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THESYNAPSE

THE MEDICAL PROFESSIONALS' NETWORK

- Percentage disability reports in the medical field
- The pharmacist's Jekyll and Hyde behaviour
- Childhood Mortality in Malta
- Meeting Dr Josie Muscat

Volume 14 Issue 05 ISSN number 2313-8084

Augmentin® ES

600 mg/42.9 mg/5 ml

Amoxicillin/Clavulanate Potassium

Powder for oral suspension

Augmentin® SR

1000 mg/62,5 mg

Amoxicillin/Clavulanic Acid

Prolonged release tablets

Spreading infectious energy and liveliness!

Mini Abridged Prescribing Information: *Please refer to full Summary of Product Characteristics (SPC) before prescribing.*

TRADE NAMES: Augmentin ES and Augmentin SR. **ACTIVE INGREDIENTS:** Amoxicillin (as trihydrate) and potassium clavulanate. **PRESENTATIONS: Augmentin ES 600 mg/42.9 mg/5 ml powder for oral suspension.** Supplied in 100 ml glass bottle with a dosing spoon. **Augmentin SR 1000 mg/62.5 mg prolonged-release tablets.** Supplied in 28 tablet packs. **INDICATIONS**: *Augmentin ES:* for the treatment of acute otitis media and community acquired pneumonia infections in children aged at least 3 months and less than 40 kg body weight, caused or thought likely to be caused by penicillin-resistant *Streptococcus pneumoniae*. *Augmentin SR:* for the treatment of community acquired pneumonia in adults and adolescents aged at least 16 years, caused or thought likely to be caused by penicillin-resistant *Streptococcus pneumoniae.* **POSOLOGY & ADMINISTRATION:** Oral use. *Augmentin ES:* recommended dose of is 90/6.4 mg/kg/day in two divided doses. *Augmentin SR:* recommended dose of two tablets twice daily for seven to ten days. To minimise potential gastrointestinal intolerance, administer at the start of a meal. **CONTRAINDICATIONS:** Hypersensitivity (and past history of) to the active substances, to any penicillins or to any of the excipients. **SPECIAL WARNINGS & PRECAUTIONS:** Before initiating therapy careful enquiry of previous hypersensitivity reactions to beta-lactams. Where an infection is proven to be due to an amoxicillin susceptible organism, a switch to an amoxicillin-only preparation should be considered. Convulsions may occur in patients receiving high doses or who have impaired renal function. Concomitant use of allopurinol increase likelihood of allergic skin reactions. Prolonged use may occasionally result in overgrowth of non-susceptible organisms. *Augmentin ES:* contains aspartame (E951), a source of phenylalanine. The suspension also contains maltodextrin (glucose). *Augmentin SR:* contains 29.3 mg (1.3 mmol) of sodium per tablet. *Refer to SPC's for full list of precautions.* **INTERACTIONS:** Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity. Concomitant use of probenecid is not recommended. If co-administration with oral anticoagulants is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin. Moreover, adjustments in the dose of oral anticoagulants may be necessary. Clinical monitoring should be performed during the combination with mycophenolate mofetil and shortly after antibiotic treatment. **PREGNANCY & LACTATION:** Use should be avoided unless considered essential by the physician. **UNDESIRABLE EFFECTS:** Very common (≥1/10): diarrhoea. Common (≥ 1/100, < 1/10): mucocutaneous candidosis, nausea, abdominal pain. *Refer to SPC's for full list of undesirable effects*. **AUTHORISATION NUMBERS:** AA 1051/00101-2. **MARKETING AUTHORISATION HOLDER:** GlaxoSmithKline Bulgaria EOOD. **LEGAL CATEGORY:** POM. **DATE OF PREPARATION:** September 2015.

In order to ensure that this product information reflects the most up-to-date clinical and post-marketing surveillance data, please always refer to the latest Summary of Product Characteristics (SPC) which is available from GlaxoSmithKline (Malta) Ltd (Tel: +356 21238131)

REPORTING ADVERSE EVENTS (AEs):

If you become aware of any AEs, medication errors and/or use during pregnancy in association with GSK products, please report the event promptly to: GSK (Malta) Limited, 1, De la Cruz Avenue, Qormi QRM 2458, Malta (Tel: +356 21238131)

Alternatively, any suspected AEs and medication errors can also be reported via the national Adverse Drug Reactions (ADRs) reporting system:

Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to the Malta Medicines Authority, Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt

Prepared: October 2015
Job No: MLT_GIB/AES/0011/14(1)

HOW SUPERSTITION IS CURING ANAEMIA IN CAMBODIA

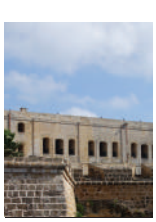
Superstition has always been closely associated with medicine. Perhaps the most well-known illustration is the infamous Pandora's box, first hinted at in 7th century BC, by the Greek poet Hesiod. In Greek mythology, Pandora is the first woman on earth who disobeys Zeus and opens the box, releasing all the evil in the world, including illness and diseases.

Nonetheless, it is an earlier document, *Ebers Papyrus,* which evidences the intimacy between superstition and medicine. Dating back to 1550 BC, this 110-page Egyptian scroll is believed to reproduce knowledge from earlier texts, possibly 3400 BC. It illustrates the relationship between medicine and various Egyptian deities. Most interestingly, it encourages mothers to breastfeed their infants for three years, "*Nothing accords more with natural law than one's mother milk*". People considered the mother deity Isis to champion this concept since she repeatedly appeared in motifs breastfeeding her son Horus. Ebers Papyrus even describes the use of milk stimulants, "*Spine of Nile-perch, fried in oil/fat, her spine is anointed therewith*". When breastfeeding failed, the mother recoursed to the deity of childbirth and fertility, Taweret.

Superstition still seems to be relevant today, at least in specific cultures. Let us consider Cambodia as an example. In 2012, it was acknowledged that 50-80% of Cambodian children < 5 years suffer from anaemia. There are various reasons for this, including iron-deficiency, vitamin A and other micronutrient deficiencies, helminths, malaria as well as hemoglobinopathies. Of these, the WHO estimates that approximately 50% is attributable to iron-deficiency. In view of this fact, iron supplements, iron fortified candies, fortified staples and micronutrient powders have all had varying degrees of success in offsetting this situation. However, such measures come at a cost and depend largely on patient compliance. Thus, researchers have advocated an adventitious source of dietary iron, namely, cast iron pots. Studies demonstrated that cooking food in iron pots increases the iron content of foods and that this iron is bioavailable. However, randomized controlled trials reported low acceptability since cast-iron pots were heavier and rusted more easily. What to do next?

A small, lightweight cast iron ingot in the shape of a smiling Cambodian fish, **The Lucky Iron Fish,** is being marketed as an alternative source of iron. Acceptance by the people was good since fish symbolize luck in Cambodian culture. Randomized controlled trials have indeed found that within a year this strategy has increased hemoglobin concentrations by 11.6g/L and reduced anemia by half, compared to the control group. This method simply involves cooking with the Lucky Iron Fish for 10 minutes and adding some citrus juice (to increase iron bioavailability). If this is not lateral thinking, then what is?

Ian Ellul



Cover: Fort Chambray in Gozo served as a convalescent depot for the wounded soldiers from the Ionian Islands (1822), Crimean war (1855), Anglo-Egyptian conflict (1882) and the First World War. Between 1934-1983 it was used as a mental hospital. Between 1937-1956, the old married quarters, renamed Sacred Heart Hospital was used as a leprosarium.

Photo credit: Dr Ian Ellul

Editor-in-Chief: Dr Wilfred Galea
Managing Editor: Dr Ian C Ellul
Sales & circulation Director: Carmen Cachia

Email: mpl@thesynapse.net
Telephone: +356 21453973/4

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OUR COLLABORATORS

GMS GERMAN-MALTESE MEDICAL SOCIETY
MMSA Malta Medical Students' Association
MPSA
MADS Malta Association of Dental Students

The magazine is distributed free of charge to all Maltese doctors, pharmacists & dentists, as well as students of the aforementioned professions, with a print run of 3500 copies.

Annual subscription rates outside Malta: Six issues €90 or equivalent, worldwide

A maintenance bronchodilator treatment for patients with COPD who are breathless

ANORO™ ELLIPTA™
umeclidinium/vilanterol
breathe...

Anoro® Ellipta® (umeclidinium bromide/vilanterol) Abridged Prescribing Information

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 on SPC how to report adverse reactions.

Kindly consult the full Summary of Product Characteristics (SmPC) before prescribing

Trade Name: Anoro® Ellipta® **Active Ingredients:** 55 micrograms umeclidinium bromide and 22 micrograms vilanterol (as trifenatate). **Pharmaceutical Form:** 55 micrograms/22 micrograms inhalation powder, pre-dispensed. **Indications:** Maintenance bronchodilator treatment to relieve symptoms in adult patients with Chronic Obstructive Pulmonary Disease (COPD). **Dosage and administration:** Inhalation only. One inhalation once daily of Anoro® Ellipta® at the same time of the day. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate and magnesium stearate). **Precautions:** Anoro® Ellipta® should not be used in patients with asthma. Treatment with Anoro® Ellipta® should be discontinued immediately in the event of paradoxical bronchospasm and alternative therapy initiated if necessary. Cardiovascular effects may be seen after the administration of muscarinic receptor antagonists and sympathomimetics therefore Anoro® Ellipta® should be used with caution in patients with severe cardiovascular disease. Anoro® Ellipta® should be used with caution in patients with urinary retention, narrow angle glaucoma, convulsive disorders, thyrotoxicosis, hypokalaemia, hyperglycaemia and severe hepatic impairment. No dosage adjustment is required in the elderly, in renal impairment or mild to moderate hepatic impairment. **Acute symptoms:** Anoro® Ellipta® is not indicated for acute episodes of bronchospasm. Warn patients to seek medical advice if use of short-acting inhaled bronchodilator increases. A re-evaluation of the patient and of the COPD treatment regimen should be undertaken. **Interactions with other medicinal products:** Interaction studies have only been performed in adults. Avoid beta- adrenergic blockers since this may weaken or antagonize the effect of $beta_2$-adrenergic agonists. Caution is advised when co-administering with strong CYP3A4 inhibitors (e.g. ketoconazole, clarithromycin, itraconazole, ritonavir, telithromycin). Anoro® Ellipta® should not be used in conjunction with other long-acting muscarinic antagonists, long-acting $beta_2$-adrenergic agonists or medicinal products containing either of these agents. Caution is advised with concomitant use with methylxanthine derivatives, steroids or non-potassium-sparing diuretics as it may potentiate possible hypokalaemic effect of $beta_2$-adrenergic agonists. **Fertility, pregnancy, and breast-feeding:** No available data. Balance risks against benefits. **Side effects:** Common: Urinary tract infection, sinusitis, nasopharyngitis, pharyngitis, upper respiratory tract infection, headache, cough, oropharyngeal pain, constipation and dry mouth. Uncommon: Atrial fibrillation, supraventricular tachycardia, rhythm idioventricular, tachycardia, supraventricular extrasystoles and rash. **Legal category:** POM. **Presentation:** Anoro® Ellipta®. 1 inhaler x 30 doses. Anoro® Ellipta® 55/22mcg. **Marketing authorisation (MA) nos:** 55/22mcg 1x30 doses [EU/1/14/898/002]; **MA holder:** Glaxo Group Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS, UK. **Last date of revision:** October 2014. Anoro® and Ellipta® are registered trademarks of the GlaxoSmithKline group of companies. All rights reserved. Anoro® Ellipta® was developed in collaboration with Theravance, Inc.

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***Gibraltar:* alternatively, any suspected AEs and medication errors can also be reported via the UK regulatory authority (MHRA):** https://yellowcard.mhra.gov.uk/

ANORO ELLIPTA was developed in collaboration with Theravance

Theravance

MLT_GIB/UCV/0004/15 Date of preparation: March 2014

AUTHORS

Dr Yana Micallef Stafrace LLD Adv. Trib. Ecc.(Melit.)
graduated in 1986, after which she started practising in the Maltese Courts as well as following a Corso Singolo on European Community Law at Padua University. Since 1989 she is partner at Micallef–Stafrace Advocates and since 2000 she is an arbitor at the Malta Arbitration Centre. Her areas of practice include litigation, damages including those arising from traffic accidents and place of work, family law, general civil, criminal and commercial law, handling of insurance claims, arbitration and mediation.

Dr Charlene Grima LLD
graduated in 2014. Her thesis was 'The Conceptual Basis and Practical Implications of Compensating Psychological Harm in Maltese Tort Law'. She currently practises with Micallef-Stafrace Advocates and is currently reading an MA (Law) at the UOM.

Charles Micallef B.Pharm.(Hons) M.Sc. PA & PH (Staff)
graduated in 1991. After receiving his postgrad in 2013, he could prescribe exercise and also plan, develop and evaluate wide-scale physical activity programmes. He publishes internationally and reviews journal papers. He has created a diabetes management model for Malta based on community development, and developed a critical evaluation tool for students, researchers and clinicians.

Dr Kathleen England MD MSc
is a consultant public health specialist within the Directorate of Health Information and Research. Her main areas of work and interest are health statistics and epidemiological research in health.

Dr Michael Spiteri MD MRCSEd DipIMC RCSEd EMDM
is an Emergency Medicine specialist with further sub-specialization in Disaster Medicine. He is the Clinical Co-Lead for major incident preparedness for MDH.

Dr Pierre Vassallo MD PhD FACA Artz fur Radiologie
specialised in radiology at the Institute of Clinical Radiology at the University of Muenster, Germany and the Memorial Sloan-Kettering Cancer Center, New York, US. He is currently Consultant Radiologist and Managing Director at DaVinci Health, Malta.

Professor Albert Cilia-Vincenti MD FRCPath
is a private consultant pathologist in Malta and Chairman of the Academy of Nutritional Medicine (London) and former scientific delegate to the European Medicines Agency (London). He is a former pathology services director to the British and Maltese health services, and a former teacher of London and Malta Universities. He trained at London's Royal Marsden, Royal Free, St George's, Charing Cross and The Middlesex hospitals.

ISSUE GUIDE

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THESYNAPSE

eLearning Videos

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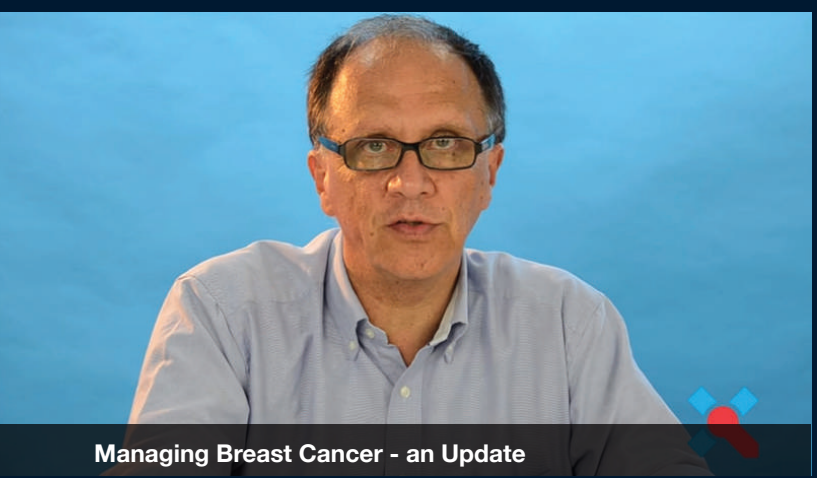
Content that matters
for the busy medical professional



Managing Breast Cancer - an Update

The management of Breast Cancer has changed dramatically over the years. Not only has the surgical techniques changed but a team approach is now the rule rather than the exception. This eLearning video is an interview with Mr Gordon Caruana Dingli. Mr Caruana Dingli is a Consultant Surgeon and head of the Breast Clinic at Mater Dei Hospital. He is also deputy chairman of the Department of Surgery and a Senior Lecturer at the University of Malta. The Breast Clinic has been running for the past fifteen years and adopts a multidisciplinary approach. Doctors who need to refer patients to the Breast Clinic at Mater Dei Hospital are requested to contact on tel 25454573 and provide a referral letter with details of the history and examination and all relevant imaging. Serious cases are fast tracked to receive prompt diagnosis and treatment.

