Remedica
FOR A HEALTHIER WORLD

Newsletter 29

Contents

Welcome note

Welcome to the 29th issue of our Newsletter where we present our associates in Iraq, our Packaging Supervisor and our product Tarem® (Erlotinib).

In our Environmental Issues we report on over-population, in Health Matters we have Bronchial Asthma and in the ABC of Pharmacy we continue with the term “Air Handling Unit”.

In Corporate Social Responsibility we have educational visits from students, our Health & Safety Week and our financial contribution to the fundraising efforts of the Cyprus Red Cross.

The main focus in Remedica News is that our company has been selected as one of the top ten in our category in the whole of the EU.

In addition we feature an article on the Transatlantic Trade and Investment Partnership. ■

Charalambos Pattihis
Group CEO

Remedica Worldwide:

Al-ASEEL Drug Scientific Bureau - Republic of Iraq

Al-ASEEL Scientific Bureau is based in Baghdad and distributes Remedica's products in the entire Iraqi region, including Kurdistan, which covers a total area of 438,317 sq km. The population of Iraq is 32,585,692 (July 2014 est.) consisting of Arab 75%-80%, Kurdish 15%-20%, Turkoman, Assyrian, and other 5%. The official languages are Arabic and Kurdish while the government system is based on the Republican parliamentary democracy and the legal system is a mixture of civil and Islamic law. Health expenditure reaches to 3.6% of the GDP. Moreover there is a physician for every 1639 people and a hospital bed for every 769 civilians.

Al-ASEEL Scientific Bureau was founded in 1/6/1999 as a leading institution in representing pharmaceutical companies, distributing its pharmaceuticals as well as other specialised medical products in Iraq.

The main office is situated in Baghdad at Al-Bataween area with two temperature controlled warehouses of 2000 m^3 each approved by the MOH for the storage of medicines. 24 employees are currently working over 12 hours a day to introduce pharmaceutical products and medical appliances to the Iraqi market for both the private and public sector. The cumulative experiences in the pharmaceutical sector of the Iraqi market for many years, as well as the satisfactory knowledge of techniques and methods of distribution and sales, gives the power to the office personnel to achieve their goals within a short period of time.

The current situation in Iraq is undergoing a phase of security instability. The shortage of infrastructure in most provinces, particularly the shortage of drinkable water and the pollution of the environment in addition to the wars that the country suffered and is still suffering, make the medical and health situation in Iraq to experience a critical stage that requires the provision of medical staff and necessary medicines on a regular basis, taking into consideration that the Iraqi medical and health plan requires a large number of hospitals in Iraq to provide an appropriate environment. There are incomplete tenders (in progress) of a large number of hospitals, which also requires the provision of other medical supplies such as medications, developed surgery tools as well as the requirements of the hospitals infrastructure to enable them to function properly.

Nowadays, the demand for medicine in Iraq, for the central and southern provinces in particular, is increasing. Al-Aseel Scientific bureau's experience in this area depend on adopting a balanced and mature policy to enable them to provide the necessary medications to the hospitals as well as the private pharmacies. This is due to the long experience in the Iraqi market and its constant needs over the previous years. All these skills enhanced the development of the company as pioneers in this field, approved by the State and the Ministry of Health in providing medicines and supplements.

Al-Aseel Scientific bureau is already representing Remedica for more than ten years and has managed within the recent period to achieve big steps in stabilising Remedica products in the Iraqi pharmaceutical market, either through finalising the registration or by sending hundreds of batches to the Iraqi central lab and passing successfully all the analysis test.

Remedica is considered now in Iraq as a pioneer and one of the most reliable European companies and is placed together with the multinational companies and as was announced by the Iraq Ministry of Health and the Syndicate of Iraqi Pharmacists in 2014. ■

Health Matters:

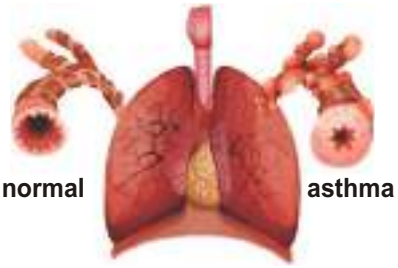
Bronchial Asthma, a quick review

Kleomenis Benidis M.D.
Pulmonologist, Pulmonary Department Nicosia General Hospital, Cyprus.
Board member - Cyprus Respiratory Society.

