

Newsletter 12

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Welcome note

Dear Readers

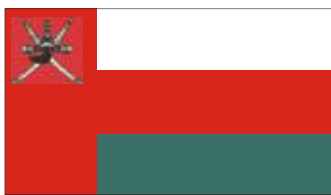
Welcome to the 12th issue of our Newsletter where we present our associates in Oman, the Manager of our Registration Department and our product Risperidone. We report on new European Union legislation on the marking of pharmaceutical products, we explain the term "pharmacopoeia" and encourage the need to be careful when taking medicines. In our news, two events stand out: the presentation of the Export Award to Remedica for the 7th time, as well as the "IN BUSINESS Award". We also include many other interesting items. Finally, we take a glimpse at the beautiful town of Morfou (still in the area now occupied by the Turkish army since 1974).



Charalambos Pattihis,
 Group Managing Director

Remedica worldwide

AL HASHAR – PHARMACY, Oman



AL HASHAR PHARMACY, a company with an annual turnover of twenty million US dollars was founded in 1972 and has thus been providing healthcare products in Oman for over 35 years. In addition to pharmaceuticals, it markets laboratory diagnostics and allied products.

Its professionally qualified team of pharmacists, regulatory personnel and medical & sales representatives endeavour to bring quality healthcare to the doorstep of every clinic, pharmacy and hospital throughout Oman. AL HASHAR PHARMACY only markets products manufactured by international companies with facilities that are first class and have been accredited by national regulatory bodies and adhere strictly to Good Manufacturing Practice (GMP) guidelines.

Located at prime locations

AL HASHAR PHARMACY in Oman is one of the oldest Remedica agents in the Middle East Region. Remedica and AL HASHAR PHARMACY started their business cooperation in 1984 following a successful visit by Remedica's current Managing Director Mr. Emiliós Savvides aimed at establishing contact and introducing the company's products.

throughout Oman, the chain of retail pharmacies contributes 30% of its total business. The dedicated team of Pharmacists and Assistant Pharmacists strive towards a common objective the provision of appropriate counseling on the indications and other attributes of each pharmaceutical product thus also fulfilling a social need.

The years of dedicated and sincere endeavour have strengthened the company and helped it develop a strong ethical image whilst its focused portfolio has enabled brand and market development as well as a good penetration in the private and state laboratory segment. Its excellent distribution network is able to provide in-depth delivery to pharmacies and clinics throughout Oman and its flat organisational structure means that the company has a short decision process which can respond rapidly to changing market needs. ■



Remedica people

In this edition we wish to introduce the Manager of our Registration Department Mr. Nikolas Ladas.

Whilst at first he began his studies in Business and Information Technology, the developments in genetics during 1996-1997 lured him into a change of direction eventually studying Biology in the United States. Following his graduation he worked there for a short period of time in a chemical company producing essential oils.

In 2001 he went to England for a post-graduate degree in Biological Research Methods where he was involved with the exploration of nutrient transfer mechanisms from trophocytes to the ova in the ovaries of hemipterans, an order of insects that includes aphids and cicadas.

Having completed his studies, he returned to Cyprus and was employed as a Registration Scientist in Remedica's Registration Department. During this time he participated in many seminars and training courses in the general area of Regulatory Affairs, such as

Regulatory Affairs in the EU, Preparation of Registration Dossiers in CTD form, Managing the CTD Lifecycle, Bioequivalence, Preparing the eCTD and Pharmacovigilance. In 2008 he took over as Manager of the Registration Department where he works tirelessly to the increase the number of Marketing Authorisations granted to Remedica in various countries.

He is married with one child and lives in Larnaca. In his free time he likes to study world history but is particularly interested in the history of the Hellenes.

He is a football fan and loves everything about his native town. According to him, Larnaca is a proven beacon of civilisation in Cyprus and the greater ancient Greek area since its history stretches back before 4000 BC until the present. ■



The ABC of Pharmacy: pharmacopoeia

A pharmacopoeia is a book published by a government agency containing a list of drugs and excipients, formulae, methods for the preparation of medicinal products and tests for their purity, strength, stability and other specific characteristics. These are included as monographs.