This eLearning video is supported by an unrestricted educational grant from Da Vinci Health
www.davincihealth.com

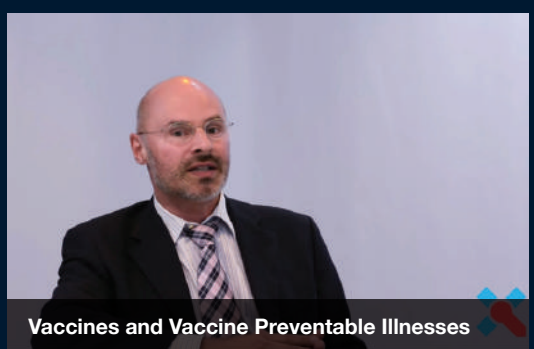
DA VINCI HEALTH

Emergency preparedness

Emergency preparedness is very important in all societies. A mass casualty incident is any incident where the number of casualties and the requirements to deal with that incident outweights the available resources.

In this video Dr Michael Spiteri, Consultant in Emergency Medicine discussed the principles behind emergency preparedness.

Visit **www.thesynapse.net/videos** for these and other interesting eLearning videos



Vaccines and Vaccine Preventable Illnesses

Dr Mark Muscat is a public health specialist with long experience working in the field of epidemiology and surveillance of communicable diseases. During eight years of work at the Statens Serum Institut of Denmark. Dr Muscat co-ordinated the vaccine-preventable disease (VPD) network EUVAC.NET and issued regular surveillance reports. Created the format for and moderated the updating of national vaccination schedules of all 32 EUVAC.NET-participating countries. Moderated the EUVAC.NET forum for VPD outreak reporting and was the scientific and logistic organizer of the network's annual meetings. He also collaborated with various gatekeepers in scientific publications on measles and rubella. He also worked for one year in the Department of Antibiotic Resistance and Hygiene and contributed to publications on antibiotic usage and the DANMAP report 2003. He was part of the team working in the Vaccine-preventable Diseases and Immunisation Unit for 2 years especially in the field of measles and rubella elimination.

Antibiotics - Handle with Care

The first World Antibiotic Awareness Week aims to increase awareness of global antibiotic resistance and to encourage best practices among the general public, health workers and policy makers to avoid the further emergence and spread of antibiotic resistance.

The theme of the campaign, Antibiotics: Handle with Care, reflects the overarching message that antibiotics are a precious resource and should be preserved. They should be used to treat bacterial infections, only when prescribed by a certified health professional. Antibiotics should never be shared and the full course of treatment should be completed ñ not saved for the future.

Prof Michael Borg discusses the importance of judicious use of antibiotics

Available on the App Store

Google play

astellas

Prescribing Information Presentation: Betmiga™ prolonged release tablets containing 25 mgor 50 mg mirabegron. **Indication:** Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome. **Dosage:** Adults (including the elderly): Recommended dose: 50 mg once daily. Children and adolescents: Should not be used. **Contraindications:** Hypersensitivity to active substance or any of the excipients. **Warnings and Precautions:** Should not be used in patients with end stage renal disease, severe hepatic impairment and severe uncontrolled hypertension. Not recommended in patients with severe renal impairment and moderate hepatic impairment concomitantly receiving strong CYP3A inhibitors. Dose adjustment to 25 mg is recommended in patients with moderate renal and mild hepatic impairment receiving strong CYP3A inhibitor concomitantly. Caution in patients with a known history of QT prolongation or in patients taking medicines known to prolong the QT interval. Not recommended during pregnancy and in women of childbearing potential not using contraception. Not recommended during breastfeeding. **Interactions:** Clinically relevant drug interactions between Betmiga™ and medicinal products that inhibit, induce or are a substrate for one of the CYP isozymes or transporters are not expected, except for inhibitory effect on the metabolism of CYP2D6 substrates. Betmiga™ is a moderate and time-dependant inhibitor of CYP2D6 and weak inhibitor of CYP3A. No dose adjustment needed when administered with CYP2D6 inhibitors or CYP2D6 poor metabolisers. Caution if co-administered with medicines with a narrow therapeutic index and significantly metabolised by CYP2D6. When initiating in combination with digoxin the lowest dose for digoxin should be prescribed and serum digoxin should be monitored. **Adverse Effects:** Urinary tract infection, tachycardia, palpitation, atrial fibrillation, blood pressure increase, leukocytoclastic vasculitis. Prescribers should consult the Summary of Product Characteristics in relation to other side effects. **Pack and Prices:** Country specific. **Legal Category:** POM. Product Licence Number: Betmiga™ 25 mg EU/1/12/809/003; Betmiga™ 50 mg EU/1/12/809/010. **Date of Preparation:** November 2012 **Further information available from:** Astellas Pharma Europe B.V. P.O. Box 344, 2300 AH Leiden, The Netherlands. Betmiga™ is a Registered Trademark. For full prescribing information please refer to the Summary of Product Characteristics. 20140312-UR-BTMA-08

Adverse events should be reported. Report adverse events to E.J. Busuttil Ltd. Tel: +356 21 44 7184

GALVUS and EUCREAS

COMPREHENSIVE POWER TO ADVANCE TYPE 2 DIABETES TREATMENT

GALVUS is a DPP-4 inhibitor that improves glycemic control through powerful islet enhancement[1]

EUCREAS is the combination of a DPP-4 inhibitor, GALVUS, and metformin[2]

Galvus®
PRESENTATION: Each tablet contains 50 mg of Vildagliptin **INDICATIONS:** For the treatment of type 2 diabetes mellitus in adults: As monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. As dual oral therapy in combination with metformin in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin; a sulphonylurea in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance; a thiazolidinedione in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate. As triple oral therapy in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control. Vildagliptin is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control **DOSAGE:** When used as monotherapy, in combination with thiazolidinedione, in combination with metformin and a sulphonylurea or in combination with insulin (with or without metformin), the recommended daily dose of Vildagliptin is 100mg, administered as one dose of 50 mg in the morning and one dose of 50 mg in the evening. When used in combination with a sulphonylurea, a lower dose of the sulphonylurea may be considered to reduce the risk of hypoglycaemia. Galvus can be administered with or without a meal. Doses greater than 100 mg are not recommended. Galvus is not recommended for use in children and adolescents (< 18 years). The safety and efficacy of Galvus in children and adolescents (< 18 years) have not been established. No data are available. The recommended dose for patients with moderate/severe renal impairment is 50mg once daily. If a dose of Galvus is missed, it should be taken as soon as the patient remembers. A double dose should not be taken on the same day. No dose adjustments are necessary in elderly patients (≥ 65 years. The safety and efficacy of Vildagliptin as triple oral therapy in combination with metformin and a thiazolidinedione have not been established. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients WARNINGS / **PRECAUTIONS:** Galvus should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. There is limited experience in patients with ESRD on haemodialysis. Therefore Galvus should be used with caution in these patients. Galvus is not recommended in patients with hepatic impairment, including patients with pre-treatment ALT or AST >3x the ULN. Liver function tests should be performed prior to treatment initiation, at three month intervals during the first year and periodically thereafter. Should an increase in AST or ALT of 3xULN or greater persist, withdrawal of Galvus therapy is recommended. Patients who develop jaundice or other signs suggestive of liver dysfunction should discontinue Galvus. Clinical experience in patients with NYHA functional class III treated with Vildagliptin is still limited and results are inconclusive. Routine monitoring of diabetic patients for skin disorders such as blistering or ulceration is recommended. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Galvus should not be administered during pregnancy or breast-feeding since no studies on the effect on human fertility have been conducted for Galvus. Should be used with caution in patients with renal impairment. Sulphonylureas are known to cause hypoglycaemia. Patients receiving Vildagliptin in combination with a sulphonylurea may be at risk for hypoglycaemia. Therefore, a lower dose of sulphonylurea may be considered to reduce the risk of hypoglycaemia. Use of Vildagliptin has been associated with a risk of developing acute pancreatitis. If pancreatitis is suspected, Vildagliptin should be discontinued. If acute pancreatitis is confirmed, Vildagliptin should not be restarted. Caution should be exercised in patients with a history of acute pancreatitis. **INTERACTIONS:** Vildagliptin has a low potential for drug interactions. No clinically relevant interactions with other antidiabetics (glyburide, pioglitazone, metformin), amlodipine, digoxin, ramipril, simvastatin, valsartan or warfarin were observed after co-administration with Vildagliptin. As with other oral antidiabetic medicines, the hypoglycaemic effect of Vildagliptin may be reduced by certain active substances, including thiazides, corticosteroids, thyroid products and sympathomimetics. **ADVERSE REACTIONS:** Rare cases (>1/10,000 to <1/1,000) angioedema, abnormal liver function tests, hepatic dysfunction (including hepatitis). Monotherapy: Common (>1/100 to <1/10): dizziness, Uncommon (>1/1,000 to <1/100): headache, constipation, arthralgia, hypoglycaemia, oedema peripheral. Very rare (<1/10,000): URTI, nasopharyngitis. Combination with metformin: Common: tremor, headache, dizziness, nausea, hypoglycaemia, hyperhidrosis, asthenia. Uncommon: fatigue. Combination with sulphonylurea: Common: tremor, headache, dizziness, asthenia, hypoglycaemia. Uncommon: constipation. Very rare: nasopharyngitis. Combination with Thiazolidinedione: Common: weight increase, oedema peripheral, Uncommon: headache, asthenia, hypoglycaemia. Combination with insulin: Common: decreased blood glucose, headache, chills, nausea, gastro-oesophageal reflux disease. Uncommon: Diarrhoea, flatulence. Frequency not known: urticaria, pancreatitis, hepatitis and abnormal liver function tests (reversible upon discontinuation of the medicinal product), bullous or exfoliative skin lesions. Combination with metformin and a sulphonylurea: Common: hypoglycaemia, dizziness, tremor, hyperhidrosis, asthenia. **LEGAL CATEGORY:** POM **PACK SIZES:** 7, 28 tablets **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Frimley Business Park Camberley GU16 7SR United Kingdom. **MARKETING AUTHORISATION NUMBERS:** EU/1/07/414/001, 003. **Please refer to Summary of Product Characteristics (SmPC) before prescribing.** Full prescribing information is available on request from Novartis Pharma Services Inc, Representative Office Malta, P.O. Box 4, Marsa, MRS 1000, Malta. Tel +356 21222872. 2015-MT- GAL-19-JUN-2015

Eucreas®
PRESENTATION: Each 50 mg/850 mg film-coated tablet contains 50 mg of vildagliptin and 850 mg metformin hydrochloride. Each 50 mg/1000 mg film-coated tablet contains 50 mg of vildagliptin and 1000 mg metformin hydrochloride. **INDICATIONS:** Eucreas is indicated in the treatment of type 2 diabetes mellitus patients, indicated in the treatment of adult patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets. Eucreas is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled with metformin and a sulphonylurea. Eucreas is indicated in triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in adult patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control. **DOSAGE:** The dose of antihyperglycaemic therapy with Eucreas should be individualised on the basis of the patient's current regimen, effectiveness and tolerability while not exceeding the maximum recommended daily dose of 100 mg vildagliptin. Eucreas may be initiated at either the 50 mg/850 mg or 50 mg/1000 mg tablet strength twice daily, one tablet in the morning and the other in the evening. For patients inadequately controlled at their maximal tolerated dose of metformin monotherapy: The starting dose of Eucreas should provide vildagliptin as 50 mg twice daily (100 mg total daily dose) plus the dose of metformin already being taken. For patients switching from co-administration of vildagliptin and metformin as separate tablets: Eucreas should be initiated at the dose of vildagliptin and metformin already being taken. For patients inadequately controlled on dual combination with metformin and a sulphonylurea: The doses of Eucreas should provide vildagliptin as 50 mg twice daily (100 mg total daily dose) and a dose of metformin similar to the dose already being taken. When Eucreas is used in combination with a sulphonylurea, a lower dose of the sulphonylurea may be considered to reduce the risk of hypoglycaemia. For patients inadequately controlled on dual combination therapy with insulin and the maximal tolerated dose of metformin: The dose of Eucreas should provide vildagliptin dosed as 50 mg twice daily (100 mg total daily dose) and a dose of metformin similar to the dose already being taken. Eucreas should be taken with or just after food to reduce gastrointestinal symptoms associated with metformin. Patients > 65 taking Eucreas should have their renal function monitored regularly. Eucreas is not recommended for use in patients less than 18 years old. For use in renal or hepatic impairment, see contraindications and precautions below or refer to the SmPC for more information. The safety and efficacy of vildagliptin and metformin as triple oral therapy in combination with a thiazolidinediones have not been established. **CONTRAINDICATIONS:** Hypersensitivity to vildagliptin or metformin hydrochloride or to any of the excipients. Diabetic ketoacidosis or diabetic pre-coma. Renal failure or renal dysfunction defined as creatinine clearance < 60 ml/min. Acute conditions with the potential to alter renal function e.g. dehydration, severe infection, shock or intravascular administration of iodinated contrast agents. Acute or chronic disease which may cause tissue hypoxia e.g. cardiac or respiratory failure, recent myocardial infarction, shock, hepatic impairment, acute alcohol intoxication, alcoholism, lactation. **WARNINGS / PRECAUTIONS:** Eucreas is not a substitute for insulin in insulin-requiring patients and should not be used in patients with type 1 diabetes. Due to the risk of lactic acidosis, renal function could be monitored at least once yearly in patients with normal renal function and at least two to four times/year in patients with serum creatinine at the upper limit of normal and in elderly patients. Eucreas is not recommended in patients with hepatic impairment, including patients with pre-treatment ALT or AST >3x the ULN. LFT's should be performed prior to treatment initiation, at three month intervals during the first year and periodically thereafter. Should an increase in AST or ALT of 3x ULN or greater persist, withdrawal of Eucreas therapy is recommended. Patients who develop jaundice or other signs suggestive of liver dysfunction should discontinue Eucreas. Routine monitoring of diabetic patients for skin disorders such as blistering or ulceration is recommended. As Eucreas contains metformin, treatment should be discontinued 48 hours before elective surgery with general anaesthesia and not usually resumed earlier than 48 hours afterwards. The IV administration of iodinated contrast agents can lead to renal failure. Therefore due to metformin active ingredient, Eucreas should be discontinued prior to or at the time of the test and not reinstituted until 48 hours afterwards and only after renal function has been re-evaluated and found to be normal. Eucreas should not be administered during pregnancy or lactation. Sulphonylureas are known to cause hypoglycaemia. Patients receiving vildagliptin in combination with a sulphonylurea may be at risk for hypoglycaemia. Therefore, a lower dose of sulphonylurea may be considered to reduce the risk of hypoglycaemia. The use of vildagliptin has been associated with a risk of developing acute pancreatitis. If pancreatitis is suspected, vildagliptin should be discontinued; if acute pancreatitis is confirmed, vildagliptin should not be restarted. Caution should be exercised in patients with a history of acute pancreatitis. **INTERACTIONS:** Vildagliptin has a low potential for drug interactions. No clinically relevant interactions with other antidiabetics (glyburide, pioglitazone, metformin), amlodipine, digoxin, ramipril, simvastatin, valsartan or warfarin were observed after co-administration with vildagliptin. Interactions with metformin hydrochloride that are not recommended include alcohol, cationic active substances e.g. cimetidine and intravascular administration of iodinated contrast media. Combinations requiring caution include metformin hydrochloride with medicines tending to produce hyperglycaemic activity e.g. glucocorticoids, beta agonists and diuretics. The dose of antihyperglycaemic medicinal products may need to be adjusted in combination with ACE inhibitors. **ADVERSE REACTIONS:** Rare cases (>1/1,000 to <1/1,000) angiodema, hepatic dysfunction (including hepatitis) have been reported with vildagliptin. Vildagliptin Monotherapy: Common (>1/100 to <1/10): dizziness, Uncommon (>1/1,000 to <1/100): headache, constipation, arthralgia, hypoglycaemia, oedema peripheral. Very rare (<1/10,000): URTI, nasopharyngitis. Metformin monotherapy: Very common (>1/10) Nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. Common: metallic taste. Combination vildagliptin with metformin: Common: tremor, headache, dizziness, nausea, hypoglycaemia. Uncommon: fatigue. Combination with metformin and sulphonylurea: Common: hypoglycaemia, dizziness, tremor, hyperhidrosis, asthenia, decreased blood glucose, headache, chills. Combination with insulin: Decreased blood glucose, headache, chills, nausea, gastro-oesophageal reflux disease, diarrhoea, flatulence. For a full list of Adverse reactions, please refer to the SmPC. **LEGAL CATEGORY:**POM **PACK SIZES:** 30, 60 film-coated tablets **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Frimley Business Park, Camberley GU16 7SR, United Kingdom. **MARKETING AUTHORISATION NUMBER:** EU/1/07/425/002–003, EU/1/07/425/008-009. Please refer to Summary of Product Characteristics (SmPC) before prescribing. Full prescribing information is available upon request from Novartis Pharma Services Inc, Representative Office Malta. P.O. Box 4, Marsa, MRS 1000, Malta. Tel +356 21222872. 2015-MT-EUC-17-JUN-2015

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NOVARTIS PHARMACEUTICALS

Galvus® vildagliptin

Eucreas® vildagliptin/metformin

1. Novartis Europharm Ltd. Galvus® Summary of Product Characteristics
2. Novartis Europharm Ltd. Eucreas® Summary of Product Characteristics

AN OVERVIEW

PERCENTAGE DISABILITY REPORTS IN THE MEDICAL FIELD

YANA MICALLEF STAFRACE
& CHARLENE GRIMA

Tort can be defined as a wrongful act, resulting in injury to another person, or property, or reputation, amongst others, for which the injured party can seek compensation. It involves the responsibility for the payment of damages in cases where a person causes harm to another, independently of any prior agreement or contractual relationship. Liability in tort depends on one important factor, that is, the existence of fault; in fact Article 2031 of the Maltese Civil Code provides that every person shall be liable for the damage which occurs through his fault. The main aim of tort law is that of providing relief for the harm suffered to tort victims.[1]

Broadly speaking, compensation following an injury falls under two main headings, *damnum emergens* and l*ucrum cessans*. The first pertains to the repayment of expenses incurred whilst the second is tied to the loss of future earnings arising from a permenant disability.

