Need for ethical promotion of healthcare products

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Need for ethical promotion of healthcare products

Healthcare stakeholders need to share responsibilities with healthcare authorities by self-regulation to ensure the ethical promotion of their products.

The bulk of the role of regulation and enforcement of ethical promotion has traditionally come under the purview of healthcare authorities. However, as the pharmaceutical industry continues to evolve and grow, the involvement of multiple stakeholders is becoming increasingly necessary.

Self-regulation can be viewed as keeping tabs on the processes or activities by the people or organizations involved in them rather than solely by an external authority such as the government. Effective self-regulation is critical as it provides consumers with a double layer of protection. This is advantageous to consumers, businesses and government, explained Eisah Abdul Rahman, Senior Director of Pharmaceutical Services, Ministry of Health.

She said there exists a Code of Conduct for pharmaceutical advertising which marketers have to abide by in the different media.

Dato’ Eisah said the pharmaceutical industry, together with the Pharmaceutical Association of Malaysia (PhAMA), has been work-
ing closely with the Medicine Advertisement Board (MAB) to ensure compliance with the industry code and to establish an appropriate channel of communication when non-compliance occurs. She said these efforts could also be practised by other healthcare sectors like medical devices and generic pharmaceuticals.

The marketing and promotion of healthcare products involves interaction with both healthcare professionals and the public. Therefore, communication between pharmaceutical companies and healthcare professionals is important as it keeps both parties in the loop about new therapy options. The awareness of new treatment regimes also benefits patients.

Promotion involves disseminating information about a product, product line, brand or company. The Medicines (Advertisement & Sale) Act 1956 (MASA) states that advertisements include any notice, circular, report, commentary, pamphlet, wrapper or other documents and any announcements made orally or by means of producing or transmission through light or sound.

Dato’ Eisah said that while communication with healthcare professionals is essential, integrity and credibility should not be overlooked. Advertisers or marketers have a social obligation to provide unbiased information in advertisements to help consumers make informed choices. In this regard, MASA plays a role by prohibiting certain advertisements relating to medical matters and regulating the sale of substances recommended as medicines. This ensures marketing campaigns are ethically conducted, thus protecting consumers.

MASA has been granted the power to monitor and regulate advertisements to the MAB. It is within MAB’s purview to set policies and guidance on related advertisements prioritizing integrity. Requirements and relevant information pertaining to advertisements can be accessed at www.pharmacy.gov.my.

Dato’ Eisah said the number of advertising applications to the MAB has steadily increased over the years. In 2012, MAB received 2133 advertisements for approval, a 23% increase from 2011.

In line with the expanding market, the MAB secretariat has reviewed existing procedures and shortened the application approval timeframe from seven to five working days, effective 2013.

Some of the challenges faced by MASA are the emergence of various innovative products in the food-drug, device-drug and cosmetic-drug inter-phase categories. These interface products are governed by a different set of laws, thus their regulation is tricky. The Ministry of Health, led by the Pharmaceutical Services Division, is exploring the possibility of establishing a single enforcement entity to coordinate all issues relating to the control and regulation of goods and services.

Dato’ Eisah also brought up online advertising, which poses a huge challenge for regulators. Being borderless by nature, it is complicated for law enforcement authorities to track business activities and modus operandi.

She reiterated that self-regulation needs a strong commitment from all stakeholders. There is also a need for a strong legal framework to enforce penalties, punish offenders and impose deterrent sanctions.

She urged the industry to gear up to work with the authorities in implementing self-regulation in the safety, efficacy and quality of drugs to ensure the wellbeing of patients.
More men popping vitamins for health, appearance

Increasing numbers of men in the UK are taking natural health supplements, but product launches for men’s vitamins are lagging behind, according to a new report.

The dietary supplement market aimed specifically at men grew by 25% in the UK last year, the 23 September report compiled by market analysts Mintel showed.

However, while more men are taking supplements, such as cod liver oil, zinc and magnesium, the number of product launches of natural health supplements specifically for men is still relatively low, a Mintel spokesperson told the Daily Mail.

“Men who buy grooming products to boost self-esteem or feel more attractive are now in the majority; however, there have been few vitamin launches targeted at men, particularly when it comes to vitamins with appearance benefits.”

According to the report, one-in-five men have taken vitamins “occasionally” in the past 12 months, mostly when they are feeling rundown.

Men reported they took vitamins to boost their general health, with 56% saying they took it to improve their immune system, 40% for bone health, 24% to boost energy levels, 14% to combat ageing and 22% to improve brain.
In this Series, find out what these experts have to say about the importance of early diagnosis of rheumatoid arthritis, their perspectives on overcoming compliance issues and updates on novel treatments.

Professor Josef Smolen talks about early intervention and treatment targets in rheumatoid arthritis.

Professor Robert Moots discusses how treatment has evolved for patients with rheumatoid arthritis and the importance of compliance.

Dr Chi-Chiu Mok shares his perspectives on overcoming the challenges and issues in the management of rheumatoid arthritis in Asia.

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For a 5-minute update, go to www.mims.asia/video_series.
Most of us have been on the giving and receiving end of the age-old advice to increase our intake of vitamin C when we start to feel the nasty beginnings of a cold. Vitamin C, or ascorbic acid, is synonymous with boosting the immune system.

Studies have shown that vitamin C concentrations in plasma and leukocytes decrease during infections and stress. Vitamin C supplementation has been found to enhance the human immune system’s antimicrobial and natural killer-cell activities, lymphocyte proliferation, chemotaxis and delayed-type hypersensitivity. [Ann Nutr Metab 2006;50(2):85-94]

Vitamin C can also help provide protection from the toxic effects of reactive oxygen species (ROS). ROS is generated as a by-product of normal aerobic respiration, during inflammation and after exposure to environmental toxins. [Cent Eur J Med 2011;6(1):1-10]

Vitamin C also helps the body absorb zinc, an important trace element. Zinc cannot be produced by the body, thus the daily dietary need of zinc has to be met through diet or taking supplements. Zinc is required for the production of various enzymes in the body. Zinc, like vitamin C, also aids the immune system in warding off illnesses.

What better way to meet the body’s nutritional needs than by taking supplements that combine several nutrients in an easy-to-consume form?

Kordel recently launched a Vitamin C 1000mg + Zinc 10mg dual-action effervescent tablet. The tablet is put in water, where it breaks down and releases carbon dioxide. The fast-dissolving action results in a fizzy solution.

A major advantage of effervescent tablets is that the nutrients are absorbed by the body at a quicker rate. People who dislike or have trouble swallowing pills can also breathe a sigh of relief with this easier-to-consume option.

For the nauseous, the effervescence can help settle the stomach. The rapid absorption also means that some nutrients may have been absorbed into the body even though the nauseous individual may throw up.

The tablets are also sugar-free and use natural coloring from beetroot and beta-carotene, making them a healthier choice of supplements.
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A lot is said about keeping our major organs like the heart, brain and liver healthy in order to keep diseases at bay. However, maintaining good colon health is equally important as it is not just a garbage chute.

Keeping our colon in good health provides many benefits, including a lowered risk of developing colorectal cancer, efficient absorption of water and minerals, and a lower risk of irritable bowel syndrome (IBS), chronic constipation and diarrhea.

In an interview with Pharmacy Today, Bengt Jepssen, assistant dean of the Medical Faculty of Lund University, Sweden, said: “Maintaining good colon health is extremely important. This is because we have approximately 1 kg of bacteria in our bodies, made up of 500 different types of bacteria. Both good and bad bacteria exist in a very delicate balance. We have seen many clinical situations where patients have a disrupted balance, with some bacteria dominating over the others, and the patients do not feel well and are in a diseased state.”

The adoption of healthy lifestyle habits, which are crucial for wellbeing, also applies to maintaining good colon health. Some ways of keeping the digestive tract happy is by drinking plenty of fluids, consuming alcohol and caffeine in moderation, regular exercise and eating a balanced fiber-rich diet. Exercise helps promote blood circulation to the colon, while fiber aids movement of waste through the digestive tract.

“One measure we can take to maintain good colon health is to eat regularly, which is also good for energy levels. Many stomach upsets can be attributed to not eating regularly and skipping meals. The 1 kg of bacteria can be seen as an extra organ in the body. We are finally starting to understand what it does and how important it is to maintain the balance of the bacteria by making lifestyle changes,” said Professor Dr Jepssen.

