any power cuts.

This was judged as crucial not only to minimise the damage to the economy but also to prevent many companies with perishable goods going out business with all the accompanying negative effects including adding to the already high unemployment that has hit in Cyprus in the last couple of years.

The summer holidays, which some companies extended by another one or two weeks, helped ease the situation, as the reduced consumption meant that the energy saved could be used to power air-conditioning units of domestic consumers in order to cope with the summer heat.

This has also provided valuable time for the implementation of emergency measures including the installation of new power generators and the repair of a back up unit at the destroyed station.



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4

2) Remedica sponsored a scientific lecture. (photo 3, 4)

For second year, a scientific lecture by the Limassol branch of the Cyprus Association of Medical Representatives in collaboration with the Cyprus Mental Health Association was sponsored by Remedica. The subject was concerned with the latest issues regarding depression, bulimia nervosa and anorexia nervosa. The lecture was very successful and sparked the public's interest.

3) Remedica has been chosen to represent Cyprus at a Corporate Social Responsibility conference that is to be held under the auspices of the Responsible Industries of the Mediterranean (RIMED) programme.

Participants will represent companies and organisations from Mediterranean countries including Spain, Italy, Malta, Greece and Cyprus. The official results of a survey that has been carried out in many large organisations in all participating countries will be presented in Rome on the 29th September where Cyprus will be represented by Dr. Eudokia Balamou from the Larnaca District Development Agency and Mr. Andreas Hadjipanayis from Remedica.



Larnaca District Development Agency participates in the project RIMED as a partner.



5

4) Remedica has sponsored an exhibition of paintings by Skevi Paraskeva Socratous. (photo 5)

This was Skevi's second private exhibition and was entitled "Fytis - people and countryside" where the landscape and figures of simple people are illustrated in a way that their traditions, customs and values are harmoniously presented. ■

Regulations: Pharmacovigilance

Pharmacovigilance has been defined by the World Health Organisation as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.

Article 106 of Directive 2001/83/EC specifically placed a requirement on the European Commission in consultation with the European Medicines Evaluation Agency (EMA - "the Agency"), Member States and interested parties to draw up guidance on the collection, verification and presentation of adverse reaction reports in order to facilitate the exchange of information about human pharmacovigilance within the Community. Similarly, Article 26 of Regulation (EC) No 726/2004 includes a requirement for the Commission, in consultation with the Agency, Member States and interested parties to draw up a guide.

The resultant document is identified as "Volume 9A of The Rules Governing Medicinal Products in the European Union - Guidelines on Pharmacovigilance for Medicinal Products for Human Use" It includes technical requirements for the electronic exchange of pharmacovigilance information in accordance with internationally agreed formats.

It brings together general guidance on the requirements, procedures, roles and activities in this field, for both Marketing Authorisation Holders and Competent Authorities of medicinal products for human use; it incorporates international agreements reached within the framework of the International Conference on Harmonisation (ICH).

In addition, the European Commission is also required to publish a reference to an internationally agreed medical terminology.

Volume 9A replaces Volume 9 originally published in 2001 describing pharmacovigilance requirements for both human and veterinary medicinal products. The newer version (volume 9A) has been issued and brings the topic up-to-date and, amongst other things, places more stringent requirements on the reporting of adverse drug reactions whilst relaxing those for Periodic Safety Update Reports on generic products.

To comply with its pharmacovigilance requirements, Remedica has set up a department that includes two medical doctors, and is in contact with Remedica's representatives in the various countries as well as the relevant competent authorities, including the EMEA.