In respect of compensation under *damnum emergens* Maltese courts are relatively consistent in their approach, in that once there is sufficient proof of actual losses, compensation is granted. On the other hand, this is not the case with respect to compensation under *lucrum cessans* arising from permanent disability. Given that Maltese law does not yet provide any form of guidance in respect of how one can determine a percentage rate of disability, one may question the manner in which medical practitioners conduct their medical reports in cases of tort. In other words, can it be argued that ultimately the determination of compensation in any given case depends on the medical practitioner's 'opinion'? For this reason it is essential to evaluate some of the notions which are generally given weight by medical practitioners in order for a harmed individual to be adequately compensated.

It is important to note that the court is not bound by medical reports. In fact, one particular provision of the Code of Organisation and Civil Procedure provides that "The Court is not bound to adopt the report of the referees against its own conviction."[2] This means that the final decision is that of the judge, this being the case irrespective of whether the medical report in question is a reliable one, being drawn up competently and diligently.

WHAT MAKES A MEDICAL REPORT A RELIABLE ONE?

It can primarily be argued that for a medical report to be a genuine one the medical practitioner should most importantly make it understandable. The percentage rate of harm should be meticulously justified rather than providing a medical report without any explanation for the percentage rate of harm.

One might still question the manner in which a rate of permanent disability is calculated or determined by medical practitioners. What criteria should a medical practitioner really bear in mind before determining the percentage rate of harm suffered by an aggrieved individual? In this regard it should be kept in mind that up till now, compensation in Malta is only granted for material losses; consequently the percentage rate of harm should be limited to the harm caused to a person's 'working' or 'potential working' ability rather than any other ability affected by the harm suffered. Therefore, in cases where a person suffers a permanent incapacity, total or partial, yet is still able to maintain his or her employment and to generate the same income he or she earned prior to the injury, the percentage rate of disability suffered would not be very high. Thus, the notion of 'disability' or 'incapacity' referred to in the sphere of tort compensation, is a disability or an incapacity for the affected person to work or else to earn or generate the same income (or 'potential' income) one would have been able to earn (or 'potentially' earn), had no tortious event occurred. On the other hand, case-law also shows that if, despite the harm suffered, one retains his or her employment, there can still be an entitlement to compensation if that harm makes it difficult for such person to amplify his or her earnings. This is due to the fact that what matters is the effect that the injury has on the victim's prospective (not actual) earning ability.[3] Nevertheless the 'effect' of the disability on the victim's patrimony is a matter which should be dealt with by the court, thus a medical practitioner should determine the disability on a purely medical basis rather than legally; this in fact would make a medical report a reliable one.

One should note that there might be instances where despite the fact that more than one medical practitioner is appointed to conduct a medical report no single percentage rate of disability is agreed upon. In fact, this is one of the disadvantages behind the nonexistence of regulating guidelines in the sphere of tort compensation, since ultimately a medical practitioner's opinion is inevitably a subjective estimation of the harm caused to a particular victim. Perceptibly whenever there are divergent opinions - regarding the same tort victim - on the part of different medical practitioners, the court will decide which percentage rate of disability is the most suitable. In such cases the medical report would to a certain extent be set aside by the court.

Interestingly, medical reports which address physical disabilities caused in a particular case, without referring to the psychological aspect of the affected individual are still common. In this respect it can be argued that there might be instances where tort victims are in fact not granted the compensation they really deserve due to the fact that no reference to other aspects of the individual - particularly the psychological aspect - is made, other than the physical aspect. Hence unfortunately, psychological harm is at times ignored; yet this can be caused by the occurrence of physical harm.[4] The fact that there are several psychological and psychiatric illnesses which can potentially occur consequent to a traumatic experience[5] leads one to question the true worth of certain medical reports relied upon by the court, being reports which solely deal with physical harm and which do not even refer to the mental status of the victim after the tort. Although it is true that as aforesaid, Maltese Law caters for material losses only, a medical report should always reflect the real medical circumstances consequent to a tortious event; this means that psychological harm should be referred to if this is inflicted upon the victim. Nevertheless, in reality there is still scepticism associated with psychological harm, as well as a general fear of compensation syndrome, i.e. when a person shows symptoms that are out of proportion, in order to receive compensation; in fact, in Malta, reference to psychological harm can only be found in relatively recent judgments. Recently, references to Anxiety disorders such as Post-Traumatic Stress Disorder, Acute Stress Disorder and Adjustment Disorder are becoming common.6 Therefore, the psychological impact of certain physical injuries should be given sufficient consideration since unfortunately, psychological harm may last longer than the physical harm which is suffered, although it might be barely noticeable in some cases.

WHAT ABOUT THE CASES WHERE MORE THAN ONE TYPE OF PERMANENT DISABILITY OCCURS? SHOULD MEDICAL EXPERTS DECIDE ON A SINGLE PERCENTAGE RATE OF HARM OR DETERMINE EACH PERCENTAGE OF DISABILITY SEPARATELY?

One may refer to cases where a person suffers both physical and psychological harm; in these cases the general approach adopted by the Maltese courts is that a single percentage rate which covers all the permanent harm caused by the same event, is usually determined, thus implying that a particular 'totality' of harm is suffered.[6] In fact, in one particular judgment[7] the Court of Appeal elucidated that the medical examination conducted on a person who suffers more than one form of disability, shall *always* give consideration to the fact that the individual person is a single entity which shall not be divided into separate compartments in order to give a percentage rate for each type of disability suffered. The reasoning behind the court's explanation is that if a percentage rate of disability had to be given for each type of disability, the victim's final disability may amount to more than a hundred percent (100%)[6] and this would clearly not make sense.

... IN CASES WHERE A PERSON SUFFERS A PERMANENT INCAPACITY ... YET IS STILL ABLE TO MAINTAIN HIS OR HER EMPLOYMENT AND TO GENERATE THE SAME INCOME HE OR SHE EARNED PRIOR TO THE INJURY, THE PERCENTAGE RATE OF DISABILITY SUFFERED WOULD NOT BE VERY HIGH

It is quite evident that the determination of a percentage rate of harm caused to a tort victim in any given case is not simple. In fact, in one particular recent local case[8] the court-appointed psychologist refused to quantify the harm suffered by the victim since according to her the harm caused was too 'abstract' to be rated by a percentage. In this respect it can be argued that specific personal injuries affect aspects of one's life which cannot be given a 'price' simply because they are of great value. One can here refer to the loss of independence which certain physical injuries may cause to the aggrieved. Additionally, when psychological harm ensues, mental stability may never be regained, and this is another form of deprivation of the aspects of life that are priceless for every human being. Nevertheless, it is only just that adequate compensation is awarded to persons who suffer harm consequent to another person's fault. The appointment of medical experts is indeed one of the means by which the court can at least be guided in order to determine the compensation to be awarded in any given case for the victim to retain a decent life as much as possible

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FOR FURTHER INFORMATION PLEASE CONTACT

Micallef – Stafrace Advocates
11A, Strait Street, Valletta VLT 1432
T: 2122 3142, 2124 8034
M: 9949 9393
E: yana@micallefstafrace.com

Relvar Ellipta is for patients (≥12 years) in need of asthma maintenance therapy[1]

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Because I simply don't have space for asthma

For patients like Maria, every day is full on, so even small reminders of asthma can have an impact. So, when they're uncontrolled on ICS alone, choose new Relvar Ellipta:

- The first ICS/LABA combination to deliver continuous 24-hour efficacy[2]
- In a practical, once-daily dose[1]
- Delivered in an easy to use device that patients prefer to their current inhaler[3,4*]

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(fluticasone furoate and vilanterol inhalation powder)

Practical efficacy

Relvar Ellipta (fluticasone furoate/vilanterol) Abridged Prescribing Information

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 on SPC how to report adverse reactions.

Please refer to the full Summary of Product Characteristics before prescribing

Trade Name: RELVAR ELLIPTA. **Active Ingredients:** 92 micrograms or 184 micrograms of fluticasone furoate and 22 micrograms of vilanterol (as trifenatate). **Pharmaceutical Form:** 92 micrograms/22 micrograms or 184 micrograms/22 micrograms inhalation powder, pre-dispensed. **Indications:** *The 92 micrograms/22 micrograms dose:* for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta$_2$-agonist and inhaled corticosteroid) is appropriate; and for the symptomatic treatment of adults with COPD with a FEV_1<70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy. *The 184 micrograms/22 micrograms dose:* for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta$_2$-agonist and inhaled corticosteroid) is appropriate. **Dosage and Method of Administration:** *For Athsma:* One inhalation of Relvar Ellipta 92/22 micrograms or 184/22 micrograms once daily. Patients usually experience an improvement in lung function within 15 minutes of inhaling Relvar Ellipta. However, the patient should be informed that regular daily usage is necessary to maintain control of asthma symptoms and that use should be continued even when asymptomatic. If symptoms arise in the period between doses, an inhaled, short-acting beta$_2$-agonist should be taken for immediate relief. A starting dose of Relvar Ellipta 92/22 micrograms should be considered for adults and adolescents 12 years and over who require a low to mid dose of inhaled corticosteroid in combination with a long-acting beta$_2$-agonist. If patients are inadequately controlled on Relvar Ellipta 92/22 micrograms, the dose can be increased to 184/22 micrograms, which may provide additional improvement in asthma control. *For COPD:* One inhalation of Relvar Ellipta 92/22 micrograms once daily. Relvar Ellipta 184/22 micrograms is not indicated for patients with COPD. Relvar Ellipta is for inhalation use only. It should be administered at the same time of the day, each day. **Contraindications:** *Hypersensitivity* to the active ingredient or excipients. **Precautions for Use:** Fluticasone furoate/vilanterol should not be used to treat acute asthma symptoms, for which a short-acting bronchodilator is required. Caution in severe cardiovascular disease, moderate-to-severe hepatic impairment, pulmonary tuberculosis or in patients with chronic or untreated infections, history of diabetes mellitus and for paradoxical bronchospasm and pneumonia in patients with COPD. **Drug Interactions:** Beta-blockers, CYP3A4 inhibitors, P-glycoprotein inhibitors and sympathomimetic medicinal products (refer to the full Summary of Product Characteristics for list of drugs). **Fertility, Pregnancy and Lactation:** ***Pregnancy:*** No adequate data available. ***Lactation:*** insufficient information available. ***Fertility:*** There is no data in humans. Animal studies indicate no effect on fertility. **Effect on Ability to Drive or Use Machines:** No or negligible influence. **Undesirable Effects:** Very common side effects include headache and nasopharyngitis (refer to the full Summary of Product Characteristics for complete list of undesirable effects). **Overdose:** There is no specific antidote. Treatment of overdose should consist of general supportive measures. **Local Presentations:** Relvar Ellipta 92 micrograms/22 micrograms inhalation powder, pre-dispensed and Relvar Ellipta 184 micrograms/22 micrograms inhalation powder, pre-dispensed. **Legal Category:** POM. **Marketing Authorisation Holder:** Glaxo Group Limited, 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom **Marketing Authorisation Numbers:** EU/1/13/886/001-6 **DATE OF PREPARATION:** December 2013.

In order to ensure that this product information reflects the most up-to-date clinical and post-marketing surveillance data, please always refer to the latest Summary of Product Characteristics (SPC) which is available from GlaxoSmithKline (Malta) Ltd (Tel: +356 21238131).

REPORTING ADVERSE EVENTS (AEs):

Malta & Gibraltar: **If you become aware of any AEs, medication errors and/or use during pregnancy in association with GSK products, please report the event promptly to:** GSK (Malta) Limited, 1, De la Cruz Avenue, Qormi QRM 2458, Malta (Tel: +356 21238131).

Malta: **alternatively, any suspected AEs and medication errors can also be reported via the national Adverse Drug Reactions (ADRs) reporting system:**

Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to the Malta Medicines Authority, Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt

Gibraltar: **alternatively, any suspected AEs and medication errors can also be reported via the UK regulatory authority (MHRA):** https://yellowcard.mhra.gov.uk/

*Patients' current or previous maintenance inhalers: HandiHaler/ DISKUS/ MDI/ HFA (COPD); DISKUS/ MDI/ HFA (asthma).[4]

References: 1. Relvar Ellipta Summary of Product Characteristics. GlaxoSmithKline; 2013. **2.** Bleecker ER *et al.* Fluticasone furoate/vilanterol 100/25mcg compared with fluticasone furoate 100mcg in asthma: a randomized trial. *JACI In Practice* 2013 (in press). **3.** Svedstater H *et al.* Ease of use of a two-strip dry powder inhaler (DPI) to deliver fluticasone furoate/vilanterol (FF/VI) and FF alone in asthma. *ERS.* 2013. **4.** Woepse M *et al.* Qualitative assessment of a two-strip dry powder inhaler (ELLIPTA™) for COPD and asthma. *EAACI.* 2013.

MLT_GIB/RESP/0006/14 Date of preparation: January 2014

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The image represents an average patient experience, and does not show an actual patient.

References: 1 Terpstra IJ, Acne treatment with 4% erythromycin and 1.2% zinc acetate Cardiff 1988; 255-259. **2** Stainforth J et al. Dermatol Treat 1993 4: 119-122. **3** Schachner L et al. J Am Acad Dermatol 1990; 22(3): 489-495.

Prescribing information: Zineryt® Abbreviated Prescribing Information for 30 ml:
Presentation: After constitution, Zineryt® contains 40 mg/ml erythromycin and 12 mg/ml zinc acetate, as an erythromycin-zinc complex. **Uses:** Topical treatment of acne vulgaris. **Dosage and administration:** For children, adults and the elderly: Apply twice daily over the whole of the affected area for a period of 10 to 12 weeks. **Contra-indications:** Contra-indicated inpatients hypersensitive to erythromycin, macrolide antibiotics, zinc, di-isopropyl sebacate or ethanol. **Other warnings and precautions:** Cross-resistance may occur with macrolide antibiotics, with lincomycin, or clindamycin. Contact with the eyes and mucous membranes of the nose and mouth should be avoided. **Use in pregnancy and lactation:** Not-contra-indicated. **Side-effects:** Occasionally a burning sensation or slight redness of the skin due to the alcohol base of Zineryt®; this is transient and of minor clinical significance. **Overdosage:** Not expected in normal use. In idiosyncratic hypersensitivity wash well with soap and water. Zineryt® is a Registered Trademark. Please refer to the full Summary of Product Characteristics before prescribing.