Most countries produce pharmacopoeias but some of the older ones have become international standards: these include the United States Pharmacopoeia (USP), the British Pharmacopoeia (BP), the European Pharmacopoeia (Ph.Eur) and the Japanese Pharmacopoeia (JP). The addition of this abbreviation after the name of a drug or a medicine indicates that it complies with the



standard set out by the relevant publication. It therefore represents a seal on the quality of the product.

The word pharmacopoeia is derived from the Greek words *pharmakon* [φάρμακον] (drug) and *poiein* [ποιεῖν] (to make). The size of the pharmacopoeias has increased over the years and the BP now consists of 4 volumes: it is also available in electronic form. ■

Our Products-Risperidone

Risperidone is a selective monoaminergic antagonist with unique properties. It has a high affinity for serotonergic 5-HT₂ and dopaminergic D₂ receptors. Risperidone binds also to alpha₁-adrenergic receptors and, with lower affinity, to H₁-histaminergic and alpha₂-adrenergic receptors.

Risperidone is indicated for:

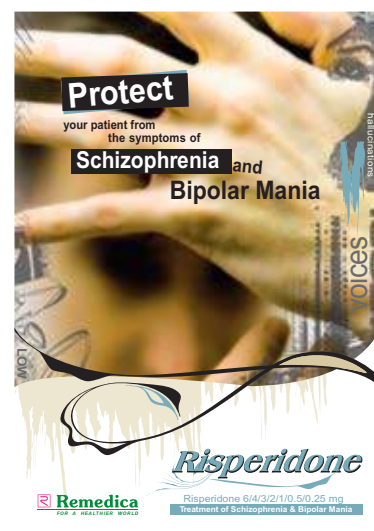
- the treatment of schizophrenia
- the treatment of moderate to severe manic episodes associated with bipolar disorders
- for the short-term treatment (up to 6 weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others
- for the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with sub-average intellectual functioning or mental retardation diagnosed

according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours which require pharmacological treatment.

The antipsychotic effect of risperidone is thought to be related to its ability to block dopaminergic D₂ receptors and serotonin (5-HT₂) receptors. The balanced central serotonin and dopamine antagonism appears to reduce the incidence of extrapyramidal side effects compared to other neuroleptic drugs.

Risperidone is well absorbed and rapidly distributed and can be administered once or twice daily for the treatment and prevention of symptoms of sudden (acute) and long lasting (chronic) psychotic disorders, including schizophrenia.

Remedica's Risperidone is available in 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg and 6mg Tablets. ■



Literature:

1. Dollery 2nd Edition, 1999 ppG65-G69, 2. Martindale 33rd Edition, 2002 pp 719-721,
3. BNF No 46 2003, 4. Pajonk F-G, Progress in Neuro-pharmacol and Biological Psychiatr, 2004; 28. 15-23.

Health matters: Taking care taking medicines

It should always be remembered that the active ingredient in a medicine is a potentially dangerous substance and is only therapeutic over the correct dosage range. Overdosing can be lethal but this is unlikely to happen if the directions are followed.

There are two different ways by which a patient may be legally given medicines: either as a result of them being prescribed by a medical practitioner or by purchasing them from a pharmacy in accordance with the advice of a pharmacist. The latter are usually known as over-the-counter (OTC) medicines. In many countries it is also possible to buy medicines in general retail outlets where no medical advice is available but in this instance the pack size is limited and the product may only be sold in accordance with the licence.



Whatever the means by which a patient obtains a medicine, in order for the treatment to be effective and safe then it is important that the instructions are followed. Such instructions will be provided by the prescriber and/or the pharmacist and are supported by the Patient Information Leaflet (PIL) which is included in the packet. This has been written by the manufacturer and approved by the body which granted a licence (marketing authorisation) for the product.

A strategy to ensure that medicines are taken in safe and effective way begins when you seek advice about your health, be it from a doctor or a pharmacist.

(I) Prepare a list of all the medicines that you are taking and remember to include all OTC products such as vitamins, pain killers and antihistamines.





(ii) Be sure to point out any allergies to medicines which you know that you have.

Once you have received your medicine then read the labels carefully and regularly, sometimes the directions will have been changed.