Jepssen was speaking at the launch of BiO-LiFE and PROBI’s Lactobacillus plantarum 299v (BiOLiFE PROBI LP299V), a probiotic product that promotes healthy intestinal micro-flora. LP 299v refers to the particular strain of bacteria in the product.

“Almost one-third of the general population has some form of gastrointestinal problem. This product is not a prescription for such problems, but a supplement that provides support,” said John Goebel, general manager of BiO-LiFE.

“LPP299V blocks harmful bacteria from sticking to the intestinal walls, thus allowing the intestine to maintain its health and function normally. Besides that, LPP299V helps strengthen the intestinal walls and facilitates the work of the intestines. In addition, this probiotic strain has the ability to stimulate growth of good bacteria to help keep the intestines healthy and functioning properly,” said Mr Goebel.

When Pharmacy Today asked Professor Dr Jepssen if it is necessary for a pharmacist to advise someone with poor intestinal health to also consult a healthcare professional, he said pharmacists can recommend that they first start on probiotics and to stay on it for a while as the effects are not immediate because the colonization of bacteria takes two to three weeks.

Pharmacists should advise people to seek professional help if there are ominous signs like weight loss and constant pain as IBS pain is not constant.
Affordable contraceptives answer to rising need

By Malvinderjit Kaur Dhillon

There is an increase in the proportion of females seeking hormonal contraceptives in Malaysia, a market survey conducted in several South East Asian countries has shown.

The survey, involving GPs, pharmacists and obstetricians and gynecologists in Indonesia, Malaysia, Philippines and Thailand, found a 12% increase in hormonal contraceptive needs among Malaysian women.

This increase can be attributed to heightened contraceptive use among the sexually active, plus the expanding hormone therapy market. From this 12% increase, 1-in-3 females were prescribed female hormones therapy for a range of conditions including for contraceptive purposes (76%), menstrual side effects (61%), acne (43%) and endometriosis (74%).

The survey results also indicated that among the different hormone therapies available, combined oral contraceptive (COC) pills were the preferred choice. Due to the popularity of COC, these pills should ideally mimic the hormones in the human body, have minimum side effects and provide added health benefits.

“COC pills contain a synthetic version of two female hormones – progesterone (often referred to as progestin) and estrogen – and are primarily intended to prevent pregnancies. The pills also offer a number of additional and immediate health benefits such as reducing menstrual pain, acne, mood swings, ovarian and endometrium cancer risk, and improving other reproductive health conditions,” said K.K. Iswaran, a consultant obstetrician and gynecologist.

“In developed countries, some patients use the pills exclusively to improve or prevent menstrual-related disorders and certain reproductive health conditions such as irregular periods, endometriosis and premenstrual syndrome (PMS),” said Dr. Iswaran.

Among the healthcare professionals surveyed, drospirenone COC pills were the gold standard in female hormonal therapy due to their effectiveness, good safety profile and minimal side effects. However, the cost of drospirenone limits patient accessibility.

The cost of drugs seems to play a huge role in the choice of drugs and this could be seen from the results of the survey, which showed that the respondents were inclined towards generic drugs. This could largely be due to them seeing generics as a cost-effective alternative without having to sacrifice efficacy.

“In Malaysia, the use of modern contraceptive pills is very low: less than 4% of women between the ages of 15 and 49 use them. Cost and side effects have always been the main concerns for women when choosing a
contraception method. With the availability of newer generic modern contraceptive pills with lesser side effects such as weight gain, women now have more choices and are able to enjoy the added health benefits that these newer pills can offer,” said Professor Dr. Jamiyah Hassan, a consultant obstetrician and gynaecologist at the University Malaya Medical Centre (UMMC) and secretary of the Asia Pacific Council of Contraception (APCOC).

The survey, conducted by Exeltis Pharma, was carried out to investigate the treatment landscape and the unmet contraception needs of women in Malaysia and the region.

Exeltis Pharma also presented a new patient education leaflet to raise public awareness of the added health benefits of COC pills as well as to encourage women to be accountable for their own wellbeing. The leaflets, supported by the Obstetrical & Gynaecological Society of Malaysia (OGSM), Federation of Reproductive Health Associations Malaysia (FRHAM) and International Planned Parenthood Federation, East & South East Asia and Oceania Region (IPPF ESEAOR), will be distributed at clinics, hospitals pharmacies and tertiary education institutions.
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References:

The benefits and superiority of breastfeeding

Breast milk is the best food for infants as it provides the best nutrition, immune defence and protection from diarrhea, colic, regurgitation and constipation for infants. Breastfeeding should be initiated at once after or within one hour of delivery. Good maternal nutrition is essential to prepare and maintain breast-feeding. Mothers should be reminded the benefits of breast milk, and also it is the most economical food for infants. Working mothers should also be encouraged to continue breastfeeding even after they resume their full time jobs. The introduction of partial bottle feeding will have a negative effect on breastfeeding. Before using infant formula, a mother should be aware of the financial and social implications and the possible health hazards of formula feeding. Inappropriate food or feeding method may lead to health problems. However, if mothers decide to supplement with an infant formula or not to breastfeed at all, they should seek advice from their health professionals before starting the use of infant formula. Mothers should be professionally instructed on the importance of infant feeding methods, including the cost of infant formula and the health hazards of inappropriate foods or feeding methods. Mothers who are unable to breastfeed should seek professional advice. It is important to warn mothers of the difficulty of reversing a decision not to breastfeed.

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Canadian study on smoking initiation among young people aged 12 to 24 has found that 14% of those who smoke start the habit after high school.

The study, conducted on 1,293 participants from 10 high schools in Montreal, showed that 75% of participants started smoking by the last survey cycle of the study. In addition to those who had started smoking after high school, 44% initiated smoking before high school and 43% during high school. The study was published in the Journal of Adolescent Health.

The phenomena of teens starting to smoke early, between the ages 12 and 18, is well known, and many prevention programs are in place to target this group. However, very few prevention programs target young adults.

“Our study indicates that it is also important to address prevention among young adults, especially because advertising campaigns of tobacco companies specifically target this group,” said Jennifer O’Loughlin (Ph.D.), a professor at the University of Montreal School of Public Health and lead author of the study. If smoking onset among young adults can be prevented, she said, the likelihood of them never becoming smokers is high.

Though smoking rates in general have declined in the past three decades, the researchers believe the tobacco industry may be increasing efforts to appeal to the young adult group. This trend prompted the researchers to identify predictors of smoking initiation in young adults, to aid in prevention efforts.

Among the smokers who start late, the researchers found that smoking onset is usually associated with high levels of impulsivity, poor performance in school and higher levels of alcohol consumption compared to peers.

According to Ms O’Loughlin, some in the late smoking group showed a greater degree of impulsivity compared to the other participants of the study. It is possible that impulsive behavior becomes more freely expressed when the young person becomes an adult and parents no longer exert control.

“We can postulate that parents of impulsive children exercise tighter control when they are living with them at home to protect their children from adopting behaviors that can lead to smoking, and this protection may
diminish over time,” she explained.

As for those with poor academic performances, the authors surmised that the risk of smoking initiation increased because the participants had left school and started working in places where smoking rates were higher.

Young people also tend to frequent places where they can consume alcohol, and may be influenced to start smoking then. “Since alcohol reduces inhibitions and self-control, it is an important risk factor for beginning to smoke,” said Ms O’Loughlin.

Data was collected from self-report questionnaires from participants enrolled in a cohort study called Nicotine Dependence in Teens (NDIT). Collection of data began in 1999 in the Greater Montreal Area. The questionnaires were sent out in 22 cycles over 13 years. At inception, participants were in grade 7, and 12.7 years of age on average.

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**Bilingual book highlights potential benefits, hazards of common local herbs**

By Pank Jit Sin

A newly launched bilingual book brings to light the toxic and curative nature of many commonly found plants.

The book, entitled ‘Medicinal, Environmental Protective and Healthy Plants,’ was written by Yang Sok Hoong and Pie Wan Koon, both practitioners of traditional Chinese medicine (TCM) and graduates of the Kuala Lumpur Academy of Traditional Chinese Medicine.

In the book, Yang and Pie highlight local plants which could be used for medicinal purposes, but not delve into their use in detail. Yang said many herbs can be toxic if used improperly. Some can be irritants, but once processed, have medicinal properties.