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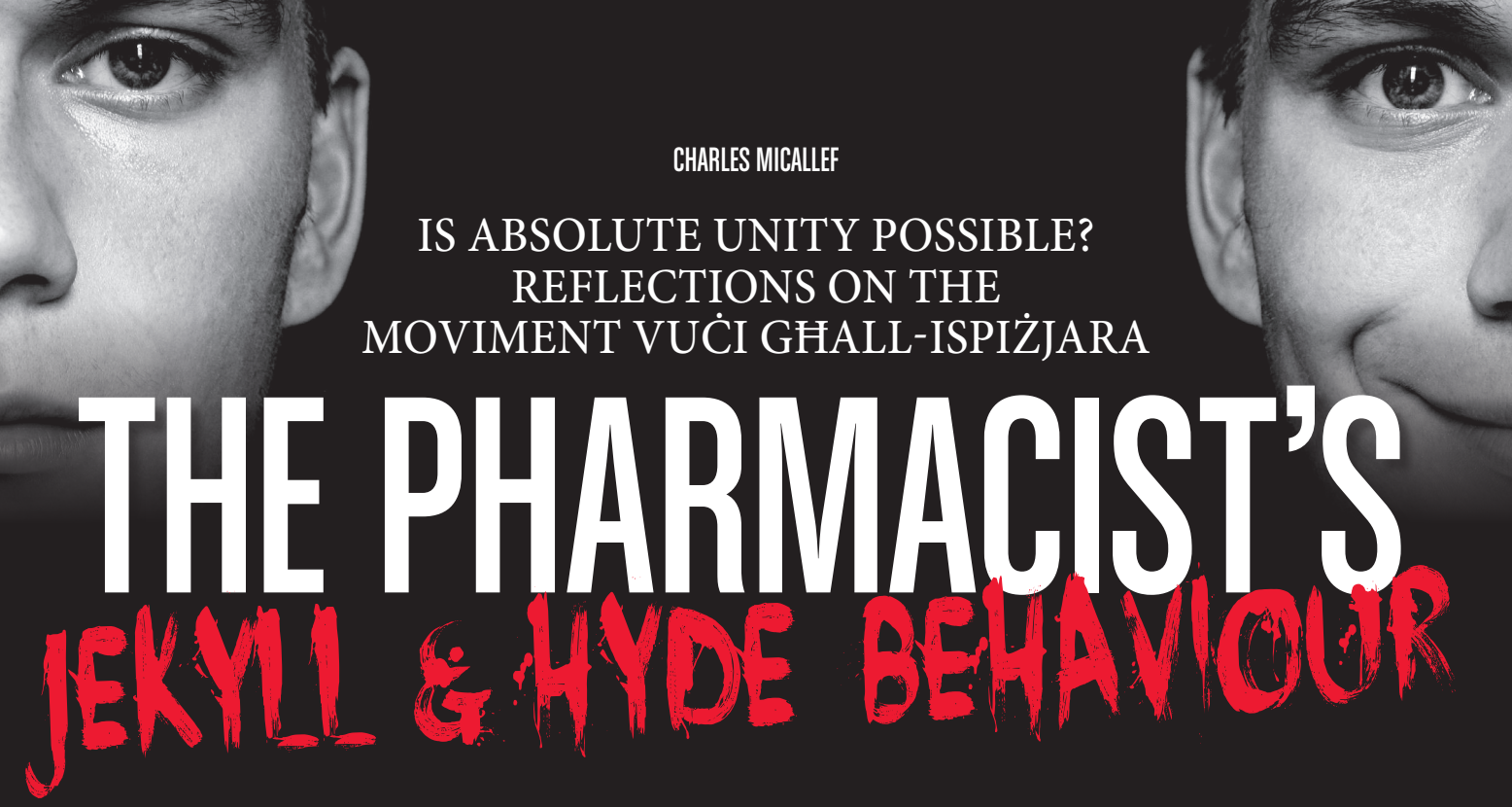

CHARLES MICALLEF

IS ABSOLUTE UNITY POSSIBLE? REFLECTIONS ON THE MOVIMENT VUĊI GĦALL-ISPIŻJARA

THE PHARMACIST'S JEKYLL & HYDE BEHAVIOUR

INTRODUCTION: THE BIRTH OF A PROFESSIONAL ASSOCIATION BASED ON IDEALISM

The article titled, '*Moviment vuċi għall-Ispiżjara*' which appeared in *The Synapse* earlier this year[1] proved to be interesting. Mr Alfie Palmier, the leader of this movement, is of the opinion that despite the various specialities within the profession, all pharmacists share the same convictions (opinions). He further believes that with collaborative efforts, common goals can be achieved. Nice words indeed!

In this article, the author will delve in the dual nature of the pharmacist, focusing on community practice. There are two reasons why unionisation issues relating to a community pharmacists' perspective will be discussed. First, this is the area where the author has most experience. Second, according to a report published in 2013 by the Pharmacy Council of Malta,[2] the principal area of full-time practice was represented by 40% of pharmacists working in the community. Those working on a reduced hour basis and as part-timers were not included in this figure.

At the risk of sounding pessimistic, throughout his experience as a pharmacist and as a once active trade-unionist, the author always visualized a duality which can be called, 'the Dr Jekyll and Mr Hyde behaviour'. This description stems from the basic fact that a pharmacist can pass through two major phases of transition in one's career, that of an employee and that of an employer. Non-arguably, this means that the views and expectations are expected to change drastically throughout such distinct phases.

EXAMPLES THAT SUPPORT THE JEKYLL AND HYDE BEHAVIOUR

The following examples illustrate the observations on the two distinguishable natures of the pharmacist. The first scenario takes us to the old issue of the liberalisation of permits for private pharmacies. A good number of pharmacist-employees used to complain against the tight regulations that had restricted them from freely opening new pharmacies and this was especially felt at a time when hundreds of applications were frozen. Somehow or other, some of them managed to establish their own pharmacies. As pharmacy owners employing other people they became pharmacist-employers. They now support a quasi-monopolistic attitude which, to a certain extent is understandable because no one wants to invest in something with a declining turnover due to nearby competitors.

The second example takes us to the issue of the pharmacy of your choice (POYC). I have personally witnessed several pharmacist-employees working in private pharmacies complaining about the extra responsibilities and the additional workloads that had been abruptly imposed on them. However, when these same pharmacists became employers, not surprisingly, they started praising the perceived success of this scheme. Again, it depends on one's perspective. For example, in terms of revenue generation, they are correct in saying that the POYC scheme is a must for every private pharmacy.

Therefore, in view of these examples the author finds it hard to imagine how this new movement can be one voice for all pharmacists when there seems to be such diversity between the employee and employer status of the pharmacist. The following section will discuss aspects relating to contrasting circumstances in the pharmacist's life which will be illustrated with respect to other professions.

LOOKING AT OTHER PROFESSIONS

Is this dual behaviour also evident in other professions? Let us take the medical profession as a start. Excluding private hospitals and sick leave verification companies where doctors may directly employ peers, the majority of doctors are either employed by government or work as private family doctors. The latter are mainly either self-employed or have group

practices where they regulate their own pay. So, in most cases, doctors are not dependent on the generosity of other doctors for their remuneration.

In view of the above, when it comes to salary, doctors unlike pharmacists, do not tend to have opposing opinions; but is pay the only issue determining unity and strength of membership to an organisation? If we are to make parallel comparisons between doctors and pharmacists it is imperative to make equivalent comparisons. Whereas current regulations on the opening of new pharmacies can present challenges for single-union representation of pharmacists, doctors do not have restrictions on where to open hospitals and clinics. In view of this fact, this issue proves to undermine pharmacists' unionisation on one hand and strengthen doctors' unionisation on the other.

With the nursing profession, the story is much more straightforward. The absolute majority of nurses are employees and hence complete representation by one union is possible. Mr Palmier also tried to make lame comparisons with educators. Whether teachers work in state, church or private schools, generally they all share the same expectations such as salary increases, smaller class size and more helpers (basically, learning support assistants [LSAs]). These universal interests facilitate the representation of teachers by one union. Similar to medics who see patients on the side in the evening, teachers who conduct part-time tuition regulate their own remuneration.

In the article, Mr Palmier added that continued professional development is becoming mandatory in various European countries. If this were the case for Malta, community pharmacists would unfortunately have to attend such courses late in the evening after 7-8pm, whereas teachers, being practically all employees, would be lucky to have not only these short courses offered during normal school hours or during recesses, but also, according to the last electoral programme of the party now in government, a variety of sponsored Masters' full-time programmes.

Furthermore, the collegiality of educators is evidenced by the fact that when teachers have disputes relating to conditions of work the recognised union may not think it twice to rope in the LSAs in their industrial actions. Contrastingly, the pride of pharmacists sometimes precludes the affiliation of pharmacy technicians in their unions. What is also admirable with practically all educators from various levels of teaching is their complete unity in using consistent and persuasive talk about their conditions of work.

AMBIGUITY GALORE

With reference to the interview with Mr Palmier in the last issue of *The Synapse*,[3] the author found it very confusing. Mr Palmier's vision is open to different interpretations. At first he seemed to be somehow convinced that he wants to establish a union when he used words like "... vision of unity ...", "... needs (of pharmacists that) were being ignored" and "... the need for a radical change". In my opinion, knowing that the Chamber of Pharmacists has a record history of experience and well-established roots, an extreme shake (or "a radical change") can only be achieved by challenging it through a new association as happened in the late nineties, when a new section within the *Union Ħaddiema Magħqudin* was established. Then Mr Palmier moderates himself by saying things like "... this movement is not a union ..."; "... we stand stronger together", "the Chamber is a legacy, it is our house and it has done a great deal of good".

What exactly was Mr Palmier implying when he said, "... the baton had to be passed on to the younger generation of pharmacists ..."? Was he referring to an internal change in leadership within the structure of the Chamber or to "the baton" being transferred to his new association? So, what does he actually have in mind? Apart from his sweet talk and mere publicity, he should tell us what is exactly meant by "... the moulding process that would bring about effective and tangible change". Why is he reluctant to illustrate his views with specific examples?

CONCLUSION: SOME OPTIMISM DESPITE DIVERGING OPINIONS AND UNCERTAINTY

Union success is not measured with the 'blind' influx of members initially wanting to enrol into a new association in protest at all costs because they were tired of seeing the same union faces doing relatively little for them. Indeed, the strength of a union is seen in achieving the best packages in the shortest possible time frames for its members who usually present themselves with high expectations. So far we have seen the challenge in uniting pharmacists with diverging opinions due to the dual nature which has been amply explained.

We have also seen how Mr Palmier does not really know what he wants to achieve. Should he further establish his independent movement and continue strengthening his position to eventually acquire official recognition (he is proud to have acquired a good number of votes), or amalgamate with the Chamber (or *Kamra*, as they call it nowadays) and take over internally ("... the Chamber understands the need for inclusion")?

On a positive note however, competition is always healthy. Therefore, even if the *Moviment Vuċi għall-Ispiżjara* does not leave a significant impact on the lives of most pharmacists, I am confident that it would still act as a stimulant for the legitimate unions to start listening to the pleas of all members and non-members. Hence, some good will always come out

Finally, this account was only based on personal experience and observations. Even if reliable research one day confirms the theory of the pharmacist's Jekyll and Hyde behaviour, one should always exert caution in making generalisations

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Relvar Ellipta is for symptomatic treatment of patients with a FEV_1 <70% predicted normal (post-bronchodilator) and an exacerbation history[1]

COPD

For many patients like Joe with a history of exacerbations, COPD already takes up too much space in their life, yet they fear losing even more. So, when they need maintenance therapy, choose new Relvar Ellipta:

- The first ICS/LABA combination to deliver continuous 24-hour efficacy[2]
- In a practical, once-daily dose[1]
- Delivered in an easy to use device that patients prefer to their current inhaler[3,4*]

RELVAR™ ELLIPTA™

(fluticasone furoate and vilanterol inhalation powder)

Practical efficacy

Relvar Ellipta (fluticasone furoate/vilanterol) Abridged Prescribing Information

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 on SPC how to report adverse reactions.

Please refer to the full Summary of Product Characteristics before prescribing

Trade Name: RELVAR ELLIPTA. **Active Ingredients:** 92 micrograms or 184 micrograms of fluticasone furoate and 22 micrograms of vilanterol (as trifenatate). **Pharmaceutical Form:** 92 micrograms/22 micrograms or 184 micrograms/22 micrograms inhalation powder, pre-dispensed. **Indications:** *The 92 micrograms/22 micrograms dose:* for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting $beta_2$-agonist and inhaled corticosteroid) is appropriate; and for the symptomatic treatment of adults with COPD with a FEV_1 <70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy. *The 184 micrograms/22 micrograms dose:* for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting $beta_2$-agonist and inhaled corticosteroid) is appropriate. **Dosage and Method of Administration:** *For Athsma:* One inhalation of Relvar Ellipta 92/22 micrograms or 184/22 micrograms once daily. Patients usually experience an improvement in lung function within 15 minutes of inhaling Relvar Ellipta. However, the patient should be informed that regular daily usage is necessary to maintain control of asthma symptoms and that use should be continued even when asymptomatic. If symptoms arise in the period between doses, an inhaled, short-acting $beta_2$-agonist should be taken for immediate relief. A starting dose of Relvar Ellipta 92/22 micrograms should be considered for adults and adolescents 12 years and over who require a low to mid dose of inhaled corticosteroid in combination with a long-acting $beta_2$-agonist. If patients are inadequately controlled on Relvar Ellipta 92/22 micrograms, the dose can be increased to 184/22 micrograms, which may provide additional improvement in asthma control. *For COPD:* One inhalation of Relvar Ellipta 92/22 micrograms once daily. Relvar Ellipta 184/22 micrograms is not indicated for patients with COPD. Relvar Ellipta is for inhalation use only. It should be administered at the same time of the day, each day. **Contraindications:** *Hypersensitivity* to the active ingredient or excipients. **Precautions for Use:** Fluticasone furoate/vilanterol should not be used to treat acute asthma symptoms, for which a short-acting bronchodilator is required. Caution in severe cardiovascular disease, moderate-to-severe hepatic impairment, pulmonary tuberculosis or in patients with chronic or untreated infections, history of diabetes mellitus and for paradoxical bronchospasm and pneumonia in patients with COPD. **Drug Interactions:** Beta-blockers, CYP3A4 inhibitors, P-glycoprotein inhibitors and sympathomimetic medicinal products (refer to the full Summary of Product Characteristics for list of drugs). **Fertility, Pregnancy and Lactation:** ***Pregnancy:*** No adequate data available. ***Lactation:*** insufficient information available. ***Fertility:*** There is no data in humans. Animal studies indicate no effect on fertility. **Effect on Ability to Drive or Use Machines:** No or negligible influence. **Undesirable Effects:** Very common side effects include headache and nasopharyngitis (refer to the full Summary of Product Characteristics for complete list of undesirable effects). **Overdose:** There is no specific antidote. Treatment of overdose should consist of general supportive measures. **Local Presentations:** Relvar Ellipta 92 micrograms/22 micrograms inhalation powder, pre-dispensed and Relvar Ellipta 184 micrograms/22 micrograms inhalation powder, pre-dispensed. **Legal Category:** POM. **Marketing Authorisation Holder:** Glaxo Group Limited, 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom **Marketing Authorisation Numbers:** EU/1/13/886/001-6 **DATE OF PREPARATION:** December 2013

In order to ensure that this product information reflects the most up-to-date clinical and post-marketing surveillance data, please always refer to the latest Summary of Product Characteristics (SPC) which is available from GlaxoSmithKline (Malta) Ltd (Tel: +356 21238131).

REPORTING ADVERSE EVENTS (AEs):

Malta & Gibraltar: **If you become aware of any AEs, medication errors and/or use during pregnancy in association with GSK products, please report the event promptly to:** GSK (Malta) Limited, 1, De la Cruz Avenue, Qormi QRM 2458, Malta (Tel: +356 21238131)

Malta: **alternatively, any suspected AEs and medication errors can also be reported via the national Adverse Drug Reactions (ADRs) reporting system:**

Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to the Malta Medicines Authority, Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt

Gibraltar: **alternatively, any suspected AEs and medication errors can also be reported via the UK regulatory authority (MHRA):** https://yellowcard.mhra.gov.uk/

References: 1. Relvar Ellipta Summary of Product Characteristics. GlaxoSmithKline; 2013. **2.** Boscia JA *et al*. Effect of Once-Daily Fluticasone Furoate/Vilanterol on 24-Hour Pulmonary Function in Patients With Chronic Obstructive Pulmonary Disease: A Randomized, Three-Way, Incomplete Block, Crossover Study. *Clin Ther.* 2012; **8**: 1655-66. **3.** Riley JH *et al*. Delivery of umeclidinium/vilanterol using a new twin strip device (ELLIPTA™) to COPD patients. 2013 (in press). **4.** Woepse M *et al*. Qualitative assessment of a two-strip dry powder inhaler (ELLIPTA™) for COPD and asthma. *EAACI.* 2013.

MLT_GIB/RESP/0007/14 Date of preparation: January 2014

Theravance | gsk

Augmentin® SR

1000 mg/62,5 mg

Amoxicillin/Clavulanic Acid

Prolonged release tablets

- ✓ Unique bilayer tablet with immediate and sustained release delivery of amoxicillin provides superior efficacy against resistant pathogens[1,2]
- ✓ Recommended by leading Guidelines in the treatment of Community Acquired Pneumonia[3,4]
- ✓ Most common adverse effects are diarrhoea, nausea, vomiting and mucocutaneous candidiasis[5]
- ✓ Indicated for use in adults & adolescents aged ≥16 years; 2 tablets BD for 7-10 days[5]

Spreading infectious liveliness!