Asthma is a chronic inflammatory disease that causes the airways of the lungs leading to wheezing, shortness of breath, chest tightness, and coughing[3]. Allergies are strongly linked to asthma and to other respiratory diseases such as chronic sinusitis, middle ear infections, and nasal polyps. Most interestingly, a recent analysis of people with asthma showed that those who had both allergies and asthma were much more likely to have nighttime awakening due to asthma, miss work because of asthma, and require more powerful medications to control their symptoms[1].

Between 100 and 150 million people around the globe suffer from asthma and this number is rising. In Western Europe as a whole, asthma has doubled in ten years, according to the UCB Institute of Allergy in Belgium[2]. According to the CDC, more than 25 million Americans, including 6.8 million children under age 18, suffer with asthma today[1].

Asthma - Inflamed Bronchial Tube



Causes[3]

In persons who have sensitive airways, asthma symptoms can be triggered by breathing in substances called allergens or triggers.

Common asthma triggers include:

- Animals (pet hair or dander)
- Dust mites
- Certain medicines (aspirin and other NSAIDS)
- Changes in weather (most often cold weather)
- Chemicals in the air or in food
- Exercise
- Mold
- Pollen
- Respiratory infections, such as the common cold
- Strong emotions (stress)
- Tobacco smoke

Many people with asthma have a personal or family history of allergies, such as hay fever (allergic rhinitis) or eczema. Others have no history of allergies.

Symptoms[3]

Most people with asthma have attacks separated by symptom-free periods. Some people have long-term shortness of breath with episodes of increased shortness of breath. Either wheezing or a cough may be the main symptom. Asthma attacks can last for minutes to days, and can become dangerous if the airflow is severely blocked.

Symptoms include:

- Cough with or without sputum (phlegm) production
- Shortness of breath that gets worse with exercise or activity
- Wheezing

Other symptoms that may occur:

- Abnormal breathing pattern - breathing out takes more than twice as long as breathing in
- Breathing temporarily stops
- Chest pain
- Tightness in the chest
- Pulling in of the skin between the ribs when breathing (intercostal retractions)

Emergency symptoms that need prompt medical help:

- Bluish color to the lips and face
- Decreased level of alertness, such as severe drowsiness or confusion, during an asthma attack
- Extreme difficulty breathing
- Rapid pulse
- Severe anxiety due to shortness of breath
- Sweating

Examination and Tests[3]

Your Pulmonologist will use a stethoscope to listen to your lungs. Wheezing or other asthma-related sounds may be heard. Tests that may be ordered include:

- Allergy testing - skin or a blood test to see if a person with asthma is allergic to certain substances, measurement of Total IgE.
- Perform Lung function tests, including peak flow measurements
- Chest x-ray
- Arterial blood gas (usually only done with patients who are having a severe asthma attack)

Talk with your Pulmonologist about the use of Peak Flow Meter. A peak flow meter is a simple device to measure how quickly you exhale air out of your lungs. It can help you see if an attack is coming, sometimes even before symptoms appear. Peak flow measurements help let you know when you need to take medicine or other action.

Treatment[2,3]

Because asthma is a chronic condition, it usually requires continuous medical care. Medication is not the only way to control asthma. It is also important to avoid asthma triggers - stimuli that irritate and inflame the airways. Each person must learn what triggers he or she should avoid.

The goals of treatment are:
- Control airway swelling
- Stay away from substances that trigger your symptoms
- Help you to be able to do normal activities without asthma symptoms

There are two kinds of medicines for treating asthma:

Long-term Medicines. These are also called maintenance or control medicines. You must take them every day for them to work. Take them even when you feel ok. Some long-term medicines are breathed in (inhaled), such as steroids and long-acting beta-agonists. Others are taken by mouth (orally).

Quick-relief Medicines. These are also called rescue medicines. They are taken: for coughing, wheezing, trouble breathing, or an asthma attack, just before exercising to help prevent asthma symptoms caused by exercise.

A severe asthma attack requires an emergency checkup by your Pulmonologist. You may also need a hospital stay. There, you will likely be given oxygen, breathing assistance, and medications given through a vein (IV).


Pollen


Mold


Dust mites


Pet dander

References
1. Asthma Health Center, www.webmed.com/asthma
2. WHO, Bronchial asthma
3. Medlineplus Medical Encyclopedia

Remedica People

In this issue we present two of our employees from the Production Department, Mr Pambos Konstantinou (Supervisor of the Coating Section) and Mr Yiannakis Charalambous (Supervisor of the Granulation Section) with the longest service.

Mr Pambos hails from Ineia of Paphos. After finishing elementary school, he had to look for a job where the only one available locally was as a trader in fabrics and, later on, became a tailor.