Apart from identifying plants with medicinal properties, the authors recommend some well-known air purifiers and filters, such as the spider plant (Chlorophytum comosum), aloe (Aloe vera) and aluminium plant (Pilea cadierei), that can be placed close to living spaces and near workstations to cleanse the air, filter particulates and absorb radiation. With more and more hours being spent in the office and in enclosed areas, the importance of such plants becomes more evident as they serve to freshen the air and calm the nerves.

The book also brings to notice some beautiful ornamental plants which are highly toxic and could potentially be hazardous to children and small pets. These include the angel’s trumpet (Brugmansia spp.), oleander (Nerium oleander), dumb cane (Dieffenbachia spp.) and the ubiquitous (Zamioculcas zamiifolia), which are commonly used for ornamental purposes.

The book is available at MPH and Popular bookstores nationwide.
Long-lasting relief from congestion with an added moisturising ingredients

Otrivin* contains two moisturising ingredients frequently used in pharmaceutical and cosmetic products.¹

**Sorbitol**
- Normalises level of liquid in mucosa, does not lead to drying and irritation²
- Provides soothing effect³
- Is used as moisturiser⁴

**Methylhydroxypropylcellulose**
- Strengthens moisturising effect⁵
- Prevents nasal mucosa from dryness⁶

Benefits for your patients

- **Double action**
- Vasoconstrictor effect of Otrivin*⁷
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- **Fast relief of nasal congestion within few minutes**⁹
- Significantly decreased common cold symptoms (e.g. blocked nose, runny nose, sore throat and ear ache)¹⁰
- Prevent drying of nasal mucous membrane, soothes away irritation caused by dryness¹¹

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Notes:

1. Active ingredient: Xylometazoline hydrochloride, Pharmacological form: Nasal drops 0.05% and 0.1%, Nasal spray 0.05%. Available from 0.5% solution. Otrivin is used to relieve nasal congestion due to colds, flu, or allergy. It helps relieve nasal congestion and allows easier breathing.

2. Otrivin is available as a nasal spray and nasal drops. It is used to relieve nasal congestion due to colds, flu, or allergy. It helps relieve nasal congestion and allows easier breathing.

3. Otrivin is available in two different strengths: 0.05% and 0.1%. It is used to relieve nasal congestion due to colds, flu, or allergy. It helps relieve nasal congestion and allows easier breathing.

4. Otrivin is available as a nasal spray and nasal drops. It is used to relieve nasal congestion due to colds, flu, or allergy. It helps relieve nasal congestion and allows easier breathing.

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11. Otrivin is available in two different strengths: 0.05% and 0.1%. It is used to relieve nasal congestion due to colds, flu, or allergy. It helps relieve nasal congestion and allows easier breathing.
The issue of using polyethylene microbeads for decorative or exfoliation purposes in personal care products has come to the fore recently with cosmetic giant Unilever announcing its plan to phase out their use by 2015.

**What are microbeads?**
Microbeads are small spherical plastic particles, made from polymers of ethylene oxide, i.e., polyethylene, and used in a wide range of products, such as body and face scrubs, shower gels and other cleansing products. They are both cheap to manufacture and their perfectly spherical shape means they are gentler on the skin than some natural products.

They are labeled ‘polyethylene’ in ingredient lists so are easy to spot. However, consumers should be aware that some products will play up their use of natural ingredients, but still use microbeads as well.

According to Judi Beerling at organic product researchers, Organic Monitor, some natural soft scrubs can be more aggressive as the particles are not so spherical. Think of the old apricot kernel or walnut scrub products that were quite rough and abrasive, Ms Beerling said.

New grinding technology means natural vegetable scrubs can be less harsh, but they will never be completely spherical, she said.

**What’s wrong with them?**
For several years now, there has been concern about microbeads not being biodegradable. In essence, they wash off people and go down the plughole into the waste water system, eventually ending up in the ocean.

Indistinguishable from a grain of sand or other microorganisms, they may look like a tasty snack for marine life.

A 2008 Plymouth University study found that microplastic particles remained in mussels for over 48 days. The smaller the particle, the greater the potential for it to accumulate in the tissues of marine organisms, the study said. [Environ Sci Technol 2008; 42(13):5026–31]

However, as technical editor of Personal Care magazine Chris Smith said, the amount of microbeads floating around the ocean which come from cosmetics is small compared with those which come from other discarded plastic products and synthetic fibers in clothes.

While the major concerns have been their effect on the marine environment, Ms Beerling said the fact they are not natural is reason enough to avoid them.

“From my perspective, they are not natural and come from an unsustainable petrochemical source, so I would never use them in natu-
natural cosmetic products,” she said.

What are the alternatives?
There are many natural scrub particles available such as crushed apricot kernel or almond shells and grains, jojoba, salt, sugar and sand, although they are likely to be more expensive.

They also often require gamma irradiation to ensure the microbial count is acceptable, Ms Beerling said. Otherwise, more expensive, and sometimes less effective, heat sterilisation is an option.

One new development is the eco scrub which uses polylactic acid – a biodegradable, naturally derived polymer that works just as well as polyethylene, with a similar spherical soft feel.

Another good alternative, said Mr Smith at Personal Care magazine, are waxes which can either be made from synthetic materials or products such as jojoba, carnauba and rice bran.

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Dinner rituals can affect weight status

By Angeline Woon

Family dinner rituals can affect the body mass index (BMI) of children as much as lifestyle and eating habits, reveals a new study.

The study, conducted by researchers at the Food and Brand Lab, Cornell University, US, and appears in an upcoming issue of the journal Obesity, correlated dinner rituals with both the parents’ and child’s BMIs. It was found that parents with higher BMIs tended to eat with the television turned on. Conversely, parents and children with lower BMIs ate at the dining room or kitchen. Another finding of the study was that girls who helped their parents prepare dinner were more likely to have a higher BMI, but this was not true for boys who helped out in the kitchen.

Additionally, boys whose families stayed together for the entire meal had lower BMIs. This was also reflected in their parents. The reason for girls who help out in the preparation dinner having higher BMIs is not clear, but it was suggested that girls who helped out with dinner might want an active role in the meal.

The study suggests that family meals and their rituals may be a ‘battleground to prevent obesity.’ Having less distraction or more supervision seems to be the key in these findings. The study suggests that an engaging and more interactive dinner could lead to slimmer families.
EUBOS Cream Bath Oil

Eubos Cream Bath Oil contains a high concentration of polyunsaturated fatty acids, lecithin, Camomile extract and Bisabolol that penetrate deep into skin during bathing or showering, thus regulating moisture as well as lipid content. This alkali-and-soap-free, neutral pH, synthetic detergent-lipid combination provides gentle cleansing, repair and care for the body, and is suitable for those with dry, scaly and stressed and sensitive skin. It is particularly ideal for protecting the sensitive, delicate skin of babies from skin irritations as well as conditions such as Eczema, Psoriasis, Nappy Rash, Cradle Cap and Prickly Heat. It is also recommended for bath or shower in the case of dry skin which tends to tighten and itch.

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For showering: Apply to damp skin for few minutes to allow Eubos Cream Bath Oil to take effect, then rinse without using soap.

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Pharmacists play a vital role in managing osteoarthritis pain in the elderly by helping them understand their treatment options and the condition itself.

Of the 140 types of arthritis, osteoarthritis – a weakness in the joints – is the most common. Almost half of people over the age of 60 suffer from osteoarthritis, and the majority of people over the age of 80 have it.

People should see a health professional if they are experiencing the following symptoms for more than two weeks to check for osteoarthritis: stiff joints after getting out of bed or sitting for a long time; pain in or near the joints; swelling in or near the joint; muscle weakness and a creaking or creaking sensation with bone movement.

Arthritis New Zealand (www.arthritis.org.nz) educator Luliano Tinielu said pharmacists play a vital role in explaining to patients why they need to take their osteoarthritis medication and the correct way to take it.

“GPs only have 15 minutes with their patients. That’s where the pharmacist comes in; by helping patients understand the logic behind taking their medications properly.”

Osteoarthritis sufferers most often experience joint pain in the knees, hips, spine and hands.

The main treatment is pain relief in the form of paracetemol. As osteoarthritis is classified as a non-inflammatory form of arthritis, non-steroidal anti-inflammatory drugs (NSAIDs) are generally ineffective.
In cases of extreme pain, health professionals may recommend a medication which combines paracetamol and codeine.