Mini Abridged Prescribing Information: *Please refer to full Summary of Product Characteristics (SPC) before prescribing.* **TRADE NAME:** Augmentin SR. **ACTIVE INGREDIENTS:** Amoxicillin (as trihydrate) and potassium clavulanate. **PRESENTATION:** 1000 mg/62.5 mg prolonged-release tablets. Supplied in 28 tablet packs. **INDICATION**: Treatment of community acquired pneumonia in adults and adolescents aged at least 16 years, caused or thought likely to be caused by penicillin-resistant *Streptococcus pneumoniae.* **POSOLOGY & ADMINISTRATION:** Oral use. Recommended dose of two tablets twice daily for seven to ten days. To minimise potential gastrointestinal intolerance, administer at the start of a meal. **CONTRAINDICATIONS:** Hypersensitivity (and past history of) to the active substances, to any penicillins or to any of the excipients. **SPECIAL WARNINGS & PRECAUTIONS:** Before initiating therapy careful enquiry of previous hypersensitivity reactions to beta-lactams. Where an infection is proven to be due to an amoxicillin susceptible organism, a switch to an amoxicillin-only preparation should be considered. Convulsions may occur in patients receiving high doses or who have impaired renal function. Concomitant use of allopurinol increase likelihood of allergic skin reactions. Prolonged use may occasionally result in overgrowth of non-susceptible organisms. Contains 29.3 mg (1.3 mmol) of sodium per tablet. *Refer to SPC's for full list of precautions.* **INTERACTIONS:** Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity. Concomitant use of probenecid is not recommended. If co-administration with oral anticoagulants is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin. Moreover, adjustments in the dose of oral anticoagulants may be necessary. Clinical monitoring should be performed during the combination with mycophenolate mofetil and shortly after antibiotic treatment. **PREGNANCY & LACTATION:** Use should be avoided unless considered essential by the physician. **UNDESIRABLE EFFECTS:** Very common (≥1/10): diarrhoea. Common (≥1/100, <1/10): mucocutaneous candidosis, nausea, abdominal pain. *Refer to SPC's for full list of undesirable effects*. **AUTHORISATION NUMBER:** AA 1051/00102. **MARKETING AUTHORISATION HOLDER:** GlaxoSmithKline Bulgaria EOOD. **LEGAL CATEGORY:** POM. **DATE OF PREPARATION:** July 2014. **In order to ensure that this product information reflects the most up-to-date clinical and post-marketing surveillance data, please always refer to the latest Summary of Product Characteristics (SPC) which is available from GlaxoSmithKline (Malta) Ltd (Tel: +356 21238131). *REPORTING ADVERSE EVENTS (AEs)*: If you become aware of any AEs, medication errors and/or use during pregnancy in association with GSK products, please report the event promptly to:** GSK (Malta) Limited, 1, De la Cruz Avenue, Qormi QRM 2458, Malta (Tel: +356 21238131). **Alternatively, any suspected AEs and medication errors can also be reported via the national Adverse Drug Reactions (ADRs) reporting system:** Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to the Malta Medicines Authority, Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt.

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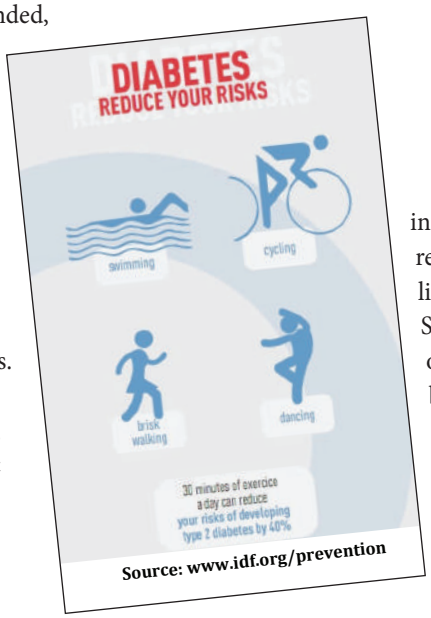
Job No: MLT_GIB/AES/0002/15(2)

DIABETES: AN EVER-GROWING PROBLEM

TRICIA MICALLEF

Diabetes is a condition, which, if tackled properly can be controlled, allowing the patient to have a relatively normal quality of life. However, if left unattended, complications can be life-threatening.

According to the International Diabetes Foundation, in 2014 there were 35,200 cases of diabetes in Malta, this not including those with impaired glucose tolerance and impaired fasting glucose, which can both lead to diabetes. This leaves Malta with the second highest percentage of diabetes in the Mediterranean, surpassed only by Cyprus.



Source: www.idf.org/prevention

Due to the increasing problem of diabetes incidence in the Maltese islands, we must try to educate the general public as early as possible about the benefits of a healthy lifestyle with an emphasis on preventive measures.

Prevention of type 2 diabetes occurs mainly through lifestyle changes such as physical activity and healthy eating. Apart from the psychological benefits, physical activity aids in maintaining weight loss, reducing blood pressure and heart rate, and increasing insulin sensitivity.

Risk factors to avoid include smoking, which increases abdominal fat accumulation and insulin resistance, and stress/depression which may be linked to both diabetes and cardiovascular disease. Sleep deprivation (< 6 hours) impairs the balance of hormones regulating food intake and energy balance, whilst sleeping too much (> 9 hours) may also be associated with a higher risk of diabetes.

As our contribution to this education, the Malta Pharmaceutical Students' Association (MPSA) holds numerous health campaigns where free blood glucose testing, blood pressure and BMI screening are carried out. Furthermore, an annual diabetes campaign is held during World Diabetes Day. At these events, information material is given out in order to prompt the public's interest for further reading on the disease and its prevention as well as instill healthy lifestyle changes

MICHAEL SPITERI

FAILING TO PREPARE IS PREPARING TO FAIL

By their very nature, mass casualty events are difficult to predict; therefore the nature, location and time of incidents, as well as their impacts are almost unclear to the disaster planners. The ability of an emergency medical system to deal with acute, unexpected increases in medical demands during disasters is a concept endorsed by the vast majority of emergency planners.

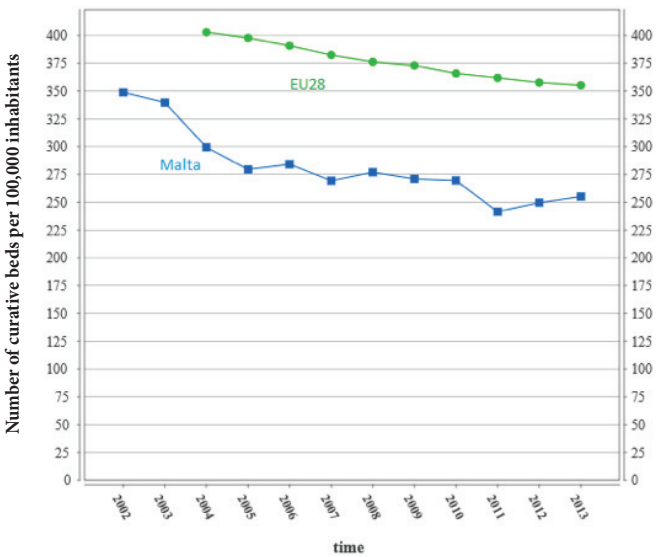
Although enjoying stability and relatively free from severe adverse natural phenomena, Malta still had its fair share of mass casualty events. Most of the major mass events were restricted to times of war and unrest in the rest of the world. As a result, our Island is dotted with the remains of grand historical buildings that served as hospitals and medical camps in the past. However, coming closer to our times, we have also witnessed incidents which although not on such a large scale, still tested our resilience and capacity.

Over the past years there have been numerous attempts to determine which method is best suited to ensure that the level of preparedness of a health system caters for the requirements on the day of an incident. Resource management is an element of disaster preparedness, where surge capacity is defined as the maximum potential delivery of required resources, either through augmentation or modification of resource allocation. At the hospital setting, it is the ability to increase available resources in order to cope with an unplanned sudden increase in patients, which is based on a qualitative and quantitative conceptual framework on the basis of four main pillars; stuff, staff, space and systems, better known as the 4S system. Surge capacity and capability come at a cost and it is a fact that no one, either the government or a private medical sector, can afford to pay for unused capacity. Therefore, emergency planners are responsible for achieving the best balance between cost and requirements to maintain the required capacity and capability of a hospital for disasters.

It is a fact that the level of medical care in Malta rose exponentially over the past and today it is regarded amongst the top players in Europe. However, for the reasons mentioned above, our surge capacity and resilience did not enjoy the same growth. On the contrary, the total number of available acute medical beds in Malta over the past thirty years is now probably at its lowest since the Second World War. It is historically documented that up to May 1917 the total number of hospital beds in Malta was just short of 27,000.[1] Ever since, the decline in the number of hospital beds is of course fully justifiable given the fact that there was certainly no financial justification to account for the continued upkeeping of hospitals and other health care facilities when the acute demand was not as high.

A recent study[2] focusing on the surge capacity of Mater Dei Hospital indicated that, although it provides an excellent medical service on a day-to-day basis, it might face significant challenges in the event of a mass casualty event. The root of this difficulty to surge to meet the demands of even a modest mass casualty event is multi-factorial and complex. One of the main reasons for this limitation lies within the fact that unlike other bigger countries, Malta has only one major hospital which is responsible to deliver the care to a whole nation. This responsibility will still need to be carried during a mass casualty event. Although, some smaller hospitals do exist in Malta, our country is probably almost unique, since in the vast majority, private hospitals utilise the medical services of professionals who are also included within the public sector. Therefore, it is anticipated that during such events, private hospitals might actually have a difficulty in providing extra services. This study also concluded that the overall training of medical staff in major incident and mass casualty preparedness is still very low. As a result it is expected that during such events, medical professionals will try to provide the same level of medical care that is provided on a day-to-day basis which will result in the creation of significant critical bottlenecks within the system.

Figure 1: Number of curative beds per 100,000 inhabitants across the EU and Malta



Another challenge which has been highlighted within our health care system is space. This phenomenon is similarly witnessed in other health care systems around the world, and as described above it transcends from the value for money mindset which does not allow for any unused bed capacity. Figure 1 clearly shows that in the vast majority, countries across the European Union actually witnessed a decrease in their curative hospital bed capacity over the past years.

As health care professionals, we have been entrusted with the responsibility of ensuring the best possible care of our patients. This responsibility will also need to be extended during exceptional and unexpected ciscumstances. In view

... THE TOTAL NUMBER OF AVAILABLE ACUTE MEDICAL BEDS IN MALTA OVER THE PAST THIRTY YEARS IS NOW PROBABLY AT ITS LOWEST SINCE THE SECOND WORLD WAR

of this commitment, our medical community should look beyond our day-to-day operations and should start considering and formulating plans to improve on our surge capacity. This might sound counterintuative when such requirments are superimposed on our day-to-day challenges to cope with routine load; however it is during these periods of heavy workload that the need for surge increases. Although the space and structural capacity need significant investment and are considered as medium to long-term investments, the concept of including major incident training in acute speciality training should be considered. This new approach has been adopted in the local national Emergency Medicine specialist training curriculum and it is aimed to better prepare our frontliners to provide emergency medical care under non-routine circumstances. It is through these initiatives that we take our level of preparedness to the next level. Not being prepared is not an option; it is just a recipie for failure

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STAR TREK SYMPOSIUM - MALTA 2016

Star Trek has shown devices and gadgets that later actually came into common use. For example, tablet computers first appeared in Star Trek in 1966 in *The Original Series*. These were originally large, wedge-shaped devices, operated almost exclusively through the use of a stylus. They eventually became flatter when depicted in the series in the late 1980s and were called PADDs (Personal Access Data Devices). These devices had a touch interface and were used not only for work but also for play, including watching video and listening to music – just as we do today; however, the first true tablets (ipads) were only launched in 2010.

Come and explore the world of Star Trek with us at the Star Trek Symposium next year, on 15-16th July, 2016, commemorating the 50th anniversary of Star Trek - startreksymposium.com

59% of children wake at night due to their asthma[1]

Seretide® Evohaler®
50 mcg from 4 years[3]

Poppy is **50%** less likely to wake at night when using Seretide compared to baseline[2]

Seretide® Diskus®
100 mcg from 4 years[4]

Help Poppy by prescribing Seretide

Seretide is the only ICS/LABA proven to achieve guideline-defined asthma control in children[2]

Safety Information

Very common side effects: Headache and nasopharyngitis.
Common side effects: Candidiasis of mouth and throat, pneumonia, bronchitis, hypokalaemia and hoarseness/dysphonia
Special warnings and precautions for use: Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods. These effects are much less likely to occur than with oral corticosteroids.
It is important that patients are reviewed regularly and the dose of inhaled corticosteroid is reduced to the lowest dose at which effective control of asthma is maintained. Monitor height of children on prolonged inhaled steroid therapy.