After 1974 he came to Limassol and joined the organisation in 1977, at a time when the main line of business was the production of carbon dioxide gas, aerosols and cosmetics. When production of pharmaceuticals first begun, the Production Department did not comprise the distinct Sections like today, and Pambos thus worked as an operator in all stages of the production process. He witnessed the first tentative steps in small-scale tablet making using manually-operated machines such as a tablet press and granulation with a handheld spray gun.

He had the honour and good fortune to have worked and be trained alongside the founder, Mr Chris Pattichis, to whom he is grateful for everything he taught him. When the Production Department was organised into Sections, he took over as Supervisor of the Coating Section. He is the first employee to come to work every morning at 5.30.

He is married and has 3 children.

Mr Yiannakis graduated from a technical school and hails from Pelendri.

After completing his military obligations, he worked as a fitter and subsequently migrated to Iraq where he worked for 2 years at a construction site.

He joined the company's workforce in 1983 and had the opportunity to work in all sections of the production process under the guidance of Dr. Loukas Eleftheriou (Production Manager) where he carried out the first formulation trials that resulted in many of the company's products.

He was trained alongside Dr. Loukas by an expert from Denmark on the use of granulating machines. In recognition of his performance and contribution, in 1998 he was promoted to Supervisor of the Granulation section which he leads to this day transferring his valuable knowledge and experience to younger staff.

He is married and has 4 children.

Environmental Issues:
Overpopulation

Overpopulation is described as the state where the current number of human beings has overcome the carrying capacity of the earth to sustain them. *As Wright and Nebel* suggest, since the dawn of human existence until the 1800s, human population has been increasing in a slow and steady rate. Human population had reached 1 billion benchmark in around 1830s. One hundred years later human beings had been doubled in numbers. In 1960s the human population had exceeded 5 billion individuals. Another billion had been added in the population in 1999 resulting to 6 billion individuals. Nowadays, the global human population reached 7.3 billion individuals.

The reasons for the rapid explosion of human population lie in advances and breakthroughs of science and technology. Applied science provided the discovery of the causes of diseases which contributed to high mortality rates. As years went by, pharmaceuticals and vaccines had been developed, which provided the means for tackling of many often fatal diseases like pneumonia, smallpox, diphtheria, measles and scarlet fever. Moreover, hygiene and food quality standards had been developed resulting to the reduction of disease spreading and the improvement of human immune system respectively. While average life span increased during time, yet the fertility rate had remained unchanged. The combination of all these factors has led to the explosion of population.

Although human average life span has been rapidly increased, this came at a toll for the environment, as the earth was struggling to sustain these numbers. Overpopulation led to an increased demand for living space, natural resources, water, food and provisions. Demand for food and housing has driven land use changes in order to be turned into agricultural land and households respectively. As an effect, deforestation, landscape alternation and loss of biodiversity has been inevitable. In addition, increased energy demand for heating and transportation has driven the extraction of natural resources like timber and hydrocarbons. This led to global warming and climate change as effect deforestation and the increasing release of carbon dioxide to the atmosphere.

Moreover, as a result of overpopulation, increased consumption of natural resources has also led to an increased waste and wastewater production. Following this, even more land is required in order for the waste to be disposed or managed.

It should be noted that overpopulation could lead to unsustainable effects that have the potential to threat human population itself. Taking into consideration that the earth's carrying capacity is limited, further steps should be taken in order for overpopulation to be tackled.

These include the introduction of family planning education and practices, especially in developing countries where personal or communal beliefs encourage an increased fertility rate. Overpopulated countries and local authorities could also implement measures to encourage family planning and a reduction of fertility rate.

Although overpopulation is seen by many as a major environmental concern, yet still, in order for this issue to be tackled effectively, further actions should be taken at a global scale. ■

Corporate Social Responsibility:
Remedica Cares

1) Educational visits to Remedica from students. (photo 1, 2)
Students from the Medical Representatives course and that of Pharmacy Assistants (Technicians) course of the KES College visited Remedica and were given a tour of its facilities. The students were briefed about the company's operations and its contribution to both a local level as well as worldwide by Mr. Andreas Hadjipanayis, Marketing Manager and Mrs. Maria Roussou Quality Control Manager.

In the framework of the course on International Marketing, MBA students from the University of Cyprus visited Remedica where they had the opportunity to learn from the company's Marketing Manager, Andreas Hadjipanayis, about pharmaceutical marketing and how the pharmaceutical sector operates both on a global as well as a local level.