However, as the condition progresses, some people do experience inflammation in the joints. In such cases, the pharmacist can recommend ibuprofen or a cream or gel to rub into the skin to reduce the pain and swelling.

Arthritis New Zealand said the feedback it receives from osteoarthritis sufferers is that when pharmacists explain the importance of taking their medication and provide cues, such as taking medication at meal times, this helps patients adhere to the medication regimen, said Mr. Tinielu.

“If patients understand the logic, they are more likely to take their medications properly,” he said.

He believes pharmacists are under-utilized in arthritis management, and that having them discussing the condition with the patient is beneficial.

Supplements not widely effective
Alternatives to medication, such as natural health products, including glucosamine, chondroitin and fish oil, are sometimes recommended for treating arthritis, but there is no firm evidence to support their use, said Mr. Tinielu.

The supplements are thought to reduce stiffness and pain in the joints.

A 2009 Cochrane summary on the use of glucosamine for improving pain in osteoarthritis sufferers showed that after six months, pain improved at about the same level in people taking placebo as it did in those taking glucosamine supplements.

However, one brand of supplements, Rotta, did appear to show slightly greater pain relief in the people taking them, compared with those not taking them.

A Best Practice Advocacy Centre (BPAC) resource, Symptomatic Management of Osteoarthritis, has said that a capsaicin cream, which contains a chilli pepper extract, could help relieve joint pain.

BPAC advises people to assess the effectiveness of capsaicin cream or glucosamine and to discontinue use if it is not effective after three months.

It also said there is no clinical evidence for the effectiveness of multivitamin and mineral supplements, copper bracelets and acupuncture in treating osteoarthritis symptoms.

On the other hand, some sufferers report that these supplements are effective, but pharmacists should be aware this is an expensive treatment for people to maintain.

Exercise, diet help improve joint pain
While age is a major trigger for osteoarthritis, excessive weight can also trigger the condition because it puts strain on the joints.

Pharmacists should encourage people with osteoarthritis to exercise regularly and maintain a healthy diet to help control their weight.

Exercises which involve stretching, strengthening and aerobics are essential to maintain and restore joint movement, reduce pain and stiffness, improve muscle strength, manage weight and increase energy and wellbeing.
Viartril®-S is a glucosamine with 90% ABSORPTION\(^2\) into your body.

Once daily\(^3\) for excellent pain relief on joints to maintain an active lifestyle. Are you taking the original glucosamine?

Ask your Pharmacist about Viartril®-S.
Elderly at risk of food-drug interactions

The more drugs people are on, the greater the chance of interactions with food, which may inhibit their vitamin and mineral uptake, a New Zealand professor of pharmaceutical nutrition says.

As the elderly tend to be on more medications, they fall into the high-risk category for drug and nutrition interactions, said Professor Gil Hardy, of Auckland University’s School of Pharmacy.

Around 50% of the local elderly population are on omeprazole and other proton-pump inhibitors, which can impair their absorption of vitamins C, B12 and iron, said Professor Hardy.

Patients on these drugs can benefit from supplements, including a B12 intramuscular injection.

Proactive community pharmacists should point out the possibility of interactions to patients when they pick up their prescriptions, although, as this is such a new area of research, neither they nor GPs tend to be well versed in the subject, said Professor Hardy.

According to the New Zealand Nutrition Foundation, about 5% of older people at home, 25% in acute and rehabilitation hospitals, and over 50% in nursing homes are undernourished.

One of the ways to combat this is by offering extra-fortified drinks during the day.

Old-age psychiatrist Chris Perkins said the reasons elderly people may not be eating well include living on their own, suffering from dementia and forgetting to eat or how to cook, not being able to get to the shop, not having good teeth and being served uninspiring food in some residential homes.

Community pharmacists can help remind customers living in their own homes to eat regularly by initiating a conversation about food, said Dr Perkins.

Evidence on the value of supplements for elderly residential care patients is inconclusive but, if supplements are used, it is important, for adherence and absorption, to give them at meal times.

Research into the impact of vitamins C, E, B6, B12 and folate on reducing dementia has produced some positive results, but the evidence is inconsistent.
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Dementia currently affects around 50,000 people in New Zealand, but due to the country’s ageing population, this figure is predicted to triple by 2050. In 2008, the economic cost of dementia was estimated at NZ$712.9 million.

There is no cure for dementia. However, the news is not all bad, and recent reports from two separate locations in Europe have shown that the incidence of new cases of dementia is slowing.

According to Alzheimer’s New Zealand, dementia is caused by physical changes in the structure of the brain which can affect memory, thinking, behavior, personality and emotion.

Because dementia is a progressive syndrome, symptoms will gradually worsen. The most common form is Alzheimer’s disease, although there are several other forms.

No single factor has been identified as a cause for dementia or Alzheimer’s disease. It is likely a combination of factors, including age, genetic inheritance and environment.

There is currently only one subsidized Alzheimer’s medicine in New Zealand, called Donezil®, old-age psychiatrist and Alzheimer’s New Zealand board member Chris Perkins said. Donezil’s expired patent now makes it affordable, Dr Perkins said.

It is part of a group of four drugs called cholinesterase inhibitors, which help slow the progression of dementia in the early stages, she said.

The other non-subsidized drugs available are Aricept®, rivastigmine and galantamine.

Some drugs suit some people better than others, so it would help if all four were subsidized to give people the opportunity to see which works best for them.

However, none is particularly effective and the drugs work for only about 18 months or so.

Another drug, memantine, is also available and works by preventing excess entry of damaging calcium ions into the brain cells. It can work when dementia is more advanced and in combination with other drugs.

Pharmacists would be welcomed in aged care

It would be fantastic to have more pharmacists working in aged care, Dr Perkins said.

She has found pharmacists very helpful at finding out which pills are adding to a dementia patient’s confusion, such as antidepressants and prostate drugs.

Community pharmacists can also play a major role, Dr Perkins said.

With the average age of dementia onset at 78, most people are on a lot of pills then, so phar-
Pharmacists can help by making up blister packs and dispensing drugs in other ways to make it easy for patients to remember to take them.

Simplifying a medicine regimen is good. If a pharmacist can get someone onto long-acting twice-daily pills instead of short-acting ones they take four times a day, the patient can take them when someone is home with them to help them remember.

If a community pharmacist notices an elderly person has forgotten to pick up his repeats, ringing the person or his GP or family member is helpful.

People go to their pharmacy very often and know their pharmacist, so if the pharmacist observes a patient becoming muddled or confused, it is a good idea to inform the GP or family.

People usually know and trust their pharmacist, so are happy for them to pass on information to other health professionals.

“I’ve found it very useful as a doctor when a patient’s pharmacist has rung to give me an update,” Dr Perkins said.

**Good for heart, good for brain**

While there have been no major breakthroughs in curing Alzheimer’s disease, there is evidence that education and improvements in other medical treatments are decreasing new occurrences of the disease, Dr Perkins said.

The improved treatment of hypertension, diabetes and cholesterol is helping to reduce dementia, as some dementia has a vascular dimension to it.

“What’s good for the heart is good for the brain,” she said.

The number and severity of strokes is also falling, which, in turn, helps with dementia, Dr Perkins said.

**Non-pharma prevention**

Non-pharma preventions are all about stimulating the brain, learning new things, socializing and exercising.

So, activities which combine all three, like going for a walk with someone who can teach you another language, for example, is excellent, as is learning new dance steps, Dr Perkins said.

In a study published in the American Heart Association journal Stroke, older, non-disabled people who regularly engaged in physical activity reduced their risk of vascular-related dementia by 40% and cognitive impairment from any cause by 60%. (2012;43(12):3331–35)

Even if physical activity does not actually stop you getting dementia, it will make you a bit clearer and put you in a better position to cope with the disease, Dr Perkins said.
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Use it or lose it. That motto can be ascribed to many things – not least the health of the ageing human body and mind.

Keeping fit and active is recognized as the best way to stay well as people age and the idea has been incorporated into New Zealand government health policy.

The Ministry of Health has published detailed guidelines recommending at least 30 minutes of aerobic physical activity five days each week, as well as flexibility, balance and ‘resistance’ activities.

Exercise can include anything from walking to the shops and doing the vacuuming to bowls, tai chi and ballroom dancing.