Seretide™ (salmeterol xinafoate and fluticasone propionate)
Kindly refer to full Summary of Product Characteristics (SPC) before prescribing.
Abridged prescribing information. Presentations: For Malta and Gibraltar: *Seretide Diskus* – Each dose provides 50 microgram salmeterol xinafoate and 100 microgram, 250 microgram or 500 microgram respectively of fluticasone propionate. *Seretide 50 Evohaler* - Each dose provides 25 microgram salmeterol xinafoate and 50 microgram of fluticasone propionate. For Gibraltar only: *Seretide 125, 250 Evohaler:* Each dose provides 25 microgram salmeterol xinafoate and 125 microgram or 250 microgram of fluticasone propionate. **Therapeutic Indications:** For Malta and Gibraltar: *Seretide Diskus and Evohaler:* is indicated in the regular treatment of asthma where use of a combination (long-acting beta-2-agonist and inhaled corticosteroid) is appropriate. *Seretide Diskus* is indicated for the symptomatic treatment of patients with COPD with a FEV_1<60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy. *Seretide 50 Evohaler* is used in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta-2-agonist or patients already adequately controlled on both inhaled corticosteroid and long-acting beta-2-agonist. For Gibraltar only: *Seretide 125, 250 Evohaler:* is indicated in the regular treatment of asthma where use of a combination (long-acting beta-2-agonist and inhaled corticosteroid) is appropriate. Used in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta-2-agonist or patients already adequately controlled on both inhaled corticosteroid and long-acting beta-2-agonist. **Dosage and administration:** Seretide is for inhalation use only. ***Seretide Diskus:*** Asthma – Adults and adolescents 12 years and over: one puff twice daily of Seretide 100 or Seretide 250 or Seretide 500 (each containing 50 mcg of salmeterol xinafoate and 100 mcg, 250 mcg or 500 mcg respectively of fluticasone propionate). Patients should be given the strength of Seretide containing the appropriate, lowest fluticasone propionate dosage for the severity of their disease. A short term trial of Seretide may be considered as initial maintenance therapy in adults or adolescents with moderate persistent asthma (defined as patients with daily symptoms, daily rescue use and moderate to severe airflow limitation) for whom rapid control of asthma is essential. In these cases, the recommended initial dose is one inhalation of 50 micrograms salmeterol and 100 micrograms fluticasone propionate twice daily. Once control of asthma is attained treatment should be reviewed and consideration given as to whether patients should be stepped down to an inhaled corticosteroid alone. Regular review of patients as treatment is stepped down is important. Seretide is not intended for the initial management of mild asthma. Seretide 50/100 micrograms strength is not appropriate in adults and children with severe asthma. Children 4-11 years: Seretide 100 Diskus (50 mcg salmeterol and 100 mcg fluticasone propionate) – one puff twice daily. ***Seretide Diskus:*** COPD: Seretide 500 Diskus (50 mcg of salmeterol xinafoate and 500 mcg fluticasone propionate) – one puff twice daily. ***Seretide 50 Evohaler:*** Adults and children 4 years and older: Two inhalations twice daily. For Gibraltar only: ***Seretide 125, 250 Evohaler:*** Adults and adolescents 12 years and older: Two inhalations twice daily. **Contra-indications:** Hypersensitivity. **Warnings and Precautions:** Seretide should not be used to treat acute asthma symptoms for which a fast- and short-acting bronchodilator is required. Patients should not be initiated on Seretide during an exacerbation, or if they have significantly worsening or acutely deteriorating asthma. Serious asthma-related events and exacerbations can occur during Seretide therapy; sudden and progressive deterioration in control or increased use of bronchodilator therapy warrants urgent medical assessment especially in patients of African-American origin (SMART). As with all inhaled medication containing corticosteroids, Seretide should be administered with caution in patients with pulmonary tuberculosis, severe cardiovascular disorders, including heart rhythm abnormalities, diabetes mellitus, untreated hypokalaemia/patients predisposed to hypokalaemia or thyrotoxicosis. In case of paradoxical bronchospasm discontinue Seretide, assess patient and give alternative therapy if necessary. Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods, but are less likely than with oral steroids. It is important, therefore, that the patient is reviewed regularly and the dose of inhaled corticosteroid is reduced to the lowest dose at which effective control of asthma is maintained. Prolonged treatment of patients with high doses of inhaled corticosteroids may result in adrenal suppression and acute adrenal crises. Rarely, a range of psychological or behavioural effects such as psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children) may develop on prolonged use. Monitor height of children on prolonged inhaled steroid therapy. Transfer from oral steroids: Special care needed. Monitor adrenal function. Consider appropriate steroid therapy during periods of stress or elective surgery. Ritonavir can greatly increase the concentration of fluticasone propionate in plasma, therefore avoid concomitant use. There is also an increased risk of systemic side effects with other potent CYP3A inhibitors. There was an increased reporting of lower respiratory tract infections (particularly pneumonia and bronchitis) in the TORCH study in patients with COPD receiving Seretide compared with placebo; older patients, patients with a lower body mass index (<25kg/m^2) and patients with very severe disease (FEV_1<30% predicted) were at greatest risk of developing pneumonia regardless of treatment. Concomitant use of systemic ketoconazole significantly increases systemic exposure to salmeterol. This may lead to an increase in the incidence of systemic effects (e.g. prolongation in the QTc interval and palpitations). Concomitant treatment with ketoconazole or other potent CYP3A4 inhibitors should therefore be avoided unless the benefits outweigh the potentially increased risk of systemic side effects of salmeterol treatment. **Drug Interactions:** Avoid beta-blockers. Concomitant use with other beta-adrenergic containing drugs can have a potentially additive effect. Potent CYP3A4 inhibitors: Co-administration of ketoconazole (400 mg orally once daily) and salmeterol (50 mcg inhaled twice daily) resulted in a significant increase in plasma salmeterol exposure which may lead to an increase in the incidence of other systemic effects of salmeterol treatment (e.g. prolongation of QTc interval and palpitations) compared with salmeterol or ketoconazole treatment alone. The concomitant administration of ketoconazole should be avoided, unless the benefits outweigh the potentially increased risk of systemic side effects of salmeterol treatment. There is likely to be a similar risk of interaction with other potent CYP3A4 inhibitors (e.g. itraconazole, telithromycin, ritonavir). **Pregnancy and Lactation:** Experience limited. Balance risks against benefits. **Undesirable effects:** *Very Common/Common* - candidiasis of mouth and throat, pneumonia, bronchitis, hypokalaemia, headache, hoarseness/dysphonia, throat irritation (uncommon with Seretide 50 Evohaler), nasopharyngitis, sinusitis, contusions, traumatic fractures, arthralgia and myalgia, muscle cramps (uncommon with Seretide 50 Evohaler). See SPC for information on all adverse events. **Overdose:** *due to Salmeterol:* tremor, headache, tachycardia; *due to Fluticasone propionate:* temporary adrenal suppression.
MA Holder (Malta): GlaxoSmithKline (Ireland) Ltd. Trading as: Allen & Hanburys Ltd. **MA Numbers (Malta):** *Seretide Diskus:* MA 192/00901-3; *Seretide 50 Evohaler:* AA 192/00904. **Legal category**: POM. Not all pack sizes may be marketed. Date of revision of text: August 2013.

In order to ensure that this product information reflects the most up-to-date clinical and post-marketing surveillance data, please always refer to the latest Summary of Product Characteristics which is available from GlaxoSmithKline (Malta) Ltd (Tel: +356 21238131)

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Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to the Malta Medicines Authority, Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt
Gibraltar: any suspected AEs and medication errors can also be reported via the UK regulatory authority (MHRA): https://yellowcard.mhra.gov.uk/

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4. Seretide Accuhaler (fluticasone propionate/salmeterol xinafoate) Summary of Product Characteristics, Allen & Hanburys Ltd. October 2014.

Date of Preparation: **January 2015** ZINC CODE: **MLT_GIB/SFC/0002/15**

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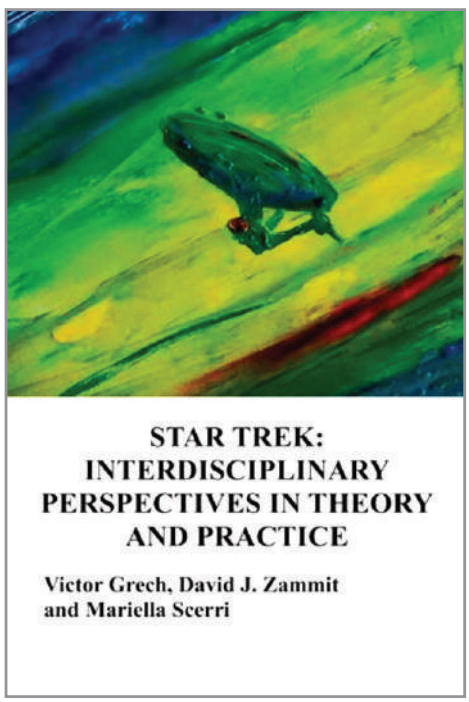
EDITOR'S PICK FOR BOOKWORMS

STAR TREK :INTERDISCIPLINARY PERSPECTIVES IN THEORY AND PRACTICE

Star Trek: Interdisciplinary Perspectives in Theory and Practice is a wonderful illustration of the well-known declamation 'To boldly go where no man has gone before.' This anthology explores various intersections between the Humanities and the Sciences within Star Trek, with a wide range of topics that include architecture, medical and ethical concepts, among others. The essays feature topics such as 'The Relevance of Star Trek in the Big Bang Theory,' 'Cardiopulmonary Resuscitation and Science Fiction,' 'Ethical Issues in Reproduction in the Star Trek Series,' 'Sentient Creatures in the Star Trek Universe to name but a few. These essays form the proceedings of the Star Trek Symposium held in Malta in 2014. Delegates and speakers worldwide came together from varied fields of medicine, nursing, humanities and architecture, providing a rich and innovative interpretation of Star Trek and science fiction in general. To our knowledge, this was the first international academic symposium devoted exclusively to Star Trek. This book aims to reach and appeal not only to academics from various disciplines but also to science fiction lovers with a penchant for Star Trek.

This first book in this series is available on Amazon.
A copy can also be directly ordered from **facebook.com/groups/MaltaSciFi/** or send an email on **info@scifi-malta.com**



Victor Grech, David J Zammit, Mariella Scerri
CreateSpace Independent Publishing Platform;
244 pages; $15
Published in September 2015

HEARD IN THE Grapevine

SWABBING OF NEWBORNS WITH VAGINAL EFFLUVIA

Studies are currently being undertaken whereby the entire body of babies [including the mouth] born by C-section are wiped with a piece of gauze which has previously been inserted into the mother's vagina for one hour before surgery. The research is being spearheaded by Prof. Maria Gloria Dominguez-Bello at The New York University School of Medicine.

The hypothesis for this research is that the disruption of the microbial populations inhabiting the human body lead to many of the modern diseases, such as allergies, autoimmune diseases and obesity. Interestingly these disease have been on the rise in developed countries is parallel to the increase in C-sections. The aim of the research is to investigate whether the odds of developing specific diseases in C-section newborns impregnated with vaginal effluvia during birth are the same as vaginally born babies.

If the hypothesis is proved right, we could start seeing vaginal swabbing rolled out as a standard procedure in hospitals, including Malta.

SMELLING TUBERCULOSIS

In Tanzania, rats have been taught to detect patients with tuberculosis by detecting early signs in human saliva. Currently, the animals work in 21 medical centers in Dar es Salaam, Tanzania's capital. What the rats are trained to do is associate the smell of TB with a reward, so it's what they call operative conditioning

CHILDHOOD MORTALITY IN MALTA HOW DO WE FARE?

KATHLEEN ENGLAND

ABSTRACT

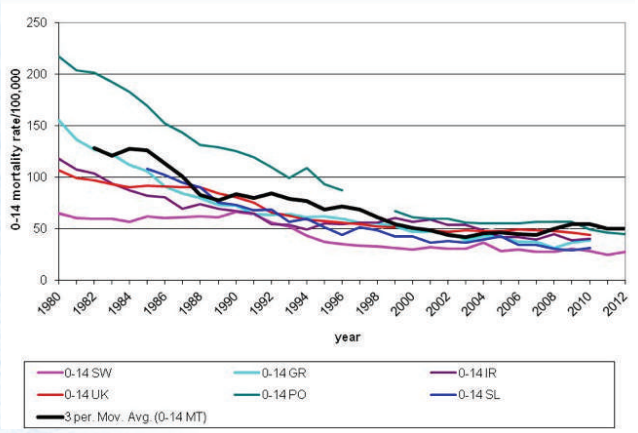
While trends in infant mortality have decreased over the years locally, rates in Malta are still higher than the European Union average. This is often attributed to the fact that Malta is the only European country in which termination of pregnancy is completely illegal. This study primarily aimed to analyse childhood mortality in children 1-14 years where the influence of mortality due to congenital anomalies is much less, compared to that in infants.

INTRODUCTION

Mortality among children of all ages has fallen markedly over the past 30 years. Reduction in childhood mortality remains high on the international agenda as witnessed by the millennium development goal 4 (MGD 4),[1] which aimed at reducing the mortality rate of children under five years of age by two thirds between 1990 and 2015. Though global under-five mortality has been reduced by more than a half, the goal of reducing it by two-thirds has not been reached. Timely, local and valid assessments of trends in child mortality along with the associated drivers of these trends can provide an important input to national, regional, and global debates on the next steps which need to be undertaken.[2]

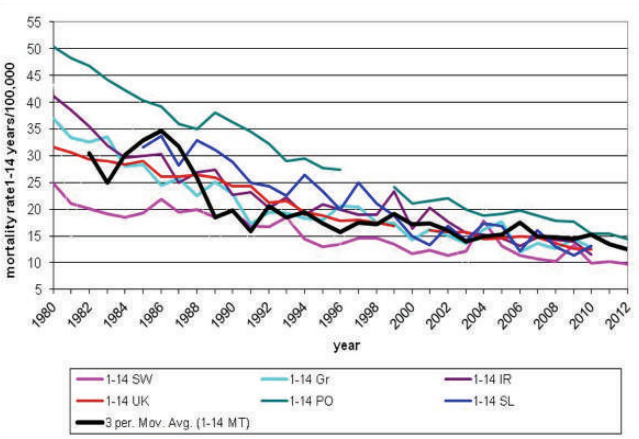
According to the European Observatory on Health Systems and Policies,[3] amongst all EU countries, Sweden was the country with the lowest mortality rate in children 0-14 years of age

Figure 1: Age-specific mortality rates 0-14 years per 100,000 population



SW-Sweden; GR-Greece; IR-Ireland; UK-United Kingdom; PO-Poland (missing data 1997-1998) ; SL-Slovenia; MT-Malta (3 year moving average)

Figure 2: Age-specific mortality rates for 1-14 years per 100,000 population



SW-Sweden; GR-Greece; IR-Ireland; UK-United Kingdom; PO-Poland (missing data 1997-1998); SL- Slovenia; MT-Malta (3 year moving average)

with a rate of 29.27 per 100,000. Romania and Bulgaria had the highest mortality rate, with rates reaching 116.8 per 100,000 in Romania. Malta placed 19th out of the 27 participating countries with a reported rate of 56.16/100,000 population. However, one must keep in mind that Malta is the only European country where termination of pregnancy is completely illegal. Mortality in the 0-14 year olds is mainly due to deaths occurring in the 1st year of life (infant mortality). In view of this fact, having no termination of pregnancy means that infants who may be aborted in other countries due to congenital anomalies which may be fatal, would be born alive and often die in the first year of life in Malta. This contributes to increased childhood mortality. This has been well documented in a study by Gatt M et al[4] which showed that, in comparison to other member states, the higher reported neonatal mortality rates in Malta are mainly attributed to lethal congenital anomalies.

Throughout the early years of life, post-infancy may still be influenced by conditions present at birth. However, many lethal congenital anomalies would have resulted in death during the first year of life and therefore, the effect of congenital anomalies on deaths beyond one year is reduced. The aim of this study was to assess trends in childhood mortality for Malta beyond one year of age and compare rates with that of other European countries.

METHODOLOGY

Using Mortality data for Malta from the WHO Mortality Database as well as the National Mortality Registry at the Directorate for Health Information and Research, mortality data for infants aged 0-1 year and those aged 1-14 years of age was extracted from 1980-2012. Similar population figures were extracted and age-specific mortality rates from 1980-2012 were calculated. These trends and rates were compared to rates from a number of countries for which data was similarly extracted from the WHO database. The countries used for this analysis were Sweden, which according to Wolfe et al[5] ranks lowest in

Figure 3: Shifting relative cause mortality in children 1-14 years in the 15 pre-2004 countries of the EU, 1960-2010[5]

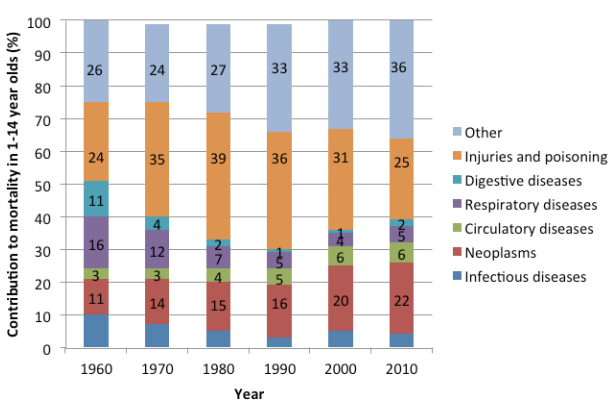
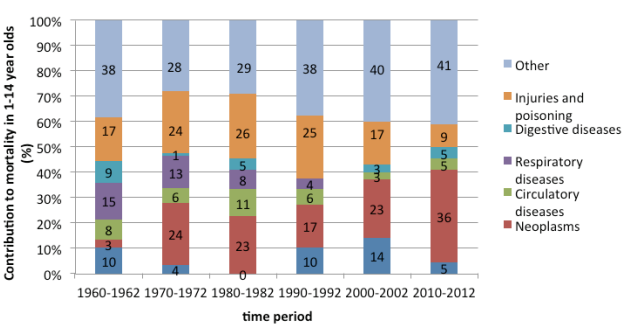


Figure 4: Shifting relative cause mortality in children 1-14 years in Malta, 1960-2012



childhood mortality, Greece representing a southern European country, United Kingdom representing a country from EU-15, Ireland and Poland which have similar laws regarding abortion and Slovenia which is a new accession country. In addition, an average mortality rate over 5 years for children aged 1-4 years, 5-9 years and 10-14 years was calculated for Malta and compared to the average for the European Union.

Trends in causes of death for children 1-14 years of age for EU-15, as depicted by Wolfe et al,[5] were then compared to those for Malta, in order to assess whether a similar pattern in the shift in causes of death is happening in Malta and the EU-15.

RESULTS

TRENDS IN CHILDHOOD MORTALITY RATES IN MALTA COMPARED TO EU COUNTRIES

Mortality rates in 0-14 years of age have been showing a decreasing trend in all countries presented, as seen in Figure 1. Deaths in this age group are principally attributed to infant mortality. Due to small numbers for Malta, a 3-year moving average has been used. Moving average is a calculation to analyze data points by creating a series of averages in order to smooth out short-term fluctuations useful especially with data involving small numbers. Whilst Malta's mortality rates in this age group are amongst the highest, this decreases in the 1-14 year age group (Figure 2), where Malta's rates overlap with most countries.

If one compares age specific childhood mortality in Malta to the EU average, in the age groups between 1-14 years, where the effect of congenital anomalies is decreased Malta's rates are much closer to the EU average (Table 1).

SHIFT IN CAUSES OF DEATH IN 1-14 YEAR OLDS IN MALTA AND EU-15

A shift in the main causes of childhood mortality in 1-14 year olds has taken place over the years as seen in figures 3 and 4 and table 2, with mortality due to infectious diseases, respiratory diseases and gastrointestinal diseases decreasing, while deaths due to neoplasms becoming more predominant. 'Other' causes of death mainly include congenital anomalies, endocrine and neurological disorders. While trends are similar in EU-15 compared to Malta for most causes, injuries are a less frequent cause of death in 1-14 year olds in Malta compared to EU-15, while neoplasms are a more frequent cause of death locally. However, numbers for Malta are very small and need to be interpreted cautiously (Table 2).

