

Newsletter 24

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Welcome note



Welcome to the 24th issue of our Newsletter where we present our associates in Slovenia, our Business Development Officer and our product Remethan®. We also have a feature article on the Cyprus Easter tradition of "Lambratzia".

Under Environmental Issues we report on the use of electric cars and in the ABC of Pharmacy we continue with the term "Marketing Authorisation". In Corporate Social Responsibility there are reports on Remedica's contribution to a Christmas fund-raising event, a donation of computers to a local school, a visit from pharmacy students, financial aid to social groceries and the donation of pharmaceuticals to Syrian refugees.

In Remedica News four topics stand out: Remedica being honoured by the Limassol Chamber of Commerce and Industry, the Lifetime Achievement Award being bestowed on the "father" of the Cyprus pharmaceutical industry and founder of Remedica, Chris Pattichis, the retirement of Androulla Ioannou and Remedica's inclusion in the 120 leading companies in Limassol.

Finally, we take a glimpse at the picturesque mountain village of Kakopetria. ■

Feature Article: "Lambratzia" or the Burning of Judas

A custom that dates back hundreds of years, the Burning of Judas has become part of the tradition of many countries around the world. Primarily an Orthodox and Catholic Christian ritual, the Burning of Judas takes place annually during the Holy Week when an effigy of Judas Iscariot is publicly burned. Although the custom does not officially belong to the Easter liturgical cycle, it nonetheless constitutes a part of the re-enactment of the story of the Passion that is practised during Easter and serves as a reminder of Judas' punishment after he betrayed Jesus Christ.

In some communities, the Burning of Judas is also believed to exorcise evil, corruption, betrayal and death, while simultaneously purifying the soul of the spectators and preparing the ground for new beginnings.



The Burning of Judas was introduced to several countries particularly by the Spanish and the Portuguese, who spread the tradition around their colonies. Consequently, countries such as Mexico, Brazil, Venezuela, Ecuador, Uruguay, Chile and The Philippines all adopted the custom and integrated it within their respective traditions. For example, in Mexico, what is known as 'La Quema de Judas' is held on Holy Saturday. It is a celebration held by numerous communities in local squares during which effigies of Judas stuffed with fireworks are burnt: smaller replicas of the effigies can be taken home and are exploded using a single firework.

Though the Burning of Judas was once widely practised across Europe, it can now be witnessed only in Greece, Cyprus, Spain and Portugal. In Greece and Cyprus, the effigy of Judas is typically made of straw and hung either outside local churches or at another high location in each community during Holy Week. Referred to in Cyprus as 'Lambratzia', the effigy is burnt in a spectacular manner on Holy Saturday in the presence of hundreds of faithful spectators.

Sources:

www.wikipedia.com
www.mexican-folk-art-guide.com ■

Remedica Worldwide: "EXCLUSIVE", Kosovo.



The company "Exclusive" which is Remedica's partner in Kosovo was

registered as a limited liability company at the Kosovo Registry of Business Organisations and Trade names with Number 70479274, on 4th April 2000 by Burim Latifi and Burim Shkodra who remain members of the Governing Board with responsibility for setting company policy in cooperation with the management team.

The main activity of "Exclusive" is the wholesale distribution of pharmaceutical products which it believes is one of society's main contributions to the promotion of health protection and is achieved by the integration of the skills of health professionals, capital investment and the creation of infrastructure.

The company's strategy is based upon:

- Operational planning and the continuous development of the pharmaceutical market in Kosovo.
- Successful adaptation to changes in the market.
- Careful consideration of customer needs and flexible and creative solutions to solving problems.
- Coordination of tasks at all management levels.
- Active participation of staff in the control of all tasks.

The fundamental principle of "Exclusive" is to serve partners, clients, customers whilst achieving commercial viability. It aims to fulfil its mission by focusing on health partnerships with the government, other enterprises and customers and in the years ahead it's aim is to strengthen its position as a sustainable business through collaborations with international partners'.