“It’s never too late to start becoming physically active,” said Ann Martin, Age Concern New Zealand’s chief executive.

“Whatever your age, regular activity will improve your health, make you feel better and make it easier to do everyday tasks.”

Staying active can help older people by increasing their strength to lift and carry groceries, improving flexibility to tie shoe laces, wash hair or hang up washing, aiding balance to climb stairs or get on and off a bus, or simply giving them the energy to play with grandchildren.

Other health benefits include reducing the risk of developing high blood pressure, cardiovascular disease, cancer, osteoporosis and diabetes, as well as easing the pain of arthritis and other physical disabilities, and improving sleep.

Exercise also benefits mental health

It can also enhance a person’s sense of well-being, and improve mood and self-esteem, while lowering stress levels and reducing the risk of depression, said Ms Martin.

“There are immediate and long-term benefits – physically, mentally and socially. There is also the benefit of helping to maintain independence in everyday living and broadening social networks, leading to new friends and a sense of purpose.”

Even people who are very sedentary are likely to receive a boost from an increase in activity.

“It is wise to start gently and build up gradually. Finding something enjoyable at a level that is comfortable is a good place to start,” said Ms Martin.

People with chronic health conditions or injuries should discuss physical activity options with their doctors first, and anyone who feels unwell or has pain during exercise should stop immediately and seek medical advice, she said.

Some doctors and practice nurses may prescribe a Green Prescription*, which includes advice on staying active.

Ms Martin said Age Concern welcomes initiatives to encourage people to engage in healthy physical activity as they age.

It’s never too late to make a difference – geriatrician

John Scott is a geriatrician with a district health board in New Zealand who divides his time between two hospitals and outpatient clinics.

Dr Scott works with older people who are frail and struggling with the demands of daily life, either because of their age or due to illnesses such as stroke or emphysema.

Some exercise program are tailored for the therapeutic needs of individual patients and there are also program to encourage people to be more active generally.

“The health benefits of exercise are enormous,” Dr Scott said. “It’s not just about being
stronger and being able to walk further without falling over. There are also benefits for mental health, mood, digestion, cardiac function and lung function. A huge part is getting people to maximize their function.

“There is no upper age limit. I see people well into their 90s and even the odd centenarian. There is no point at which you stop being able to derive a benefit.”

Dr Scott believes society’s view on what it means to be “old” is changing. “Someone in their 70s doesn’t really seem that old these days.”

Dr Scott also encourages younger people to become more active to insure their health in older age.

“The trick is making it a habit – and finding something you enjoy,” he said.

*Green Prescriptions: Practised by healthcare practitioners in New Zealand, it is a health professional’s written advice to patients to be more physically active as part of their health management.*
treats postmenopausal osteoporosis and prevents fractures.¹

Reference: 1. Richy F et al., Calcified Tissue International 2005;76;176-186
DPP-4 inhibitors safe in terms of CV outcomes

Randomized controlled trials of type 2 diabetes mellitus (T2DM) patients at moderate to high risk of major adverse cardiovascular events suggest that dipeptidyl peptidase 4 (DPP-4) inhibitors like sitagliptin (Januvia®, Merck Sharp & Dohme) are safe.

Professor Mansoor Husain, director of the Toronto General Research Institute, Canada, said this during a MSD-sponsored symposium on the occasion of the 49th Annual Meeting of the European Association for the Study of Diabetes (EASD) in Barcelona, Spain.

He said cardiovascular outcome trials involving diabetes patients, with median durations of follow up of 1.5 to 2.1 years such as EXAMINE* for alogliptin [N Engl J Med 2013;369(14):1327-35], and SAVOR# for saxagliptin [N Engl J Med 2013;369(14):1317-26] showed no adverse effects on the primary outcomes of myocardial infarction, stroke or cardiovascular death. He did note though that an increase in the pre-specified, adjudicated endpoint of heart failure was noted in the saxagliptin arm of SAVOR#, which merited further evaluation.

TECOS®, a randomized controlled trial of sitagliptin versus placebo, is another such cardiovascular trial still in progress.

Asked if he would recommend the use of DPP-4 inhibitors for patients with cardiovascular disease based on the results presented, he said, “The take-away message here is that in patients with recent acute coronary syndrome or at increased risk of cardiovascular events, if you need to use a blood sugar-lowering therapy to reach a target, DPP-4 inhibitors are safe according to available data.”

In response to concerns raised over the link of incretin mimetics and pancreatic disease, Professor Lawrence Leiter, of the University of Toronto, Canada, said there were no pancreatitis signals arising from the SAVOR and EXAMINE trials, or from a meta-analysis of 53 trials of patients on DPP-4 inhibitors and comparators. [Curr Med Res Opin 2011;27 Suppl 3:57-64]

He said sitagliptin was found to be generally safe and not associated with an increased risk in major adverse cardiovascular events, malignancies or pancreatitis. In a pooled safety analysis of sitagliptin of over 14,000 patients from 25 randomized controlled studies with up to 2 years’ duration, sitagliptin 100 mg a day was shown to be well-tolerated. In fact, incidence rates of adverse events and drug-related adverse events leading to discontinuation were higher in the non-exposed group due to drug-related hypoglycemia, particularly in patients treated with sulfonylureas. [Diabetes Ther 2013;4(1):119-45]

Sulfonylurea therapy is an important risk factor for adverse outcomes, said Professor Baptist Gallwitz, of Eberhard Karls
University, Tübingen, Germany. He said novel therapies without risk of hypoglycemia may be more favorable than sulfonylurea therapy.

Sitagliptin, he said, was associated with a lower risk of hypoglycemia compared with the sulfonylurea, glipizide. [Curr Med Res Opin 2012;28:1281-7]

In addition, DPP-4 inhibitors have positive benefits when it comes to body weight in diabetic patients. In a study with linagliptin as an add-on to metformin, compared to glimepiride, there was a reduction of 2.9 kg in patients on linagliptin in comparison to a gain of 1.4 kg in patients on glimepiride. [Lancet 2012;380(9840):475-83]

Dr. Carolyn Deacon, of the University of Copenhagen, Denmark, added that DPP-4 inhibitor therapy gives clinically meaningful reductions in blood glucose and is as good as existing oral agents.

“Though there is little to distinguish between different inhibitors in terms of efficacy and safety, they are certainly not the same. There are differences in their clinical usage such as dosing frequency, use in renal-hepatic impairment, or whether dose adjustment is needed when co-administered with other drugs,” she said. [Diabetes Obes Metab 2011;13(1):7-18]

*EXAMINE: Examination of Cardiovascular Outcomes: Alogliptin vs Standard of Care in Patients with Type 2 Diabetes Mellitus and Acute Coronary Syndrome
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Some country blokes remain to be persuaded that anything more than soap on their face is over the top.

A widely quoted British survey (by car insurance company Sheila’s Wheels) found that one-in-10 men secretly used his partner’s make-up.

The second most popular product men pilfered was moisturizer. Beauty treatment for men is certainly on the rise, and skincare is at the top of the wish list.

**Pharmacy picks up on trend**

Sunil Kumar, a New Zealand pharmacist, said there is a “very significant” demand for skincare treatment and products from men.

“We have seen growth in this category in recent years and we have confirmed the data with our retail sales,” Mr Kumar said.

He believes men are becoming more open about looking after their skin and wanting to look good.

Anti-ageing products and everyday moisturizers are among the most sought after, as well as facial scrubs and cleansers, roll-ons to counter dark circles and bags around the eyes, aftershave balms for sensitive skin and sunscreens.

Mr Kumar attributes the rising popularity to more awareness and increased advertising.

“Also, more and more big brands are starting to get into the category. Society is highly accepting for men to look after their skin and beauty. It doesn’t just have to be transvestites

**Men blushing less over skincare**

The days when men were satisfied with having the face of a Sean Connery or Harrison Ford are long gone. Primped and highly groomed role models like Chace Crawford and David Beckham have raised the bar, and men’s skincare is an accepted part of grooming. Pharmacy Today New Zealand reports
who use cosmetics,” he joked.

**Men investing in their looks**
Adrienne McDermid, a beauty and skin therapist at a beauty clinic, confirms the growing interest from men.

“Yes, men do seem more and more willing to spend time and money on good skincare,” Ms McDermid said.