2) Health & Safety Week at Remedica. (photo 3)
As part of the continued efforts by Remedica in elevating health and safety standards, the company conducted an internal awareness campaign on various topics including the safe use of ladders, proper use of fire extinguishers, working at elevated heights, avoiding contact with moving parts of machinery, risks from chemicals, inflammable materials and electricity and the proper way to lift loads. The importance of First Aid as a way to reduce the consequences of an accident was also pointed out. Emphasis was given on preventive measures and safe practices as well as on how to use preventive measures. Finally, special attention was paid to the prevention of occupational illnesses. Each day of the campaign focused on a specific theme and the whole presentation was loaded onto the company's intranet to act as a reference and to aid staff training.

3) Remedica contributes to the Cyprus Red Cross fundraising efforts. (photo 4)
The annual fundraiser of the Cyprus Red Cross was recently held in order to raise money for the needs of its various programmes and missions in Cyprus and abroad. For yet another year, Remedica supported these efforts with financial aid.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The ABC of Pharmacy:
Air Handling Unit (AHU)

An Air Handling Unit or an Air Handler is a piece of equipment used to condition the air prior its entry in several areas. By conditioning of the air we mean the Heating, Cooling, Humidification, dehumidification and Filtration of the Air.

The conditioning of the air is done in such a way to fulfil the human comfort requirements and/ or the environmental conditions of the served area in general. After conditioning the air is circulated through the area to be served by utilising supply and return fans.

The air handler is usually a large metal box that contains a blower, heating and cooling elements, filter chambers, sound attenuators, dampers and humidification / dehumidification elements. The air handler connects to ductwork that in turn, distributes the conditioned air throughout the building or area to be served.

There are some units that admit and discharge air directly to and from the building or area, without the need for ductwork.

Remedica News

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1) Remedica: one of Europe's leading companies.

The Hilton Hotel in London's Park Lane provided the elegant venue for the UK to host the Gala Event for the European Business Awards (once again sponsored by RSM) to be presented for the 11th time on 26th May 2015. More than 500 awardees and their guests were present to see the finalists receive their awards from an impressive array of European ambassadors and captains of industry.

The life achievement award went to Sir John Madejski whose inspiring acceptance speech set the tone for the whole evening: his message, it is European businesses and their leaders which have made the EU prosperous. Evidence of this was provided by statistics such as the 110 companies that were in the final round of the awards and were present on the night employed more than 2.5 million staff, generated profits of €60 billion and had a joint value of €1.5 trillion (equivalent to the wealth of Italy before the credit crisis of 2008). There were prizes being awarded in 11 categories, with 10 companies short-listed for the final round of each so there were 110 representatives drawn from 30 European states. When it is taken into account that at the outset there were 24000 candidates from 33 countries being considered then getting to this final stage was a tremendous achievement. The pinnacle for each of course was being at the final and the atmosphere became progressively more electric as each award was made.

The small party representing Remedica became more and more anxious as the time for the fifth category to be presented approached. This was for "Import/Export Award" and Remedica was one of the 10 companies to be called to the platform in the person of Charalambos Pattihis, Group Chief Executive Officer. The other countries with finalists in this category were Poland (2), Spain (2), United Kingdom (2), Luxembourg, Latvia and the Former Republic of Macedonia (FYROM) and the specialties were Healthcare, IT Technology, Manufacturing, Pharmaceutical Science and Construction. Each finalist was presented with a Ruban d'Honneur medal.

The judges were anxious to point out that decisions at this level come down to very fine margins and any one of those on the platform could easily have been the winner. It was a tremendous achievement for a company like Remedica to be selected as one of the top ten in their category in the whole of Europe, particularly when it is considered that Cyprus is the third smallest of the 28 official EU states and constitutes only 0.17% of the Union's total population.

Also, Remedica is the first company from Cyprus to reach this stage of the European Business Awards and our CEO was very proud to be among such an august group and to receive the accolades which were quite rightly bestowed upon the company which was created by his father, Chris Pattichis, some 55 years ago and is still actively involved in its day-to-day management.

However, if there was one winner on the night it would be the whole European Business Community: many of the presenters and winners gave a strong message to the host nation that it was only by remaining in the EU that all nations would continue to prosper. It is to be hoped that the UK will be in a position to be selected to host the event on a future occasion.

2) Employment opportunities in the Cyprus pharmaceutical industry.