Only take the medicines which you have been prescribed and in the stated dose; taking more than this can be dangerous as can reducing the dose if this involves cutting a tablet in half. Many dosage forms are designed to be swallowed whole.

Make sure that you read the PIL. This will contain information on the ingredients in the medicine, who should take it, instructions on its proper use, possible side effects and any special precautions about its storage and administration.

You should not be alarmed by some of the potential side effects that are listed since the manufacturer is required to include all reported side effects however rare they may be: most people take approved medicines without any problems and there are systems in place to remove any products which are found to be unsafe from the market. In the unlikely event that you should suffer a side effect which you think may be related to your medicine then you should inform a pharmacist or your doctor.

If you are prescribed a new medicine it is a good idea to ask the pharmacist about it just to be sure that it will not interfere with other medicines that you are taking.

The number of doses of medicines that are taken every day is too large to estimate. What is certainly true is that the percentage that cause unintentional harm is very, very small. ■

Corporate Social Responsibility Remedica cares

1) Remedica donates to charity the money saved from not printing Christmas cards.

(photo 1)

Instead of sending out Christmas cards to our associates both in Cyprus and in over 100 other countries where Remedica is active, we have decided to send our Christmas wishes and Seasons' Greetings via e-mail. The money thus saved has been donated to the *Pattichis Senior Citizens' Centre* which is the only one of its kind in Cyprus and has just completed 10 years of valuable service to Limassol's senior citizens. Its main purpose is to provide services such as creative occupation and entertainment, and the chance for its senior citizen-members to become more actively involved in the community.

2) Renewal of sponsorship to MS

Association. (photo 3)

At a recent meeting with the Board of Directors of the Cyprus Association of Multiple Sclerosis, Remedica announced that it has renewed its sponsorship of the Association aiming to help the

Association to further advance its goals and promote awareness to the general public.

3) The Commissioner for the Environment visits Remedica. (photo2)

Cyprus's Commissioner for the Environment recently visited Remedica and had a meeting with the company's top management in order to see the Company's recycling system at close quarters and to exchange views on its possible extension acknowledging that Remedica is well known for its environmental policy and practice. Having established the good will of both sides to contribute further to the protection of the environment, the Commissioner was presented with a commemorative gift on the occasion of the Company's 50th anniversary. ■

Dear Friends and Associates,

Remedica's management and employees wish you a Happy Holiday Season and a Healthy & Prosperous New Year.

Instead of sending out Christmas cards to our associates both in Cyprus and in over 100 other countries where Remedica is active, we have decided to donate the money to the Pattichis Senior Citizens Centre

This Centre provides services such as creative employment and entertainment, and means to its senior citizen-members to become more active citizens.



Remedica News

1) Remedica is presented with the Export Award for Industry for the 7th time. (photo 1)

On the 7th February 2011 the official ceremony of the Export Award 2009 took place, which Remedica was awarded for the 7th time. The President of the Cyprus Republic Mr. Demetris Christofias congratulated all awardees for their contribution in the development of the Cyprus economy and stressed the importance of Cyprus as a well established peripheral business centre. The General Secretary of the Cyprus Chamber of Commerce and Industry, Mr Panayiotis Loizides, mentioned that "for Cyprus which is primarily an importing country, exports constitute a vital factor in boosting our economy" and added that "Exports are one of the important injections for any economy, since through them, "fresh income" flows into the country's vaults, whilst employment is increased and its products and services are promoted to foreign markets." The Award was received on behalf of Remedica by its Managing Director Mr. Emilius Savvides from the President of the Republic. Also present at the ceremony were the undersecretary of Foreign Affairs of Greece, Ministers, Members of Parliament, Ambassadors from various countries and many business people. After the ceremony, the awardees were invited to an official lunch at the Presidential Palace.



2) Remedica staff party. (photo 2,3,4,5)

Remedica held its annual staff party recently where attendance was the biggest so far. In his speech, Remedica's Managing Director, Mr. Emilius Savvides mentioned that the company is doing well and despite the world economic crisis it is still recruiting. He also announced that Remedica has won two prestigious awards: the In-Business Magazine Award of Excellence in Industry and the Cyprus Export Award (see separate articles), both of which he said, are due to a very large part to Remedica's staff and thanked them for their valuable contribution. He then went on to present a gift and a certificate to Mrs. Christa Vasiliadou who has completed twenty years of service with the company.