The department collects, evaluates and reports all relevant ADRs and prepares Periodic Safety Update Reports (PSURs) which are sent to health authorities. In this way, the safety of Remedica's products is continuously monitored after they have been placed on the market and for as long as they remain available for supply. ■



CONFIDENTIAL REPORT OF SUSPECTED ADVERSE DRUG EVENTS							
<p>REPORTING INFORMATION</p> <p>1. Name of Reporting Person: _____</p> <p>2. Address: _____</p> <p>3. Telephone: _____</p> <p>4. Fax: _____</p> <p>5. E-mail: _____</p>							
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A glimpse of Cyprus: Agia Napa - a historical survey

The Agia Napa region is characterised by its lack of rivers, and the scarcity of cultivated land. Therefore the distribution of settlements at various times in history is dictated by the limitations of the landscape. The discovery in 2004 of an early site at Nissi Beach, on coastal formations of aeolianite, dating back to 8.500 - 10.500 B.C. marks the short presence of the first seafaring foragers on the island. The first Neolithic inhabitants, however, came much later and settled for a short period of time on a naturally protected hill-top near the coast called *Tigani* before moving inland. For five millennia the area was not populated, as no traces of the Chalcolithic, Bronze Age and Geometric periods have so far been located.

The Cypro-Archaic and Cypro-Classical remains were once again located on a small promontory on the coast. We do not know much about these people, as the only remains discovered are restricted to a few fragments of terracotta figurines from an improvised sanctuary situated on the beach at the site of *Makronissos*.

The Hellenistic period is well represented by the sanctuary of Aphrodite on the table-shaped hill referred to by Strabo and also described by Ohnefalsch-Richter as well as in the reports of the excavations at *Makronissos*. The burial customs are essentially Grecian and correspond to that of other cemeteries of the same periods all over Cyprus particularly those at Salamis and Pafos. The pottery found in tombs suggests contacts with other countries, especially those of the Greek eastern world including Syria and Anatolia, North Africa and Italy.

The Roman period was notable for the creation of a number of farmsteads resulting from the establishment of the *Pax Romana*. Strongholds such as *Palio Chorko* continued their existence but the economy of the region was from now on based on individual farms. Little is known about the organisation of the region, but the existence of a major town is evident in the later part of the Roman period but both Strabo and Ptolemaios refer to "Thronoi city and cape". The remains of Thronoi which was the most important settlement were found at the site of *Torno* west of the present village: some minor settlements like *Ziyagin* and *Kaounin* were associated with Throni. The extensive water-works at the locality of *Filina* could be considered as part of the facilities of an organised community residing at Thronoi. A number of quarries in the region provide further evidence for the organisation of the society and the specialisation of labour. Most of the major settlements of the Roman period continued to exist well into the Early Christian period.

However, the most important settlement of the Early Christian and Early Byzantine period is *Katalymata*. It seems that most of the population shifted to this new site where no remains of the pagan past were to be found. Judging from the remains, the settlement must have been a flourishing one although the site along with other minor ones were in their turn abandoned during the Arab raids of the 7th century.

The region was subsequently deserted for centuries and most likely only shepherds

wandered about the pastures until the 14th century, when the Lusignans, attracted by the charm of the region, built the Agia Napa Monastery. Gradually but steadily some people came into the region shortly after the erection of the monastery, either as part of the work force for the construction of the aqueduct or as suppliers for the monks. Many of them settled permanently and formed a community so that the village of Agia Napa became a reality which exists until the present day. However, by the end of the 20th century the small community of farmers and fishermen had grown into a town where the majority of the inhabitants now work in the tourism industry.

Apart from the beautiful and unique beaches, most of which have had a BLUE FLAG awarded by the European Union, tourists can visit the Medieval Monastery and the Aqueduct, the Municipal Museum of THALASSA, the Makronissos Hellenistic and Roman Tombs, Cape Greco and the sea caves "Palace", as well as the fishing shelter of Agia Napa.

The cultural activities of Agia Napa are all year around such as the "Summer Stave", "Cultural Winter", the Easter and Christmas events, the Flood Festival, and the children festival. The most attractive ones are the three day International festival held on the last weekend in September which attracts artistic performers from all over the world and the medieval festival in October, which takes place in the local Monastery. ■