In the context of the 7th Pancyprian Pharmaceutical Congress, Marketing Manager of Remedica, Andreas Hadjipanayis presented the international trends and prospects of the pharmaceutical market in Cyprus.

He stressed the importance of the Cyprus pharmaceutical industry and the contribution of the sector to Cyprus' GDP and the prospects for further development.

Finally he presented the employment opportunities in Cyprus for pharmacists, pharmacy technicians/assistants, and medical representatives in the pharmaceutical industry.


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TTIP- Transatlantic Trade and Investment Partnership

Introduction

The Transatlantic Trade and Investment Partnership (TTIP) aims for a formal agreement between the USA and the EU that shall "liberalise one-third of global trade". TTIP is about reducing the conflicts of duplication between the EU and the USA, thus providing economic benefits, in particular on rules regarding pharmaceutical, agricultural, and financial trading. It is estimated that the TTIP would boost the EU's economy by €120 billion, the USA economy by €90 billion and the rest of the world by €100 billion. A final agreement would have 24 chapters, grouped together in 3 parts:

1. Market access:

In this chapter there are 5 actions to be taken including:

- **Trade in goods and custom duties**
- **Services**
- **Public procurement**
- **Rules of origin**
- **Specific Industries**
- **Textiles**
- **Vehicles**
- **Pesticides**
- **Pharmaceuticals:**

Avoid unnecessary costs from different EU-USA regulations
Speed up time for product approval
Maintain and harmonise high safety standards

The EU aims to achieve recognition on each other's inspections of manufacturing plants, based on principles and guidelines known as GMP. This way both sides will benefit from each other's inspections by avoiding duplications. This agreement will enable both sides to exchange information that makes it easier to decide whether to approve medicines. TTIP will allow close collaboration in areas such as generic medicines. In the area of biosimilars regulators close collaboration will be fostered in the area of EU-USA requirements for medicines similar to biological medicines which have already authorised such as cancer or auto-immune disorders.

Remedica has put forward specific proposals to the Cyprus government, which were forwarded to the European Commission, for

-mutual recognition of inspections carried out in production premises in relation with Good Manufacturing Practice (GMP)

-mutual recognition of the standards / analytical methods and specifications

-further harmonisation of registration procedures and related documentation, and finally the

-harmonisation of guidelines and the mutual recognition of bio-equivalence studies (clinical studies carried out on humans to verify that a generic product is equivalent also in-vivo (i.e. inside the body) as the original product (reference product).

2. Regulatory cooperation

In this chapter there are 3 actions including:

- **Regulatory Cooperation:** reduction of compliance regulatory costs without lowering the levels of protection for spur growth and jobs.
- **TBT-technical barriers to entry:** this section will enable EU to use international standards to make it easier to export to the USA.
- **Food safety and animal and plant health in TTIP:** the aim is to minimise effects of regulations on trade by encouraging the EU and the USA regulators to collaborate.

3. Rules

This is the chapter with the biggest number of actions emphasising the fact that TTIP is more about simplifying rules and hence costs for facilitating trade of goods and services between EU-USA.

- **Trade and sustainable development:** The main aim is to support social progress by reinforcing labour and environmental governance, fostering civil society, involvement on TSD issues, promoting corporate social responsibility in the EU and the USA companies.
- **Energy and Raw materials:** Its aim is to promote access to energy and raw materials via the agreement on common rules.
- **Customs and trade facilitation in TTIP:** This would facilitate companies trading goods between the EU and the USA, to get their goods through customs, ensure that firms can only export goods which abide to EU rules and protect people and the environment.
- **SMEs in TTIP:** The aim here is inter alia to ensure SME's can find all the information they need to export to, import from or invest in the USA, including customs duties, taxes, regulations and customs procedures, market opportunities.
- **Investment protection in TTIP:** to guarantee that governments will treat investment between the EU and the USA in line with some basic principles which prohibit: discrimination, expropriation of foreign investments without compensation, denial of justice to foreign investors in domestic courts, abusive or arbitrary treatment of the EU and the USA investors in each other's territory.
- **Competition policy in TTIP:** to stop firms from fixing prices or abusing market power, ensure private companies can compete with state-owned ones on equal footing and make sure that state subsidised firms are done so transparently.
- **Intellectual property rights (IPR) and geographical indications (Gis) in TTIP:** to raise awareness of the role of IPR in encouraging innovation and creativity, protect the people's and firms' innovative ideas for the production of high quality products and services by enforcing IPR rules in a balanced way.
- **Government to Government dispute settlement:** sort out any differences with the USA when interpreting and implementing TTIP.