The company's business philosophy has enabled it to integrate its resources in more than 32 market centres and to grow in to a respected company through knowledge, experience, transport network, capital investment and people.

Today "Exclusive" provides reliable, comprehensive, high-quality wholesaling services for Remedica's products in the complex and heterogeneous market in Kosovo. ■



Our Products: Remethan®

Remethan® is a range of products containing salts of the non-steroidal anti-inflammatory drug (NSAID) diclofenac which has analgesic, antipyretic and anti-inflammatory properties. More specifically, Remethan® tablets and Remethan® suppositories contain Diclofenac Sodium, whereas Remethan® gel contains Diclofenac Diethylamine. Diclofenac inhibits the synthesis of prostaglandins in body tissues by inhibiting cyclooxygenase (COX).

Remethan® tablets and suppositories are indicated for the treatment of rheumatoid arthritis, ankylosing spondylitis, osteoarthritis, low back pain, frozen shoulder, tendinitis, tenosynovitis, bursitis, strains, sprains and acute gout. Remethan® is also indicated for the control of pain and inflammation in orthopaedic, dental and other minor surgery. Remethan® 25 tablets can be used for treatment of juvenile chronic arthritis in children.

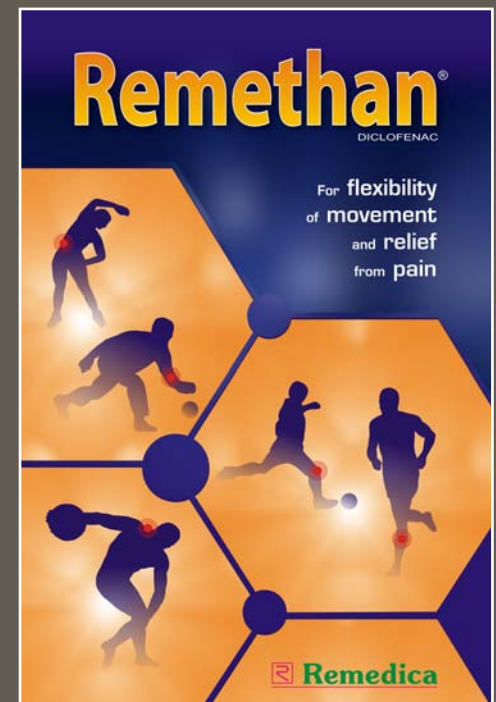
Remethan® Gel can be used for local symptomatic relief of pain and inflammation in:

- Trauma of the tendons, ligaments, muscles and joints, e.g. due to muscle sprains, strains and bruises.
- Localised forms of soft tissue rheumatism.
- Treatment of osteoarthritis of superficial joints such as the knee.

Also Remethan® Gel is suitable for the transmission of ultrasound and may be used as a couplant in combination with ultrasound therapy.

Remethan® is available as:

- Enteric-coated tablets 25mg,
- Enteric-coated tablets 50mg,
- Sustained-released, film-coated tablets 100mg,
- Suppositories 100mg
- Gel (1 % w/w).



Remedica News

1) Remedica honoured by the Limassol Chamber of Commerce and Industry. (photo 1)

As part of its 50th Anniversary celebrations, the Limassol Chamber of Commerce and Industry held a gala dinner attended by the President of the Republic of Cyprus. Remedica, as one of the oldest active members of the Chamber was honoured with an award which was presented by the President to Remedica's Managing Director, Mr. Emiliios Savvides.

2) Retirement of Androulla Ioannou.

Androulla Ioannou recently retired after 31 years of service with Remedica. Androulla was a Packaging Line Supervisor and with her meek character and professionalism which she exhibited throughout all of these years, she had won the appreciation and respect of both the company's management as well as that of her colleagues. In a moving ceremony in the company's refectory, Remedica's Management and other colleagues said their farewells and gave her commemorative presents. We wish her all the best for her retirement years.