Group Managing Director, Mr. Charalambos Pattihis, gave the Chairman of the Cyprus Multiple Sclerosis Association, Mrs. Lenia Takoushi Christoforou, a cheque, representing Remedica's financial contribution towards the association and its goals. In return, Mrs. Christoforou, presented Mr. Pattihis with a glass replica of the Association's emblem.



Group Chairman Mr. Chris Pattichis, cut the Christmas cake (or Vassilopitta) and the lucky winner of the



traditional golden coin was Yiannos Ioannou.

The staff had their own piece of fun prepared and read out by Dora Demetriou and Koula Christou. Using a traditional Cyprus rhyme ("tsiattista") they thanked the Management of the Company for plotting a good business course and for following a strategy of growth that ensures the living standard of all concerned will be preserved.

After the ceremonial part which was accompanied by a rich buffet dinner, the dancing began and lasted until the early hours of the next morning.

3) Remedica wins prestigious business award. (photo 6)

In great splendour and in the presence of the political leadership and the business people of Cyprus, the IN BUSINESS AWARDS 2010 took place for a third successive year where companies and individuals that have excelled in one of the specified categories are honoured.



In his speech, the President of the Cyprus Republic, Mr. Demetris Christofias, stated: "I congratulate the IN BUSINESS AWARDS for their initiative that has its source in the late Mr. Andi Hatzikosti. I congratulate all the recipients. Definitely such initiatives promote pioneering business activity. I consider that the promotion of research and innovation and the implementation of innovative ideas constitute foundations for the future of the Cyprus economy."

The Minister of Finance in his address asserted "Businesses are the key to the development and prosperity of a place. Today's award, presented to the best Cyprus enterprise, has a special meaning both in real as well as in symbolic terms."

The Award for the best company in the Manufacturing sector was presented to Remedica's Managing Director, Mr. Emilius Savvides by the Minister of Commerce, Industry & Tourism, who mentioned that 2010 was "a difficult year due to the world economic crisis ... but despite this ... the exports of our industrial products rose by 10% ... which was an achievement." In a brief statement Mr. Savvides stated: "It is a big pleasure for us when our achievements are being recognised. When we were starting out nobody could dream that we would reach this far, but this gives us the courage to go even further. We already have plans for the extension of our operations in Cyprus. We are building a new, four-storey manufacturing unit for anticancer products and we will be making products for other European companies."

4) Launch of Anastrozole in W. Europe.

The launch of Anastrozole in W. Europe was a big success for Remedica and went as planned and without any problems. It will thus help reduce the expenditure by the health systems of these countries, as its price is lower than the originator product. Cyprus and the countries of Eastern Europe have benefited from Remedica's lower price of Anastrozole since 2008.





5) Christmas at Remedica. (photo 7,8)

At the usual Christmas gathering, which began with Christmas carols sung by Remedica's choir, staff presented our Chairman Mr. Chris Pattichis with a flower bouquet and an ornate silver plaque with their best Season's Greetings as well as their best wishes for his name day, which is on Christmas Day. Remedica's management wished everyone a Merry Christmas and urged them to enjoy the festive season taking care not to drink and drive.



6) Managers of EURES visit Remedica. (photo 9)

On the 9th February 2011, the Managers of EURES (the European network for job mobility) from 20 EU Member States visited Remedica following an initiative of the Cyprus branch of the organisation, whilst they were attending the EURES Job Fair being held on the Island. They took the opportunity to visit various company departments and be informed about the benefit packages offered by Remedica and other Cyprus employers. Following the presentation of the company and the tour, the 20 EURES Managers met with Remedica's managing director Mr. Emiliios Savvides who, after welcoming them, described Remedica's personnel needs and emphasised the difficulty in recruiting scientists. Remedica's Human Resources Officer, Mr. Martinos Demosthenous, took part in the EURES Job Fair held in Limassol on the 10th February where he had a chance to discuss with Managers from participating countries the vacancies that cannot be filled locally and presented them with information packs which they could use to assist in the search for suitable candidates from other EU Member States.



7) Visitors from the Chemistry Department of the University of Cyprus.