“There also seems to be a trend for male clients shifting away from the relaxing fluffy facial treatments and towards more anti-aging options that are usually at higher prices and contain active ingredients for skincare. In that regard, the line between male and female clients is also becoming blurred.”

**Skincare is for real men**
The idea that men who are interested in skincare are somehow effeminate or “metrosexual” is also dying out, Ms McDermid said.

“Terms such as ‘metrosexual’ are becoming more and more irrelevant within the industry as more of those that are considered to be your average male are becoming well versed in male grooming,” she explained.

“So, instead of metrosexuals being your typical beauty salon or spa clients, you are now just as likely to get your average bloke, husbands, teenagers, etc.

“This trend is definitely reflected in our salon, and although our marketing is almost solely directed at women, business from male clientele has steadily increased over the last couple of years.”

**Shyness persists among some males**
However, the trend could take a bit longer to infiltrate more rural areas of the country.

One pharmacy has a designated space for men’s beauty products, but the category is not one of their big sellers, retail manager Andrea Franklin said.

Men’s attitudes towards skincare are evolving, but there is still some “shyness”, Ms Franklin said.

Lots of her male friends use moisturizers, but they are more likely to get their wives or partners to pick the products up at a supermarket than buy skincare products themselves.

Ms Franklin also had a customer recently who bought a lot of facial skincare products from the pharmacy’s website, which could be another way for shy men to spare their blushes.

Meanwhile, Viv Bath, a pharmacist in rural New Zealand, said there is “very little demand, if any” for men’s skincare products and treatment. It’s more an urban thing, I think.”

“We sell nail clippers – and maybe heel balm, at a push. Shave foam and gel are my most significant men’s products. Certainly not moisturizer – unless you count chap sticks.”
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It’s time to learn the ABCs of make-up

While BB cream is a hot seller in the make-up category, it may have some competition from more attractive newcomers which claim to do more for women in just a few minutes.

BB creams, or beauty balms to those losing the acronym battle, claim to be the ultimate skin perfecter. They are a cross between skincare and cosmetics, and boast redness-reducing, blemish-correcting, anti-ageing and skin-moisturizing properties. Think of these creams as a step up from tinted moisturizers.

A New Zealand cosmetics assistant, Joanne Buchanan, said these products have been around for a few years, but are increasingly popular as women attempt to juggle personal grooming with family and work.

“I think women today like products which can do more than one thing. We’re all a bit time-poor. “I think some women love to go with any new product because it’s new and exciting, but I also think a lot of it is driven by time management,” said Ms Buchanan.

These multi-purpose products originated in Asia, but have since made their way to the Western cosmetics market.

Women apply the product just as they would a moisturizer, by rubbing it into the face with their fingertips. They need to make sure their hands are clean and to completely rub the cream into the skin to avoid lines.

A Christchurch-based cosmetics company, Oasis Beauty, has capitalized on the trend and released what it believes is the only New Zealand-made BB cream, and the only natural one that director Stephanie Evans has come across worldwide.

But just as people are getting their heads around this trend, a new contender, a little further down the alphabet, has Pharmacy Today New Zealand stepping up to the plate.

Enter CC – color corrector – the make-up tool for women with uneven skin tones.

CC creams promise similar benefits to BB creams, but they are designed to help even out complexions and contain vitamins C and E.

They are best suited for people who are prone to acne or who have dull skin or skin with dark spots.

As is the case with any foundation, make sure people match the BB or CC cream to their skin tone. Advise customers to test the cream on their jaw-line and to rub it into the neck to get the closest color match.

Many brands also offer options for people with oily or sensitive skin, so be sure to check with people about their individual skincare requirements.

Don’t throw away old make-up just yet

The main draw of these products may be cutting down on the number of steps in a beauty regime, but some people may benefit from using them as an adjunct and not as a replacement. For example, women with particularly dry skin may want to use another, Ms Buchanan said.

Women can use a mineral powder on top of a BB or CC cream for increased coverage.

In most cases, Ms Buchanan would recommend these creams to women who want a lighter, more natural finish.
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JANUMET is contraindicated in patients who are hypersensitive to any component of this product. JANUMET should not be used in patients with type 1 diabetes, or for the treatment of diabetic ketoacidosis. There have been postmarketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, in patients taking JANUMET. Therefore, these reports are made voluntarily from a population of uncertain size. It is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure. JANUMET should not be used in patients with type 2 diabetes who have a history of pancreatitis. JANUMET is not recommended for use in patients with a history of severe renal insufficiency or with end-stage renal disease requiring hemodialysis or peritoneal dialysis.

**Selected Safety Information about JANUVIA**

JANUVIA is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus as initial therapy, alone or in combination with metformin, or as an add-on to metformin, PPARγ agonists, sulfonylurea, sulfonylurea/metformin or PPARγ agonists/metformin, when the current regimen, with diet and exercise does not provide adequate glycemic control.

JANUVIA can also be used as an adjunct to diet and exercise to improve glycemic control in combination with insulin (with or without metformin).

**Selected Safety Information about JANUMET**

JANUMET is contraindicated in patients with renal disease or renal dysfunction, e.g., as suggested by serum creatinine levels ≥3.5 mg/dL (≥314 μmol/L), with a creatinine clearance <30 mL/min, known hypersensitivity to any component of JANUMET, or acutely or chronic renal failure, including diabetic nephropathy, with or without coma. Temporarily discontinue JANUMET in patients undergoing radiological studies involving intravenous administration of iodinated contrast materials. JANUMET should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

There have been postmarketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, in patients taking JANUMET. Therefore, these reports are made voluntarily from a population of uncertain size. It is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure. JANUMET should not be used in patients with a history of pancreatitis. JANUMET is not recommended for use in patients with a history of severe renal insufficiency or with end-stage renal disease requiring hemodialysis or peritoneal dialysis.

Indications:
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Before initiating therapy, please consult the full Prescribing Information.
Managing benign prostatic hyperplasia

By Dr Hasniza Zaman Huri
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Department of Pharmacy,
Faculty of Medicine, Universiti Malaya

Benign prostatic hyperplasia (BPH) is a progressive disorder, which is defined as the proliferation of stromal and epithelial cells within the prostatic area. While BPH itself is not fatal, untreated BPH can potentially lead to complications like acute urinary retention (AUR) and the need for prostate-related surgical intervention.

BPH normally presents with a variety of lower urinary tract symptoms (LUTS), which can be categorized as either obstructive or irritative. Obstructive symptoms are associated with urinary hesitancy, weak urine stream, urine dribbles out of the penis, incomplete bladder emptying as well as increased post-void residual volume. In contrast, patients with irritative symptoms often experience increased frequency, urgency and nocturia. These symptoms can worsen if untreated and interfere with patients’ daily activities, consequently producing a detrimental impact on quality of life. It has been found that 87% of LUTS presented are attributable to BPH. However, it is important to know that development of LUTS does not always indicate the presence of BPH.

Pathogenesis
The exact pathogenesis of BPH is not well understood. Nonetheless, it has been long recognized that BPH-related LUTS results from both static and dynamic mechanisms. Static mechanism involves the proliferation of the stromal and epithelial cells, which leads to the enlargement of the prostate gland. There is a strong correlation between the static mechanism that causes BPH and levels of intrapro-
tatic dihydrotestosterone (DHT) and type II 5α-reductase. On the other hand, LUTS attributable to the dynamic mechanism are found to be due to the conditions that exacerbate α-adrenergic stimulation, which subsequently increase the prostatic smooth muscle tone.

Prevalence
BPH is a common disorder in the majority of men aged 60 years and above. The prevalence of BPH is progressive and the incidence rate increases linearly with age. The American Urological Association (AUA) has reported that symptomatic BPH affects 50% of men at the age of 60 and increases up to 90% during the ninth decade of life.

Likewise, the Ministry of Health of Malaysia (MOH) has demonstrated that 50% of men aged 60 years and above in Malaysia suffer from BPH. It is estimated that by 2050, 15% of the world population will be made up of senior citizens. Similarly, the proportion of senior citizens in the Malaysian population is expected to rise to about 10% by 2020. Therefore, it can be said that the increase in the proportion of elderly people in the population will definitely have a substantial impact on the prevalence of BPH.