MORTALITY DUE TO INFECTIOUS DISEASES, RESPIRATORY DISEASES AND GASTROINTESTINAL DISEASES DECREASING, WHILE DEATHS DUE TO NEOPLASMS BECOMING MORE PREDOMINANT

DISCUSSION AND SOME CONCLUSIONS

Infant and childhood mortality represent an important indicator of the health care system of a country. Mortality rates after one year of age in Malta are much closer to the EU average, compared to those under one year of age. In Malta, while childhood neoplasms are increasingly contributing to a larger percentage of deaths (3.2% in 1962 vs 36.4% in 2012), both the overall number of deaths as well as deaths from neoplasms are decreasing.

Non-communicable diseases are increasingly becoming common causes of childhood illness and death. Health services and social and cultural determinants (conditions in which people are born, grow, work, live, and age) contribute to differences in health outcomes. Development of systems more responsive to evolving child health needs is likely to necessitate reconfiguring of health services as part of a whole-systems approach to the improvement of health.[5]

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Table 1: Age-specific mortality rates per 100,000 population in Malta compared to the EU 28 average

Age of child	**Malta** (5 year average 2008-2012)	EU average for 2011
0-1	627.6 (lower CI 525.9; upper CI 748.3)	392.8
1-4	23.8 (lower CI 14.8; upper CI 38.0)	18.4
5-9	6.0 (lower CI 2.4; upper CI 13.7)	9.7
10-14	13.6 (lower CI 8.0; upper CI 22.5)	11.1

Table 2: Main causes of death in Malta in different time periods in 1-14 year olds

	Total deaths in 3 year periods					
	1960-1962	1970-1972	1980-1982	1990-1992	2000-2002	2010-2012
Infectious diseases	19	3	0	5	5	1
Neoplasms	6	21	15	8	8	8
Circulatory diseases	15	5	7	3	1	1
Respiratory diseases	27	11	5	2	0	0
Digestive diseases	16	1	3	0	1	1
Injuries and poisoning	32	21	17	12	6	2
Other	71	24	19	18	14	9
Total deaths	**186**	**86**	**66**	**48**	**35**	**22**

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DOCTOR PRENEUR

DR JOSIE MUSCAT IS THE FOUNDER AND CHAIRMAN OF THE ST JAMES HOSPITAL GROUP WHICH WAS FOUNDED IN 1984. THE 72 YEAR-OLD ENTREPRENEAUR SPEAKS TO MARIKA AZZOPARDI ABOUT HIS MOTIVATIONS, ASPIRATIONS AND THOUGHTS ABOUT REACHING 82 YEARS.

TS: Why become a doctor?
I became a doctor due to circumstances. My father was a doctor, all my uncles and my grandfather were doctors, so coming from a family of doctors, I never really considered anything else, apart from the fact that way back in 1964, there were very few university courses to choose from.

TS: Last July you celebrated 72 years of age. What do you consider to be your greatest two achievements?
As a family man my greatest achievement is having made the right choice of wife. My wife and I have been married for almost 50 years and I don't regret a single minute. We have six children and over the years we have managed to give five of them the education they wanted and each of them has his or her own profession. The youngest daughter was born with Down syndrome and our great satisfaction is that she has reached specific milestones over the years.

As a doctor my greatest achievement is having introduced several new systems in Malta, as well as machinery and techniques (such as MRI, keyhole surgery, PET Scan and IVF), which have helped a great number of people and eventually introduced also by government in state hospitals and clinics. Financially speaking, this was a great blow to me, but I opened venues for doctors and specialists, and my initiatives have been of benefit to innumerable patients.

TS: How was the Saint James Group set up?
Saint James Group started from a small room which I used as a GP. In the seventies, when private hospitals were closed by the government of the day, I opened a small private clinic with two beds. Subsequently, my children joined me and we never looked back. We kept investing and growing over the years and the various branches gave scope to the creation of the group.

TS: What is the story behind the name 'Saint James Group'?
The name was inspired by the location which is St James Square in Żabbar.

TS: In what can be regarded as the sole reconsideration of the Saint James Group, you closed the Saint James Għajnsielem hospital. What are your thoughts about this?
Saint James Għajnsielem closed after only four years in operation, but this was not because of a lack of success, but because the necessary profits to keep it running were not reached. The Gozitans typically use free hospital service at the main hospital and for such a small population the private hospital was not a profitable venture.

TS: You were also very active in the political scene. Amongst other things, you founded the Front Freedom Fighters and the Alleanza Nazzjonali. What motivated you to go into politics?
I have always been very active since my school days when I was president of the Crusaders at St Aloysius College. Eventually I

Josie & daughter Nicole meeting actor Chris Berg

80's political demonstrations

moved from this very active group to help found the Sodality Group of which I was eventually president. At sixth form I was also president of the Older Boys Sodality Group. In 1966, during my sixth year as medical student, I saw my chance of joining the Nationalist Party as a candidate for the second district. The Front Freedom Fighters was a political organisation I set up to encourage people living in the south to openly profess their Nationalist leanings and to stop them being discriminated against. In 1984, I did not contest the elections since I was not in agreement with the way the party was moving ahead. In 1992, I was approached by a number of disgruntled people who wanted help to organise Alleanza Nazzjonali which could have been a successful third party. But when it comes to votes, people tend to side with one of the two big parties.

TS: You are also the founder of the Eden Foundation. Where do you see Malta heading when it comes to services for the physically or mentally challenged persons?

When my sixth child Nicole was born with Down Syndrome, I came in touch with the reality of having a child with mental and physical disability. At the time, the country offered rudimentary facilities to assist parents and clients. I even considered going abroad for such assistance as was required. We travelled to Munich's Kinder Zentrum where we provided our daughter with the necessary therapy and education. One fine day, we decided to do something about it in Malta. Some good people I knew accepted to be trustees of the Foundation and we started from a first meeting at Dar Tal-Kleru and proceeded to occupy rent-free premises (thanks to Dennis Zammit Cutajar) in St Paul's Street, Valletta. This is where the first children were engaged. The Foundation started with 25 children and their parents, and kept growing until we moved to premises in Bulebel which had been earmarked for government use, but were never occupied.

Queen Elizabeth II officially opening Eden Foundation

I have been away nearly 10 years now, so I am not in touch with the goings-on of the Foundation, but what was started helped people with mental and physical disabilities. Today they can avail themselves of job coaches and achieve qualifications from the UOM. If anything, we have helped to raise awareness in this regard.

TS: Recently, you were in the news since Saint James Capua Hospital has been sold off. Can you possibly share with us the reasons which led you to part from your flagship investment, after running it for 12 years?

The reasons behind our decision to sell this hospital (it has not been sold yet), were twofold. First, I was foreseeing that the Health Department policy would eventually close us up, that the health system would be in the hands of foreigners, and that the health situation has become a political ball. Secondly, my great wish has always been to have a hospital in the south of Malta. Since I did not have the necessary funds to do so, I had to sell Capua to be able to construct a new hospital in Tarxien.

TS: In hindsight, is there a particular decision in your life which you would not have taken or taken in a different way?

I believe that had I not clashed head-on with the leader of the Nationalist Party, I would have advanced considerably in my political life. But thankfully, when I left politics, I believe I was instrumental in opening up new medical venues for our patients. That, in the end, is more satisfying.

TS: Any future plans?

I dream of seeing the new southern hospital inaugurated.

S: How would you wish to describe an 82 year Josie Muscat?

JM: Active, energetic, still innovative, with a clear, determined mind, and a strong heart… I'll have to pray hard for all that. Hitting 82?

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▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Refer to section 4.8 of the SmPC for how to report adverse reactions. **PRESENTATION:** Each capsule contains 143 µg of indacaterol maleate equivalent to 110 µg of indacaterol and 63 µg of glycopyrronium bromide equivalent to 50 µg of glycopyrronium. Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains 110 µg of indacaterol maleate equivalent to 85 µg of indacaterol and 54 µg of glycopyrronium bromide equivalent to 43 µg of glycopyrronium. **INDICATIONS:** Ultibro Breezhaler is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). **DOSAGE AND ADMINISTRATION:** The recommended dose is the inhalation of the content of one capsule once daily using the Ultibro Breezhaler inhaler. Ultibro Breezhaler is recommended to be administered at the same time of the day each day. If a dose is missed, it should be taken as soon as possible on the same day. Patients should be instructed not to take more than one dose in a day. Ultibro Breezhaler can be used at the recommended dose in elderly patients (75 years of age and older). Ultibro Breezhaler can be used at the recommended dose in patients with mild to moderate renal impairment. In patients with severe renal impairment or end-stage renal disease requiring dialysis it should be used only if the expected benefit outweighs the potential risk. Ultibro Breezhaler can be used at the recommended dose in patients with mild and moderate hepatic impairment. There are no data available for the use of Ultibro Breezhaler in patients with severe hepatic impairment, therefore caution should be observed in these patients. There is no relevant use of Ultibro Breezhaler in the paediatric population (under 18 years) in the indication COPD. The safety and efficacy of Ultibro Breezhaler in children have not been established. No data are available. Method of administration For inhalation use only. The capsules must not be swallowed. The capsules must be administered only using the Ultibro Breezhaler inhaler. Patients should be instructed on how to administer the product correctly. Patients who do not experience improvement in breathing should be asked if they are swallowing the medicine rather than inhaling it. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the other excipients. **WARNINGS/PRECAUTIONS:** Ultibro Breezhaler should not be administered concomitantly with medicinal products containing other long acting beta adrenergic agonists or long acting muscarinic antagonists, the pharmacotherapeutic groups to which the components of Ultibro Breezhaler belong. Asthma: Ultibro Breezhaler should not be used for the treatment of asthma due to the absence of data in this indication. Long acting beta2 adrenergic agonists may increase the risk of asthma related serious adverse events, including asthma related deaths, when used for the treatment of asthma. Not for acute use: Ultibro Breezhaler is not indicated for the treatment of acute episodes of bronchospasm. Hypersensitivity related to indacaterol or glycopyrronium. Immediate hypersensitivity reactions have been reported after administration of indacaterol, one of the components of Ultibro Breezhaler. If signs suggesting allergic reactions (in particular, difficulties in breathing or swallowing, swelling of tongue, lips and face, urticaria, skin rash) occur, treatment should be discontinued immediately and alternative therapy instituted. ***Paradoxical bronchospasm:*** In clinical studies with Ultibro Breezhaler, paradoxical bronchospasm was not observed. However, paradoxical bronchospasm has been observed with other inhalation therapy and can be life threatening. If this occurs, treatment should be discontinued immediately and alternative therapy instituted. *Narrow-angle glaucoma:* No data are available in patients with narrow angle glaucoma, therefore Ultibro Breezhaler should be used with caution in these patients. Patients should be informed about the signs and symptoms of acute narrow angle glaucoma and should be informed to stop using Ultibro Breezhaler should any of these signs or symptoms develop. Urinary retention: No data are available in patients with urinary retention, therefore Ultibro Breezhaler should be used with caution in these patients. Patients with severe renal impairment: These patients should be monitored closely for potential adverse reactions. ***Cardiovascular effects:*** Ultibro Breezhaler should be used with caution in patients with cardiovascular disorders (coronary artery disease, acute myocardial infarction, cardiac arrhythmias, hypertension). ***Hypokalaemia:*** Beta2 adrenergic agonists may produce significant hypokalaemia in some patients, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. In patients with severe COPD, hypokalaemia may be potentiated by hypoxia and concomitant treatment, which may increase the susceptibility to cardiac arrhythmias. Clinically relevant effects of hypokalaemia have not been observed in clinical studies of Ultibro Breezhaler at the recommended therapeutic dose. ***Hyperglycaemia*** Inhalation of high doses of beta2 adrenergic agonists may produce increases in plasma glucose. Upon initiation of treatment with Ultibro Breezhaler plasma glucose should be monitored more closely in diabetic patients. Ultibro Breezhaler should be used with caution in patients with convulsive disorders or thyrotoxicosis, and in patients who are unusually responsive to beta2 adrenergic agonists. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose galactose malabsorption should not take this medicine. ***Pregnancy and Lactation:*** There are no data from the use of Ultibro Breezhaler in pregnant women available. Indacaterol may inhibit labour due to a relaxant effect on uterine smooth muscle. Therefore, Ultibro Breezhaler should only be used during pregnancy if the expected benefit to the patient justifies the potential risk to the foetus. It is not known whether indacaterol, glycopyrronium and their metabolites are excreted in human milk. The use of Ultibro Breezhaler by breast feeding women should only be considered if the expected benefit to the woman is greater than any possible risk to the infant. **INTERACTIONS:** Information on the potential for interactions is based on the potential for each of its two components. Beta adrenergic blockers may weaken or antagonise the effect of beta2 adrenergic agonists. Therefore Ultibro Breezhaler should not be given together with beta-adrenergic blockers (including eye drops) unless there are compelling reasons for their use. Where required, cardioselective beta adrenergic blockers should be preferred, although they should be administered with caution. The co administration of Ultibro Breezhaler with other anticholinergic containing medicinal products has not been studied and is therefore not recommended. Concomitant administration of other sympathomimetic agents (alone or as part of combination therapy) may potentiate the adverse events of indacaterol. Concomitant hypokalaemic treatment with methylxanthine derivatives, steroids, or non-potassium-sparing diuretics may potentiate the possible hypokalaemic effect of beta2-adrenergic agonists, therefore use with caution. Inhibition of the key contributors of indacaterol clearance, CYP3A4 and P glycoprotein (P gp), raises the systemic exposure of indacaterol up to two fold. The magnitude of exposure increases due to interactions does not raise any safety concerns given the safety experience of treatment with indacaterol in clinical studies of up to one year at doses up to twice the maximum recommended indacaterol dose. **ADVERSE REACTIONS:** The presentation of the safety profile is based on the experience with Ultibro Breezhaler and the individual components. Ultibro Breezhaler showed similar adverse reactions to the individual components. As it contains indacaterol and glycopyrronium, the type and severity of adverse reactions associated with each of these components may be expected in the combination. The most common adverse reactions with Ultibro Breezhaler are: Upper respiratory tract infections. Common: Pyrexia, chest pain, musculoskeletal pain, dyspepsia, dental Caries, gastroenteritis, cough, oropharyngeal pain including throat irritation, dizziness, headache, nasopharyngitis, urinary tract infections, sinusitis, rhinitis, chest Pain, oropharyngeal pain including throat irritation, Uncommon: Fatigue, peripheral oedema, muscle spasm, myalgia, pain extremity, bladder obstruction and urinary retention, dry mouth, pruritis, rash, glaucoma, myalgia, musculoskeletal pain, pruritis/rash, paradoxical bronchospasm, epistaxis, tachycardia, palpitations, hypersensitivity, diabetes mellitus and hyperglycaemia, insomnia. Please refer to SmPC for a full list of adverse events for Ultibro Breezhaler. **LEGAL CATEGORY:** POM **PACK SIZES:** Single pack containing 10x1 or 3x10 hard capsules, together with one inhaler. **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Frimley Business Park Camberley GU16 7SR, United Kingdom. **MARKETING AUTHORISATION NUMBERS:** EU/1/13/862/003 , EU/1/13/862/007 **Please refer to Summary of Product Characteristics (SmPC) before prescribing.** Full prescribing information is available on request from Novartis Pharma Services Inc, Representative Office Malta P.O Box 4, Marsa, MRS 1000 Malta. Tel: +35621222872 2015-MT-ULT-09-OCT-2015

1. Novartis Europharm Ltd. Ultibro Breezhaler Summary of Product Characteristics.

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NOVARTIS

THE CHOLESTEROL CONTROVERSY: THE SERIES

Simultaneous with reorientation of nutritional conventional wisdom away from fat as a dietary evil and increased acceptance that refined carbohydrate is the real culprit for atherosclerosis, obesity, diabetes and metabolic syndrome, a third factor has, these last 15 years or so, solidified the evidence behind the idea that a higher fat diet may be healthier. This factor is the new science of predicting coronary artery disease, which turned everything we originally believed in about cholesterol, atherosclerosis and diet, on its head.

Ronald Krauss, one of the most influential researchers in the nutrition field, has made several important contributions towards unsettling the case against saturated fat, but the most crucial one was his discovery of a new biomarker for atherosclerosis.