3) Remedica in the 120 leading companies in Limassol. (photo 2)

In a recent issue of the business magazine "Gold" published in English, Remedica was included in a list of the 120 leading companies in Limassol. According to the magazine, Limassol may only be the second largest city in Cyprus but is the country's business centre and also an attractive tourist destination being a cosmopolitan place too.

4) Lifetime Achievement Award for the founder of Remedica, Mr. Chris Pattichis. (photo 3)

In a splendid and fully-packed ceremony organised by the IN BUSINESS Magazine, a Lifetime Achievement Award was bestowed upon the founder of Remedica, Mr. Chris Pattichis, for his contribution to the Cyprus economy. The Award was presented by the President of the Republic of Cyprus, Mr. Nicos Anastasiades, to Mr. Chris Pattichis' son, Charalambos on behalf of his father who was sorry not to be able to attend the event. Mr. Charalambos Pattihis, thanked the IN BUSINESS Magazine for this honour and stated that his father, like himself, is a low-profile person who does not enjoy the limelight of publicity, and whose main preoccupation is the business, his family and Remedica's employees. ■



Pattihis Family Scholarship

for the MSc Management degree in the department of
Management Science and Innovation at
University College London (UCL).



 **Remedica**



Environmental Issues: Electric cars.

The continual rise in the cost of fuel and the shift towards the adoption of more sustainable lifestyles has led to the increasing demand for cleaner vehicle options such as electric cars which are also known as battery-powered electric vehicles. According to the European Environment Agency, the annual sales of electric cars have increased twenty times within the EU over the three year period from 2010 to 2012 when it increased from 700 to 14.000.



Despite the fact that the concept of electric cars may seem to be new, it should be noted that electric powered vehicles were invented and used before the petrol powered ones, which nowadays are viewed as conventional. According to the International Energy Agency, the first four-wheeled electric car was invented by Andreas Flocken, a German engineer in 1888. This breakthrough followed the development of the electric-powered carriage which was developed by Robert Anderson of Scotland between 1832 and 1839 and the installation of the first direct current motor in a car by Thomas Davenport in 1834 in United States.



ELECTRIC CAR = GREEN CAR

Electric cars gain their motive and auxiliary power via an electric motor which extracts stored electricity from rechargeable batteries which are housed onboard the vehicle. The electricity used to recharge the batteries comes from grid electricity and energy recovered during the use of the brakes on the vehicle. The use of electricity to generate propulsion, means that electric cars do not emit any direct air pollutants and reduce noise. These attributes can therefore lead to a reduction of air pollution and noise in urban areas, where they threaten the health and comfort of inhabitants.

However, the use of electric cars cannot be considered to be completely "green" since the electricity needed to recharge the batteries is produced by conventional methods. Even so, this indirect air pollution is far less than the direct pollution caused by cars powered by internal combustion engines and the European Environment Agency suggests that based on the average electricity supply in Europe, the reduction can be as much as 50%. Furthermore, with the continuous increase in the supply of electricity produced by renewable sources to the grid, the indirect air pollution produced by electric cars could be even less. In addition, the same source suggests that the electric cars are generally more energy efficient compared with conventional cars.

Despite the environmental and fuel cost savings, electric cars still have major drawbacks. The International Energy Agency has suggested that the batteries are not considered to be reliable due to their low energy and power densities compared with power extracted from the combustion of fossil fuels. As a result, electric cars show limitations in performance and range as well as the logistical difficulties associated with the access and time taken to recharge batteries.

Investment in research and development and technological advances directed towards the elimination of these drawbacks will almost certainly lead to an increasing demand for electric cars. It should be noted that by 2050, the European Environment Agency estimates that electric car sales will account for 60% of new car sales and represent a 25% share of the world's cars. ■



Corporate Social Responsibility: Remedica Cares

1) Christmas fund-raiser by the Cyprus Association of Cancer Patients and Friends (PASYKAF). (photo 1,2)

Remedica sponsored the Christmas fund-raiser organised by the Cyprus Association of Cancer Patients and Friends (PASYKAF) held in Limassol. The proceeds will help the Association's efforts to continue to provide its free-of-charge services which include domiciliary nursing and relief care, social support, physiotherapy, a clinic for lymphedemas, day care centres and patient transportation.