Risk factors
It is well established that the prevalence of histologic BPH increases with age. Therefore, it is undeniable that advanced age is one of the risk factors for BPH. Besides that, studies have shown that elevated free prostate specific antigen (PSA), low functional bladder capacity (FBC) and post-void residual volume are associated with BPH. Several comorbid medical conditions like coronary heart disease, metabolic syndrome, erectile dysfunction and depression are found to be correlated to BPH. Apart from that, patients who are on antidepressants or certain treatments for cardiovascular diseases are prone to BPH. On the other hand, it has been found that patients who are not using calcium channel blockers are at higher risk of BPH. Not surprisingly, it has been identified that patients who have a family history of BPH or prostate cancer are more likely to have clinical BPH themselves. Also, lifestyle factors such as being physically inactive can also increase the risk of BPH.

Diagnostic evaluation
The AUA guidelines suggest various diagnostic tests to assess men presenting with symptoms of BPH. The initial evaluations recommended are taking of clinical history, physical examination including digital rectal examination (DRE), serum prostate-specific antigen (PSA) for men with a further life expectancy of more than 10 years and urinalysis to detect and eliminate hematuria and urinary tract infection (UTI). The International Prostate Symptom Score (IPSS) is a questionnaire that consists of seven relevant questions, and the classification ranges from mild (IPSS 0-7) to moderate (IPSS 8-19) or severe (IPSS > 20-35). Severity of symptoms can be assessed using the IPSS score in order to aid in the determination of treatment.

Treatment
BPH is a disease that may contribute to the development of LUTS. The decreased quality of life attributable to the symptoms appears to be the major factor that motivates men with BPH to seek treatment. Historically, transurethral resection of the prostate (TURP) was the commonest treatment for BPH. However, since the 1990s, different classes of pharmacological agents have been introduced for the treatment of BPH. Both the European and American Urological Association guidelines suggest pharmacological therapy for patients with moderately severe LUTS, which is characterized by an IPSS score of 8-19.
Long-acting $\alpha_1$-blockers like alfuzosin, doxazosin, terazosin, tamsulosin and silodosin, 5α-reductase inhibitors (5-ARIs) such as dutasteride and finasteride, muscarinic receptor antagonist like tolterodine as well as phosphodiesterase type 5 inhibitor (PDE5-I) like tadalafil have been approved by the US Food and Drug Administration (FDA) as appropriate pharmacological therapy to relieve LUTS secondary to BPH.\textsuperscript{17}

Monotherapy with $\alpha_1$-blockers or 5-ARIs is preferred as initial treatment, although a combination of drugs with different mechanism of actions has been shown to have synergistic effects to relieve LUTS suggestive of BPH.\textsuperscript{17} Nevertheless, the choice of therapy depends largely on the multifactorial pathogenesis of BPH-related LUTS as well as the preference of urologists and patients.

**Watchful waiting**

Watchful waiting is an option that is preferred for patients who present with mild symptoms ie, IPSS score ≤7, or patients with moderate symptoms (IPSS score 8-19), but the symptoms do not significantly interfere with their quality of life.\textsuperscript{18} It is a therapeutic strategy in which patients are not given any medication for BPH. Instead, with watchful waiting, patients are examined and monitored by their physician to detect any progression of disease as well as development of complications.\textsuperscript{19} Apart from that, supportive care and relevant advice will be given to BPH patients in order to reduce symptom distress. These include the avoidance of antihistamines, fluid restriction before bed and decreasing intake of alcohol and caffeine.\textsuperscript{16}

**Alpha$_1$-adrenergic blockers**

Alpha$_1$-adrenergic blockers ($\alpha_1$-blockers) can be used as treatment of BPH-related LUTS. They act on the dynamical component (increased smooth muscle tone) by inhibiting the $\alpha_1$-mediated sympathetic stimulation to reduce prostatic smooth muscle tone.\textsuperscript{20} These agents are suitable for rapid and effective symptomatic relief of symptoms, but are relatively not effective in reducing the size of the enlarged prostate.\textsuperscript{8} Both clinical trials and direct comparative studies have revealed that none of the $\alpha_1$-blockers, alfuzosin, terazosin, doxazosin and tamsulosin are superior to the others in terms of clinical effectiveness.\textsuperscript{21}

A selective $\alpha_1A$-adrenergic receptor antagonist, silodosin, has been approved by FDA for the treatment of BPH, but this drug is not yet available in Malaysia. Silodosin is reported to produce a greater reduction in IPSS score compared to placebo, but is not superior to tamsulosin in terms of improvement in IPSS score.\textsuperscript{22} The primary difference among these $\alpha_1$-blockers is in their side effects. Non-subtype-selective $\alpha_1$-blockers like doxazosin and terazosin have higher potential to cause vasodilatory adverse events like lowering of blood pressure and dizziness.\textsuperscript{23} This leads to the need for dose titration and blood pressure monitoring.\textsuperscript{1} In contrast, tamsulosin and silodosin have been proven to be associated with ejaculatory disorder, and this is greater in men on silodosin.\textsuperscript{24,22}

There is evidence of drug-drug interactions between $\alpha$-blockers with calcium-channel blockers like amlodipine, nifedipine, diltiazem and verapamil. This is attributed to the mechanisms of action of both classes of drugs, which lead to excessive reduction of blood pressure.\textsuperscript{25} Therefore, $\alpha_1$-blockers should be used with caution in BPH patients with comorbid hypertension to prevent manifestations of vasodilatory effects secondary to drug-drug interactions.

Apart from that, it is recommended to avoid initiation of $\alpha$-blockers in patients who are going for cataract surgery until the surgery is completed. This is due to the heightened risk of occurrence of intraoperative
floppy iris syndrome (IFIS), where the risk is higher among BPH patients who are taking tamsulosin compared to those who are on terazosin and doxazosin.1

5-alpha reductase inhibitors
5-alpha reductase inhibitors (5-ARIs) including dutasteride and finasteride have been extensively studied in the treatment of BPH. Clinical efficacy of 5-ARIs is thought to stem from their ability to inhibit 5α-reductase that will eventually block the conversion of testosterone to the more potent 5α-dihydrotestosterone, which is an androgen that is responsible for the growth of the prostate gland.26 Reduction of both serum and intraprostatic 5α-dihydrotestosterone level leads to a decrease in the size of the enlarged prostate by inducing apoptosis and atrophy of prostatic epithelial cells.27 Due to the ability of dutasteride in blocking both 5-AR type I and type II isoenzymes, it produces a more profound reduction of dihydrotestosterone level compared to finasteride, which inhibits only 5-AR type I isoenzymes.1 The AUA guidelines recommend 5-ARIs as the treatment of LUTS secondary to BPH in men with demonstrable prostate enlargement.9 Both finasteride and dutasteride lower the risk of BPH progression by actively reducing the size of enlarged prostate through decreasing the levels of dihydrotestosterone.26

The efficacy of finasteride has been proven by the PROSPECT study, which showed a continuous improvement in IPSS score, peak urinary flow rate and prostate volume during two years of the trial.28 This is supported by data from the North American and international phase III finasteride trial that enrolled a total of 1,657 patients. This six-year trial demonstrated an overall reduction of IPSS score from baseline, median reduction in prostate volume and improvement in the mean peak urinary flow rate after six years of treatment with finasteride.29 On the other hand, a systematic review of three double-blind, placebo-controlled studies revealed that patients receiving dutasteride had a reduction in prostate volume, improvement of IPSS score and an increase in peak urinary flow rate when compared with placebo.30 Nonetheless, both finasteride and dutasteride are found to be associated with sexually related adverse events like decreased libido, ejaculatory dysfunction and erectile dysfunction.1

Combination therapy of α1-blockers and 5-ARIs
Combination therapy of α1-blockers and 5-ARIs as a treatment option of BPH has gained much interest among researchers. It is recommended for patients with LUTS due to significant prostate enlargement.1 The combination of drugs works synergistically by providing short-term symptomatic relief. In the long term, it reduces the size of the enlarged prostate gland and delays disease progression.30

The MTOPS study, the largest clinical trial, which was conducted for four-and-a-half years, demonstrated the effectiveness of combination therapy of doxazosin and finasteride.31 The study showed that the combination of doxazosin and finasteride produced significant reduction in IPSS score as compared to placebo. Moreover, combination therapy was shown to be safe and more effective than doxazosin and finasteride monotherapy in the prevention of disease progression, development of AUR and the need of BPH-related surgery.31 In addition to that, a recent review conducted by Djavan et al. showed promising results of combination therapy with dutasteride and tamsulosin. This combination was found to lower the risk of disease progression, development of complications like acute urinary retention and the need of BPH-related surgical interventions.30 However, it was found that the occurrence of adverse effects
was higher in patients on combination therapy compared to those on monotherapy.