The holy grail of cardiovascular research has, of course, been finding a blood marker of ischaemic heart disease risk. Ancel Keys proposed, 60 years ago, total serum cholesterol as this marker, condemning saturated fat entirely on the basis of its capacity to raise it. Decades later, scientists begun to understand that the "total cholesterol" number wasn't actually a good predictor for heart attack risk and that it masked the more subtle measures of HDL- and LDL-cholesterol. Saturated fats raise both HDL- and LDL-cholesterol. These conflicting effects have been fatal for saturated fat, because official scientific opinion, for political and other vested interests, has favoured LDL-cholesterol over HDL-cholesterol as the biomarker of choice for the last few decades.

In the 1990s, Krauss found a way to predict coronary artery disease that both surpassed and undermined the methods upon which the dietary saturated fat-heart hypothesis had been built. Krauss had seen patients with normal-range LDL-cholesterol who suffered heart attacks. He pointed out that LDL-cholesterol predicted coronary artery disease only when very high, and that borderline-high LDL-cholesterol was meaningless. Furthermore, in various major studies,[1-5] LDL-cholesterol levels were completely uncorrelated with myocardial infarction. Indeed, many researchers today argue that "high LDL-cholesterol" is no longer especially meaningful and that there is no scientific basis for treating LDL targets.[6-7] Allan Sniderman, McGill University professor of medicine and cardiology, has even gone so far as to describe LDL-cholesterol as a "historical leftover".[8]

Krauss reported that as far back as 1950, John Gofman, medical physicist, found that LDL-cholesterol was the sum of a number of "LDL sub-fractions".[9] Krauss confirmed this in the 1980s and identified LDL particles to be either large, light and buoyant orsmall and dense. He found the small ones to be closely associated with coronary artery disease risk, whereas the large ones were not liked at all.

Krauss therefore established that "high total LDL", which by conventional standards sounded bad, was in fact not a problem since it was mainly made up of the large-particle type. Conversely, one could have relatively low LDL, which seemed a good thing, but if it was mainly made up of the small dense type, it signalled a high risk.[10,11]

With this discovery, Krauss showed why "high LDL-cholesterol", endorsed by mainstream experts, was not living up to its promises of predicting ischaemic heart disease. Public health recommendations had been issued and statin drugs prescribed to millions based on the idea that these drugs worked by lowering blood LDL-cholesterol, but the science of predicting ischaemic heart disease was still unfolding.

Krauss also tested what happened to LDL sub-fractions when subjects eat different diets. He found that when more total and saturated fats were eaten, instead of carbohydrates, there was an increase in the large "good" type LDL, while the small, dense "bad" LDL went down.[12,13] The case against saturated fat as the main dietary culprit should now have been considerably weakened – if saturated fat raised only the innocuous large-particle LDL, then its effect was relatively benign. Combined with saturated fat's ability to raise HDL-cholesterol, then it looked not just benign, but maybe even healthy, and certainly far better than the carbohydrate the public had been advised to eat in its place.

Other promising new biomarkers have been discovered and promoted more recently, such as Apo-lipoprotein B (ApoB) and non-HDL-cholesterol. But only Krauss's LDL sub-fractions can explain the problematic findings from several large studies, namely, that LDL-cholesterol cannot reliably be linked to coronary artery disease outcomes. Krauss's sub-fractions are uniquely significant and important

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DETECTING BREAST
ADVANCED AND NEW TECHNOLOGIES

Breast cancer is the most common cancer in women. This has consequently generated considerable interest in the literature with the result that Breast Cancer Screening Programs have become available in most developed countries. The aim of these screening programs is to achieve early detection of breast cancer in women who have not yet developed any symptoms. Such early detection allows early treatment, which is necessary to achieve a good treatment outcome. Treatment of early cancer results in cure in 98% of cases, while late cancer detection results in a poor outcome.

Early breast cancer detection depends on the accuracy of the equipment used and on training and experience of the specialists involved. Equipment accuracy and consequently image quality play a very important role since specialist training and experience cannot compensate for poor image quality. New technologies are contributing to improved image quality and also to new parameters that help distinguish benign from malignant disease.

Mammography is the mainstay of breast cancer screening particularly for women who are 40 years of age or older; these women have a significantly higher risk of developing breast cancer. Ultrasound (US) is used for screening younger women particularly those who are 35 years of age or less. Both mammography and breast US are frequently combined in women over 40 years of age with an improvement in diagnostic confidence and accuracy. Further evaluation with breast Magnetic Resonance Imaging (MRI) and image-guided biopsy is required when abnormal findings are present.

There have been dramatic improvements in mammographic technology in recent years. Film-screen mammography, which used chemically-processed film to record images of the breast, has been largely replaced by digital mammography since the latter methods deliver better image quality and require less exposure to radiation. Digital mammography uses two different technologies, computed radiography (CR) or full field digital mammography (FFDM).

CR mammography uses a fluorescent plate that is subsequently scanned to obtain an image of the breast. FFDM acquires an image of the breast through an array of tiny solid state detectors, which are more efficient than the fluorescent plate resulting in much better image quality (Figure 1) and a further reduction in radiation exposure.

Breast US is used as a first line for breast imaging in younger women due to the absence of ionizing radiation and the limitations mammography has in dense breasts. Image quality in breast US has greatly improved over time. Characteristics detected on standard (B mode) US have been shown to be highly accurate for distinguishing cancerous from non-cancerous disease (Figure 2). Color Doppler imaging has been shown to help further in characterizing breast lesions and for guiding biopsy.

US elastography is a new technology that is being introduced to improve detection and characterization of breast masses.

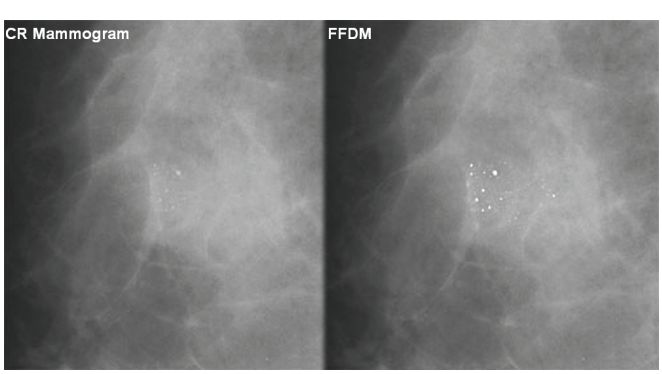

Figure 1. The presence of microcalcifications may be one of the earliest signs of breast cancer on mammography. Left (CR) and right (FFDM) mammograms show the same cluster of microcalcifications, but depiction on FFDM is far superior.

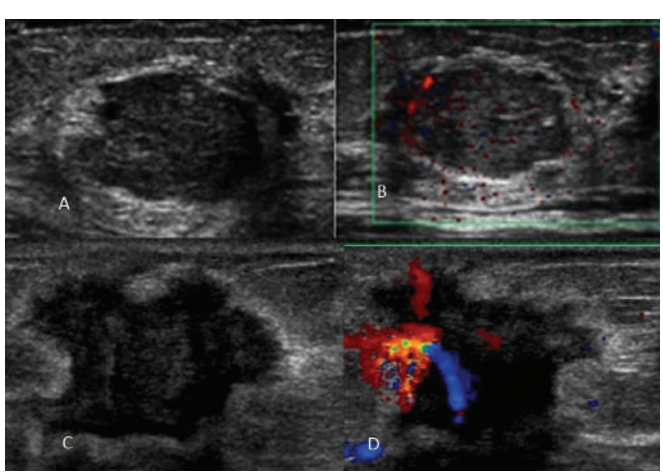

Figure 2. Image A shows an ultrasound image of a benign nodule (fibroadenoma) showing smooth margins while Image B is a color Doppler image of the same lesion showing a lack of blood vessels. Image C is an ultrasound image of an invasive ductal cancer demonstrating irregular margins with abundant blood flow shown on the color Doppler image (D).

CANCER

PIERRE VASSALLO

There are two types of US-elastography available. Strain elastography is used to evaluate how a lesion deforms when it is compressed. Lesions that are soft deform more than those that are stiff and the strain elastography scale provides a *qualitative* measure of the amount of tissue stiffness (Figure 3). Shear-wave (SW) elastography uses an US push pulse to generate shear waves. SW velocity (Vs) in the tissue is proportional to the square root of stiffness (Young modulus) of the lesion. This allows *quantitative* evaluation of tissue stiffness. Hard lesions are mostly benign, while softer lesions, which show more deformability on strain elastography and higher Vs values on SW elastography, are more likely to be malignant. Strain elastography has been shown to significantly improve accuracy for distinguishing cancer from non-cancerous lesions. SW elastography is less accurate than strain elastography due to artefacts, but a number of design improvements are currently being tested, which will likely change the situation.

MRI has been widely used for detecting and assessing breast lesions. MRI is sensitive for detecting breast cancers, with a sensitivity as high as 100% for invasive breast cancers, and therefore has emerged as an adjunctive breast imaging modality to mammography and US. MRI has limitations in lesion characterization, but it is still useful in conjunction with mammography and US for differentiating between benign breast lesions and benign-looking breast cancers. It is of particular value for evaluating dense breasts. Important indications for breast MRI include a positive BRCA 1 or BRCA 2 test or a 1st degree relative BRCA+, patients who have had prior radiotherapy to the chest wall, individuals with > 25% lifetime risk based on genetic models (some of which take breast density into consideration), for problem solving (e.g. post-operative breasts with distortion) and to search for synchronous, multifocal or multicentric disease. High T2 signal, flow restriction on Diffusion Weighted Imaging (DWI) and/or strong and rapid contrast uptake with sustained enhancement or early washout are features of malignant disease (Figure 4).

Breast imaging has developed into a complex algorithm composed of a variety of modalities all of which contribute to accurate detection and staging of cancer. Continued specialist training and constant upgrading to new and improved imaging technologies are necessary to provide the best image qualityneeded to guide optimal breast cancer management.

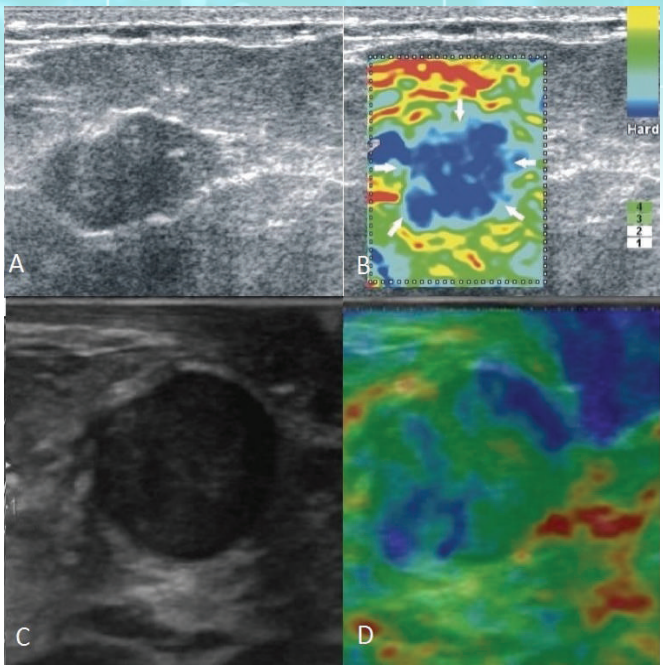

Figure 3. Image A shows a lesion with slightly irregular margins and showing abundant internal echoes that on conventional US might be suggested it to be benign. However Image B shows this to be a very "blue" lesion, which indicates a hard nodule and is strongly suggestive of malignant disease. This lesion was confirmed through biopsy to be an invasive ductal cancer. Image C depicts a rounded lesion with low echogenicity and smooth margins, however it lacks blue colour on elastography (Image D) suggesting a rather soft lesion; this was confirmed on biopsy to be a fibroadenoma, which is benign.

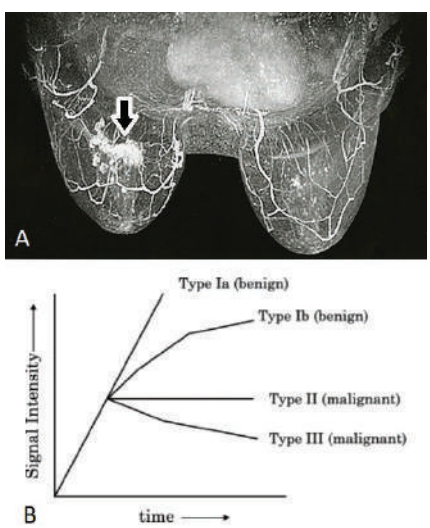

Figure 4. Image A shows a contrast enhanced T1-weighted fat suppressed image of both breasts with an enhancing mass (arrow) in the right breast that was histologically confirmed to be an invasive ductal cancer. Image B shows the enhancement patterns that are characteristic of benign and malignant lesions.

ALL TECHNOLOGIES MENTIONED ABOVE ARE AVAILABLE AT DA VINCI HEALTH

Augmentin® ES

600 mg/42.9 mg/5 ml

Amoxicillin/Clavulanate Potassium

Powder for oral suspension

- ✓ Provides extended antibacterial coverage to include the most penicillin-resistant strains.[1]
- ✓ Recommended by leading Guidelines as first line treatment in AOM.[2,3]
- ✓ Most common adverse effects are diarrhoea, nausea, vomiting and mucocutaneous candidiasis.[4]
- ✓ Indicated for children <40 kg and older than 3 months; dosed at 90/6.4 mg/kg/day in 2 divided doses.[4]

Spreading infectious energy!

Mini Abridged Prescribing Information: *Please refer to full Summary of Product Characteristics (SPC) before prescribing.* **TRADE NAME:** Augmentin ES. **ACTIVE INGREDIENTS:** Amoxicillin (as trihydrate) and potassium clavulanate. **PRESENTATION:** 600 mg/42.9 mg/5 ml powder for oral suspension. Supplied in 100 ml glass bottle with a dosing spoon. **INDICATION:** treatment of acute otitis media and community acquired pneumonia infections in children aged at least 3 months and less than 40 kg body weight, caused or thought likely to be caused by penicillin-resistant *Streptococcus pneumoniae*. **POSOLOGY & ADMINISTRATION:** Oral use. Recommended dose is 90/6.4 mg/kg/day in two divided doses. To minimise potential gastrointestinal intolerance, administer at the start of a meal. **CONTRAINDICATIONS:** Hypersensitivity (and past history of) to the active substances, to any penicillins or to any of the excipients. **SPECIAL WARNINGS & PRECAUTIONS:** Before initiating therapy careful enquiry of previous hypersensitivity reactions to beta-lactams. Where an infection is proven to be due to an amoxicillin susceptible organism, a switch to an amoxicillin-only preparation should be considered. Convulsions may occur in patients receiving high doses or who have impaired renal function. Concomitant use of allopurinol increase likelihood of allergic skin reactions. Prolonged use may occasionally result in overgrowth of non-susceptible organisms. Contains aspartame (E951), a source of phenylalanine. The suspension also contains maltodextrin (glucose). **INTERACTIONS:** Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity. Concomitant use of probenecid is not recommended. If co-administration with oral anticoagulants is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin. Moreover, adjustments in the dose of oral anticoagulants may be necessary. Clinical monitoring should be performed during the combination with mycophenolate mofetil and shortly after antibiotic treatment. **PREGNANCY & LACTATION:** Use should be avoided unless considered essential by the physician. **UNDESIRABLE EFFECTS:** Very common (≥1/10): diarrhoea. Common (≥1/100, <1/10): mucocutaneous candidosis, nausea, abdominal pain. *Refer to SPC's for full list of undesirable effects*. **AUTHORISATION NUMBER:** AA 1051/00101. **MARKETING AUTHORISATION HOLDER:** GlaxoSmithKline Bulgaria EOOD. **LEGAL CATEGORY:** POM. **DATE OF PREPARATION:** July 2014. **In order to ensure that this product information reflects the most up-to-date clinical and post-marketing surveillance data, please always refer to the latest Summary of Product Characteristics (SPC) which is available from GlaxoSmithKline (Malta) Ltd (Tel: +356 21238131).** ***REPORTING ADVERSE EVENTS (AEs):*** **If you become aware of any AEs, medication errors and/or use during pregnancy in association with GSK products, please report the event promptly to:** GSK (Malta) Limited, 1, De la Cruz Avenue, Qormi QRM 2458, Malta (Tel: +356 21238131). **Alternatively, any suspected AEs and medication errors can also be reported via the national Adverse Drug Reactions (ADRs) reporting system:** Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to the Malta Medicines Authority, Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt.

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