2) Remedica donates computers to a local school. (photo 3)

As part of its support towards local schools, Remedica donated computers to the St. John High School. The computers were delivered to the school's Principal Mr. Yiannis Stavrou by a delegation of Remedica Volunteers.



3) Visit from Pharmacy students. (photo 4)

The pharmacy students of the Nicosia University recently visited Remedica. After being briefed on the company's activities, they were given a tour of one of Remedica's manufacturing facilities as well as the analytical laboratories where they had the chance to see the latest analytical techniques used by Remedica.

4) Donations to social groceries. (photo 5, 6, 7, 8, 9)

Instead of holding its annual staff party, Remedica decided to donate the money to the social groceries set up all over Cyprus to provide free food and other essentials to people who can no longer



afford to buy them. As a consequence, Remedica was able to provide financial aid to the municipal groceries in Limassol, Paphos, Larnaca, Paralimni, the Cyprus Archbishopric in Nicosia and the Cyprus Red Cross Society.

5) Donation of pharmaceuticals to Syrian refugees.

Remedica donated pharmaceuticals worth €120,000 to the suffering people of Syria. Specifically, pharmaceutical products have been sent to a refugee camp in Jordan via the Volunteer Doctors Cyprus and the International Organisation for Migration. ■



The ABC of Pharmacy:

Marketing Authorisation



Any medicinal product¹ that is offered for sale in the European Union must be authorised by a competent authority (CA)² as being safe, effective and of suitable quality. Such authorisation is obtained by application to the CA by means of a Marketing Authorisation Application (MAA).

The form of the application that needs to be made varies according to whether the product contains a completely new active ingredient when it is referred to as a 'full' application and will have to include details of the nature of the drug and tests which have been carried out in both animals and humans in order to show that the substance is non-toxic and effective as well as details of the formulation and manufacture of the dosage form. If the product contains an active ingredient (API) which has already been approved as part of another MA then the application is termed as 'abridged' and only abbreviated details of the quality and safety of the API have to be included. However, full details of the formulation and manufacture are still required to be included. One common example of this type of application is when it is being made for a product which the applicant claims to be generically equivalent (essentially similar) to an originator product and equivalence between the two products must be demonstrated: in this case such equivalence may require the submission of data collected via studies involving the measurement of blood levels of the API produced by both products in human volunteers.

Both types of application need to include data on the stability of the final dosage form stored at a range of temperatures and relative humidity and this is used to determine the storage conditions and the length of time that the product can be offered for sale (shelf-life). The applicant must also include the procedures which will be put in place to deal with any adverse reactions or other reasons for recall of products which have been placed on the market and are subsequently found to be deficient in any way. The product information leaflet (PIL) that will be placed in the package with the medicine must

be submitted as part of the application and the CA must be consulted and approval sought for any subsequent changes in this document. Of course, given the commitment of all governments to ensure the safety of the planet, an assessment of the environmental impact of the manufacture of the product must be included.

Once the application has been made it is examined by the CA and a report will be produced by a trained assessor. Each CA has a Committee which makes recommendations as to whether a MA should be issued to the relevant government minister and it may be assisted in this process by a range of expert groups or panels. However, it is rare for a MA to be issued without the CA raising a list of questions to which the applicant is invited to provide answers and then, once all the points have been resolved, the MA may be issued. Not all applications receive approval and if they are turned down a route of appeal is available and this may take the form of a written submission or an oral hearing. If, as a result of the queries raised by CA, the applicant is willing

to carry out more work to rectify any shortcomings then re-applications are allowed. Obviously, this process involves a considerable amount of time and effort on the part of both the applicant and the CA. The costs of the latter are defrayed by the payment of a fee by the applicant.