Remedica's state-of-the-art Quality Control Laboratories were visited by academic staff of the Chemistry Department from the University of Cyprus with a view of strengthening their collaboration with Remedica. The visitors had a chance make a close inspection of Remedica's Quality Control and Research & Development laboratories. The visit also provided an opportunity to exchange ideas on various issues faced by the academic community and the pharmaceutical industry and to discuss the new postgraduate programs of the University. Remedica already cooperates with the University, for example, through summer training programs offered to students, by participation in Career Days and the recruitment of graduates.



8) New members of the Cyprus Drugs' Council visited Remedica. (photo 10)

The newly appointed members of the Cyprus Drugs' Council visited Remedica's head office where the Managing Director, Mr. Emiliios Savvides informed the Council about the company's global activities and future plans regarding pharmaceutical production. After the introduction they visited the various departments including Research & Development, Quality Control and the production facilities. One of the most important responsibilities of the Council is to review applications and to issue Marketing Authorisations for medicinal products in Cyprus. ■

Eco-friendly tips:

The contribution of Light Emitting Diode televisions to the environment

A Light Emitting Diode (LED) television screen is a Liquid-Crystal Display (LCD) that makes use of LED backlighting. The introduction of this technology to televisions has allowed major reductions of the thickness of the housing and at the same time improvements on the colour and the contrast of the display.

Although LED televisions provide a more advanced visual experience for the viewer, what is surprising is that the manufacturers have also managed to address one of the environmental concerns associated with conventional LCD televisions.

LED televisions consume much less electricity than their LCD counterparts. The difference in energy consumption of the two technologies could be up to 40%, although some of the LED producers claim that this figure could be as high as 50%. As a result, reductions in greenhouse gas emissions and atmospheric pollution due to this reduction in electricity consumption have also been achieved. These gases include carbon dioxide which is the major contributor to greenhouse effect and therefore climate change.

The global ecosystem and the lives of animals and humans are less affected and a reduction in atmospheric pollutants such as carbon monoxide, nitrous and sulphur oxides is also achieved as are particulates. In addition these pollutants contribute to the formation of acid rain and smog which affect the health of human beings as well as being damaging to buildings. It should be noted that particulate matter is highly toxic to humans due to its ability to penetrate the respiratory system and accumulate in and irritate the lungs.

Another environmental benefit of LED technology is the fact that mercury is not a constituent of the raw materials used in production as is the case with LCD technology. As a result mercury will not be released into the environment when the television is disposed of. It should be noted that mercury is



extremely toxic and can cause major adverse effects on human health. With this in mind the European Union has set Directives that call for the limitation or, in some cases, the ban of mercury in electrical and electronic equipment. Moreover mercury is a bio-accumulative substance that has the capacity to enter the food chain. This means that organisms that contain mercury, when consumed by their predators, this mercury would enter the predator's body. If these predators are in turn consumed by humans the mercury would enter the human body where it could have serious consequences on the individual's health. ■

Regulations: Data Matrix Code

Recently the European Union in its European Pack Coding Guidelines and specifically Article 62 of EUROPEAN DIRECTIVE 2001/83/EC on CODIFICATION AND TRACEABILITY ON PACKING AND LABELS FOR MEDICINAL PRODUCTS FOR HUMAN USE, has introduced a requirement for pharmaceutical products to have 2 distinctive markings on their outer box: a *data matrix* and a *vignette sticker*. In this edition we shall be explaining the former leaving the latter for our next issue.

The EU Commission has specified in the "Directive of the European Parliament and of the Council" amending Directive 2001/83/EC dated 10 December 2008 actions to be taken by Member States to protect patient safety. A special emphasis is on mass serialisation. As such "a unique standard for the coding of pharmaceutical products will be added across Europe based on the 2d (2 dimensions) data matrix ecc-200 to be introduced on all secondary packaging of prescription products sold in the European Union." This will take the form of a Data Matrix code, which is a two-dimensional matrix barcode consisting of black and white "cells" or modules arranged in either a square or rectangular pattern. The information to be encoded can be text or raw data.