Our Products: Tarem® (Erlotinib)

Tarem® film-coated tablets contain the active substance erlotinib (as hydrochloride) which belongs to the class of antineoplastic agent protein kinase inhibitor.

Erlotinib is an epidermal growth factor receptor/human epidermal growth factor receptor type 1 (EGFR also known as HER1) tyrosine kinase inhibitor. Erlotinib potently inhibits the intracellular phosphorylation of EGFR. EGFR is expressed on the cell surface of normal cells and cancer cells. In non-clinical models, inhibition of EGFR phosphotyrosine results in cell stasis and/or death.

EGFR mutations may lead to constitutive activation of anti-apoptotic and proliferation signaling pathways. The potent effectiveness of erlotinib in blocking EGFR-mediated signalling in these EGFR mutation positive tumours is attributed to the tight binding of erlotinib to the ATP-binding site in the mutated kinase domain of the EGFR. Due to the blocking of downstream-signaling, the proliferation of cells is stopped, and cell death is induced through the intrinsic apoptotic pathway. Tumour regression is observed in mouse models of enforced expression of these EGFR activating mutations.

Tarem® is indicated for the first-line treatment of patients with locally advanced or metastatic nonsmall cell lung cancer (NSCLC) with Epidermal Growth Factor Receptor (EGFR) activating mutations.

Tarem® is also indicated as monotherapy for maintenance treatment in patients with locally advanced or metastatic NSCLC with stable disease after 4 cycles of standard platinum-based first-line chemotherapy.

Additionally, it is indicated for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen.

When prescribing Tarem®, factors associated with prolonged survival should be taken into account. No survival benefit or other clinically relevant effects of the treatment have been demonstrated in patients with Epidermal Growth Factor Receptor (EGFR)-IHC negative tumours.
Tarem® in combination with gemcitabine is indicated for the treatment of patients with metastatic pancreatic cancer.

When prescribing Tarem®, factors associated with prolonged survival should be taken into account. No survival advantage could be shown for patients with locally advanced disease.
Tarem® treatment should be supervised by a physician experienced in the use of anti-cancer therapies.

Patients with Non-Small Cell Lung Cancer:
EGFR mutation testing should be performed prior to initiation of Tarem® therapy in chemo-naïve patients with advanced or metastatic NSCLC.
The recommended daily dose of Tarem® is 150mg taken at least one hour before or two hours after the ingestion of food.

Patients with pancreatic cancer:
The recommended daily dose of Tarem® is 100mg taken at least one hour before or two hours after the ingestion of food, in combination with gemcitabine. In patients who do not develop rash within the first 4-8 weeks of treatment, further Tarem® treatment should be re-assessed.

When dose adjustment is necessary, the dose should be reduced in 50mg steps.
Concomitant use of CYP3A4 substrates and modulators may require dose adjustment.

Patients with hepatic impairment:
Erlotinib is eliminated by hepatic metabolism and biliary excretion. Although erlotinib exposure was similar in patients with moderately impaired hepatic function (Child-Pugh score 7-9) compared with patients with adequate hepatic function, caution should be used when administering Tarem® to patients with hepatic impairment. Dose reduction or interruption of Tarem® should be considered if severe adverse reactions occur. The safety and efficacy of erlotinib has not been studied in patients with severe hepatic dysfunction. Use of Tarem® in patients with severe hepatic dysfunction is not recommended.

Patients with renal impairment:
The safety and efficacy of erlotinib has not been studied in patients with renal impairment (serum creatinine concentration >1.5 times the upper normal limit). Based on pharmacokinetic data no dose adjustments appear necessary in patients with mild or moderate renal impairment. Use of Tarem® in patients with severe renal impairment is not recommended.

Paediatric population:
The safety and efficacy of erlotinib in patients under the age of 18 years has not been established. Use of Tarem® in paediatric patients is not recommended.

Smokers:
Cigarette smoking has been shown to reduce erlotinib exposure by 50-60%. The maximum tolerated dose of Tarem® in NSCLC patients who currently smoke cigarettes was 300mg. Efficacy and long term safety of a dose higher than the recommended starting doses have not been established in patients who continue to smoke cigarettes. Therefore, current smokers should be advised to stop smoking, as plasma concentrations of erlotinib in smokers as compared to non-smokers are reduced.

Tarem® is available in strengths of 25mg, 50mg, 100mg and 150mg film-coated Tablets.

References: Summary of Product Characteristics of Tarceva Tablets.

Remedica
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