Once an authorisation has been granted the holder is allowed to manufacture and market the product but only strictly in line with the application that was approved. However, it also permits the applicant to seek another company to carry out the manufacture of the product provided the latter holds a manufacturing authorisation from a CA who is required by law to inspect the premises. If the MA Holder wishes to manufacture their own product then they must in addition hold a manufacturing authorisation. The MA can also be licensed or sold to another person or company who can then manufacture or procure the manufacture of the product.

Each MA is granted for a period of 5 years and renewal must be sought after this time. At the

time of this renewal, the applicant is required to submit all relevant information which is available on the product and the conditions which it is claimed to treat. In addition, and most importantly, an update on the safety of the medication must be submitted. As experience with the product is gained then further therapeutic indications may be added and these can be done by means of an application for a variation in the authorisation. For instance, it might be the case that medical practitioners decide that it is appropriate to use the medicine for a condition that it was not licensed (so-called 'off-licence' use) and if in the course of such studies it is found to be effective then it may be included in the licence by way of a variation.

From the foregoing, it can be seen that a MA for a medicinal product is a very important and valuable document. The holder must ensure that the product is manufactured, marketed and used in an appropriate way. Any infringement of the conditions in the MA can lead to the cancellation of the licence by the competent authority and this is followed by the

immediate recall of the batches of the product which have been issued for sale. Examples of such cancellations are fortunately rare and are only invoked if absolutely necessary (a higher than expected occurrence of a side effect is the most common example) and in most cases, companies take the opportunity of voluntarily withdrawing a product from the market.

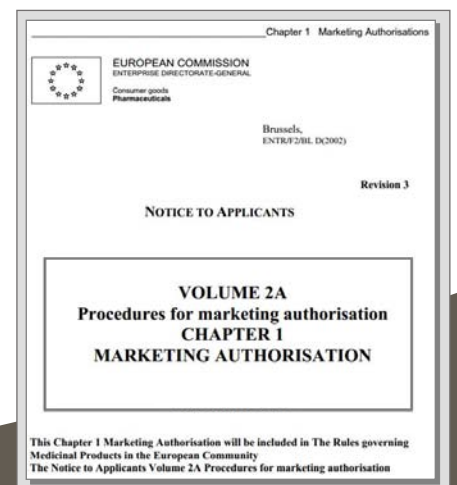
This does of course mean that if the problem can be resolved then a variation to the licence can be sought and the revised product reintroduced to the market. In recent years it has been more common for manufacturing licences to be suspended or cancelled. Finally, it is the responsibility of any person or company who imports or offers medicinal product for sale that it has be manufactured in accordance with a legal MA.

1. A medicinal product is defined as 'any substance or combination of substances presented as having properties for treating or preventing disease in human beings' or 'any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring,

correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis'.

[www.mhra.gov.uk/home/groups/is-lic/documents/publication/con007544. Accessed 23/12/2013].

2. Examples of competent authorities are the regulatory authorities of any of the member states of the EU. The US Food and Drugs Administration and the Japanese Pharmaceuticals and Medical Devices Authority. ■



Remedica people

In this issue we present our Business Development Officer, Mr. Marios Stylianides.

After completing his studies in the United States in Business Management (BSc), Human Resources (MSc) and Business Administration (M.B.A.) in 2004, he started his career as Managing Director in a multinational company based in Lebanon. The position was for one year and his job was to establish new sales offices and to register new products for the Lebanese market.

In 2005 he made a career change and went to work for a well-known construction company based in Paphos, Cyprus. After six successful years there as a general manager, he joined Remedica in August 2011 as the company's Business Development Officer responsible for the overall new business objectives worldwide.

In this role he is very keen to create and enhance key and strategic accounts and to attend worldwide exhibitions and other business functions in order to keep abreast of developments in the marketplace.

His wife is a Home Economics teacher in Cyprus and they have a 7-year old son. He likes to spend his free time with his family and friends. ■



A glimpse of Cyprus: Kakopetria: A community of rich tradition and culture.