Each Data Matrix is composed of an 'L-shape' formed by two solid adjacent borders (termed the "finder pattern") and two other edges comprised of alternating dark and light "cells" or modules (termed the "timing pattern"). The area within these edges contains rows and columns of cells which code the necessary information. The location and orientation of the symbol is provided by the finder pattern whilst the timing pattern gives the total number of rows and columns in the symbol. As more data is encoded in the symbol, the number of cells (rows and columns) increases such that the symbol sizes may vary from 8×8 to 144×144 mm.



The components of the code or the GLOBAL TRADE ITEM NUMBER (GTIN) have the following part

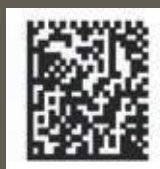
- FNC1:** Identifier for EAN 128
- 01:** application identifier for GTIN
- 0:** GTIN code: 14 characters, numeral = zero+CIP 13 digits
- 17:** application identifier for expiry date (6 digits YYMMDD)
- 10:** application identifier for batch number (up to 20 alpha-numeric characters)

Optional:

- 21:** application identifier for serial number (up to 20 alpha-numeric characters)
- e.g. **FNC1**0103400912345678**17**121024**10**12345**(21)**XXXXXXXXXXXXXXXXXX



GTIN: (01) 07046261398572
Batch: (10) TEST5632
Expiry: (17) 130331
S/N: (21) 19067811811



The Data Matrix Code will be accompanied by human readable text which will be in a font and size that are in accordance with the specific requirements of each country.

The standard requires that the data contained in the Data Matrix must be printed in plain human readable text next to the marking. The Data Matrix contains information concerning traceability and must be printed on one of the flaps (sides) of the secondary packaging. It is not permissible to print the Data Matrix Code on the underside of the packaging or on the principal face of the carton. If the Data Matrix is placed on a round surface, it must be placed so as to minimize the field depth required for correct scanning (in which case a Rectangular Data Matrix is recommended). Furthermore the Data Matrix cannot be printed on a label on the packaging. ■

A glimpse of Cyprus: Morfou

The municipality of Morfou was founded in 1883 and is one of the oldest in Cyprus. The beautiful town of Morfou is situated on the western central plain of Cyprus, near the river Serahi and its district area is about 5636 hectares. Its population at present is estimated at ten to twelve thousand.

Morfou, rich in history and tradition, has been inhabited since ancient times and this has been proven by the evidence of the many settlements that have been excavated or found around it.

As for the origin of the name Morfou, the most probable version is that it is related to the ancient Greek goddess Aphrodite and that one of the names the goddess was worshipped under in the ancient Greek world was Morfo. As Morfo, Aphrodite was worshipped mainly in Lakonia of Peloponnesus in Greece. Subsequently this version connects Morfou with the Lakonians, who probably had settled on the western part of the large central plain of the island.

The town of Morfou experienced great development and this was due mainly to its economy that flourished due to its fertile land and the endless citrus plantations that existed

in the area. Thus Morfou was always a leader in aspects such as culture, literary and other arts and in sports.

Unfortunately, on the 16th of August 1974, with the completion of the second phase of the Turkish invasion, Morfou was occupied by the Turkish invaders. Its legitimate inhabitants were displaced from their homes and forced to move to the southern parts of Cyprus. Since then, the municipality of Morfou has devoted itself to the struggle for a just and viable solution to the Cyprus Problem that would allow all displaced persons to return to the land of their forefathers.

Ever since 1974, the municipality has set the struggle for this return as its priority which it feels is justified: however it is also active in areas related to culture and the religious traditions of Cyprus by which it hopes to preserve the memory of the occupied land.

As part of these activities, the municipality has so far been twinned with nine other municipalities. Five are in Greece (Sparta, Kalavryta, Ermoupolis, Orestiada and Mesolongi), one in France (Saint Cyr-sur-Loire), one in Great Britain (Barnet), one in

Malta (Zurrieq) and finally in 2008 it was twinned with the municipality of Slovenj Gradec which is in Serbia.

Besides the twinning with the above, the municipality of Morfou has forged excellent relations with many other towns, through its participation in international and other organisations. It is also a member of the Aphrodite Town Network, of the European Grouping of Territorial Cooperation "Amphictonia" as well as of the international organisation "Peace Messenger Cities" on which it also has one of the vice-presidency seats of the Executive Committee. ■