Nestled in the foothills of the Troodos mountain range, Kakopetria stands at the highest point of the Solea Valley at an altitude of 667 metres. Surrounded by a dense forest, the village is built on the banks of the Kargotis and Garillis rivers, which merge at Kakopetria to form the river Klarios. With approximately 1,200 permanent residents and another 200 who own summer houses and visit the village frequently, Kakopetria is a distinct community rich in tradition, history and culture.

According to local folklore, Kakopetria (which in Greek means "Bad Stone" owes its name to the Stone of the Married Couple; a large stone located near the entrance to the village which is said to have once moved from its original site, crushing a newlywed couple in the process. However, another myth claims that the origin of the name of the village is due to it being founded by an unpleasant man called Petros, although it is most likely that the village derives its name from the rocky terrain that surrounded it in the past. Nowadays, Kakopetria exists in a region of wild vegetation, towering pine and poplar trees, and orchards of apple, pear, plum, cherry and fig trees.

The history of the region surrounding Kakopetria dates back to the Archaic and Classic eras of Cyprus. Excavations conducted in the 20th Century have brought to light a part of an ancient shrine that is believed to have been dedicated to the goddess Athena, a large number of terracotta fragments and limestone statues depicting Athena and Hercules, as well as bronze and

iron spear and arrow shafts, all of which are now displayed in the Archaeological Museum of Nicosia. In more recent times, the inhabitants of the village became known for the rearing silkworms and production and processing of silk. According to reports, the production of silk in Kakopetria was taken over by the British during the Second World War, who needed it to manufacture parachutes.

Nowadays, a visitor to Kakopetria will come across a beautiful combination of old and new. In the west part of the valley and between the two rivers stands the old section of the village where traditional houses with sloped, tiled roofs and wooden balconies, climbing vines and picturesque streets provide a scenic atmosphere and a lovely glimpse into the past. On the other hand, the new section of the village which is located in the eastern part of the valley boasts examples of contemporary architecture, featuring large, modern houses and buildings.

Due to its temperate climate, beautiful surroundings and traditional atmosphere, Kakopetria is a popular destination among locals and tourists. The old section of Kakopetria, the Linos Museum and the Eliomilos (olive-mill) museum provide charming examples of Cypriot tradition and culture, whereas the Stone of the Married Couple, with its link with the history and wedding customs of the region is justifiable popular attraction. The village is also famous for its two watermills; 'Milos tis Gonias' (corner mill) and 'Milos tou Hadjistavrinou'

(Hadjistavrinos' mill) both of which were constructed in 1754 and were still in operation until after the end of the Second World War. Though the latter mill has since been demolished, 'Milos tis Gonias' was restored as a working mill in 1980 and is open to visitors, who can see how it was used to produce flour from wheat or barley and discover some of the history of milling in Cyprus. In addition, and among the most notable sights in the area, is the church of Agios Nikolaos tis Stegis (Saint Nicholas of the Roof). Recognised as a UNESCO World Heritage Site, the church features a distinctive roof and an abundance of well-preserved frescoes inside which constitute excellent examples of Byzantine and post-Byzantine art.

With a camping site and a picnic site nearby, as well as two charming nature trails that take hikers through the impressive forest of the Troodos mountains, the village of Kakopetria allows its visitors to escape, reconnect with nature, and experience a region of breathtaking natural beauty, internationally-acclaimed religious heritage, which is rich in tradition and culture.

Sources:

<http://en.wikipedia.org/wiki/Kakopetria>
<http://www.kakopetria.org.cy/> ■



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Remedica Ltd - Manufacturers of pharmaceuticals
Limassol Industrial Estate,
P.O.Box 51706, CY - 3508 Limassol, Cyprus, EU.
Tel: +357 25553000, Fax: +357 25390192
E-mail: info@remedica.com.cy <http://www.remedica.eu>