**Muscarinic receptor antagonist**
Muscarinic receptor antagonists like tolterodine have been recommended by the AUA guidelines in the management of BPH-associated LUTS. Antimuscarinic agents act by modifying bladder contraction through competitive inhibition of muscarinic receptors in the bladder neurons. A study conducted by Kaplan and co-workers showed that tolterodine extended-release formulation decreased overactive bladder and voiding symptoms in men who were not responding to α-blockers. The same study revealed that the occurrence of anticholinergic side effects like dry mouth was low and urinary retention were not reported among the study population throughout the study period.

Also, deterioration of erectile and ejaculatory function among BPH patients was not reported. This suggested that the antimuscarinic effect of tolterodine in the treatment of LUTS suggestive of BPH is effective and unlikely to cause voiding difficulties as well as ejaculatory dysfunction, seen in other agents. However, an antimuscarinic agent is only recommended for BPH patients without an elevation in the post-void residual volume and for those who are suffering from irritative LUTS. Baseline post-void residue volume ought to be assessed prior to initiation of therapy.

**Phosphodiesterase type 5 inhibitor (PDE5-I)**
In 2011, the US FDA approved tadalafil, a PDE5-I, for the symptomatic management of BPH. It is especially recommended for BPH patients with concomitant erectile dysfunction. Inhibition of PDE5 by tadalafil is believed to improve BPH-related LUTS by affecting the level of cyclic guanosine monophosphate in the prostate and the urinary bladder. The cyclic guanosine monophosphate-mediated vasodilation improves prostate and bladder blood flow, which will then relieve undesirable BPH symptoms.

A study conducted by Porst et al. confirmed that tadalafil 5 mg daily was effective in reducing LUTS secondary to BPH. Also, a meta-analysis of 12 randomized-controlled trials revealed that PDE5-I was effective and safe in the management of BPH. Data have shown that a combination of PDE5-I and α-blocker results in significant improvement in peak urinary flow rate. However, the use of tadalafil as part of combination therapy with α-blockers is not recommended by the US FDA due to the risk of hypotension. Also, tadalafil interacts with nitrates and the use of tadalafil is contraindicated for patients receiving nitrates as the combination may cause excessive reduction in blood pressure.

**Complementary and alternative medicine**
Phytotherapeutic agents are now regaining interest from men with BPH, particularly those who are not satisfied with the intolerable adverse effects of pharmacological therapies. Phytotherapy appears to be one of the alternatives to replace the need for surgical intervention for a certain population of patients.

Serenoa repens, which is also known as saw palmetto, is the most frequently studied agent to be used as a standard treatment indicated for BPH. To date, worldwide there are more than a hundred marketed products containing Serenoa repens extract, but there are only three products available in Malaysia registered as drugs and supplements to improve urination. The precise mechanism of action of saw palmetto remains unknown. However, studies have found that saw palmetto is able to cause contraction of the prostatic epithelial cells, especially in the transition zone, after six months of therapy with a saw palmetto herbal blend. Also, saw palmetto extract was found...
to have mild in vivo 5-AR inhibitory effects, anti-inflammatory, anti-androgenic and anti-edematous effects\textsuperscript{35,37}.

The Saw palmetto for Treatment of Enlarged Prostates (STEP) study conducted by Avins et al. has proven the safety of saw palmetto extract. It has been demonstrated that the extract is not associated with any serious clinically relevant adverse effects\textsuperscript{38}.

Nevertheless, the AUA guidelines do not recommend the use of saw palmetto extract for the treatment of BPH. This is probably because recent studies have failed to demonstrate its clinical role and effectiveness in relieving symptoms of BPH\textsuperscript{1,36,39}.

Minimally invasive therapies (MITs)

Transurethral microwave thermotherapy (TUMT)

TUMT, which is considered an outpatient procedure, has been proposed as an alternative to relieve BPH-related LUTS\textsuperscript{40}. TUMT is a process of positioning a microwave antenna within the prostate, which then produces heat to destroy hyperplastic prostate tissues\textsuperscript{16}. Based on the review of the data and panel consensus, the AUA guidelines concluded that TUMT is effective in partially relieving BPH symptoms and recommended the use of TUMT in men with moderate or severe symptoms\textsuperscript{1}. A meta analysis conducted by Hoffman et al. has reported that TUMT was able to reduce bothersome LUTS effectively\textsuperscript{41}. However, retreatment for BPH is reported to be far more common after TUMT compared to TURP. The common adverse events reported are mild, which include dysuria, urinary retention and urinary tract infection\textsuperscript{41}. Further study is required to investigate the long-term effectiveness of TUMT therapy.

Transurethral needle ablation of the prostate (TUNA)

TUNA, similar to TUMT, is also an outpatient procedure for the treatment of BPH\textsuperscript{42}. It is a technique that applies low-level radiofrequency energy (460 kHz) to induce necrosis of hyperplastic prostate tissues, and is performed under local anesthesia\textsuperscript{16,43}. It selectively causes necrosis of the prostate tissues without causing harm to the urethra and other adjoining structures\textsuperscript{43}. A recent meta analysis involving 35 studies conducted by Bouza and colleagues suggested that TUNA was safe and effective in relieving symptomatic BPH. The most frequently reported adverse effects of TUNA are hematuria, transitory urinary retention, dysuria and irritative symptoms. In the study, TUNA was found to be superior to TURP in terms of the anesthetics used, length of hospitalization and the associated morbidity\textsuperscript{43}. However, in the long term, the efficacy of TUNA declines and the retreatment rate of patients following TUNA is higher than those who underwent TURP by 7.44 times\textsuperscript{43}.

Surgical therapy

The European BPH guidelines recommend surgical management for BPH patients with moderate or severe symptoms, patients whose symptoms do not improve following medical therapies or patients who refuse pharmacological treatment\textsuperscript{16}. Of all the surgical options available, Transurethral Resection of the Prostate (TURP) appears to be the conventional surgical option that is most commonly carried out in Malaysia. TURP is a technique of removing portions of the hyperplastic prostate gland without the need for external excision\textsuperscript{1,16}. Three forms of TURP are available, namely monopolar resection, bipolar resection and plasma-kinetic resection. The choice of therapy is based on disease severity, anatomy as well as the risks and benefits\textsuperscript{1}. Due to the use of general anesthetics, patients who undergo TURP usually require hospitalization for approximately five days\textsuperscript{1,41}. The most frequently associated complications are void-
ing difficulties, clot retention and secondary urinary tract infection. The other surgical complications that have been identified are TUR syndrome (dilutional hyponatremia), erectile dysfunction, hematuria and bladder neck contracture.

Role of pharmacists
Symptomatic BPH can have detrimental impacts on patients’ quality of life, yet people often find that it is embarrassing to talk about their symptoms. Untreated BPH can potentially lead to complications like acute urinary retention, hematuria and urinary tract infection that require immediate medical attention.

For those who seek treatment, pharmacists are responsible for considering the choice of medications based on the severity of disease and the need for immediate relieve of symptoms. α₁-blockers are usually the drug of choice for immediate alleviation of symptomatic BPH, while 5-ARIs are commonly prescribed to reduce the size of the enlarged prostate and to lower the risk of BPH progression. Besides that, in terms of pharmacoeconomics, pharmacists play an important role in selecting appropriate therapies in order to optimize the cost of care. Different therapeutic options with different costs, efficacies and side effects should be analyzed and evaluated to determine their cost-effectiveness. Watchful waiting is generally recommended for those who have low AUA scores, while pharmacological treatments as well as surgical therapy are indicated for patients who have moderate or severe LUTS attributable to BPH.

In addition to that, pharmacists can counsel patients on lifestyle modification. BPH symptoms like nocturia can be improved by fluid restriction and caffeine avoidance after dinner. While for patients who are on diuretics, it is recommended that they take diuretics in the morning instead of just before bedtime. It is not uncommon to encounter patients with BPH who are taking medications like antihistamines, anticholinergics, sympathomimetics, diuretics, antidepressant or bronchodilators that may exacerbate the symptoms of BPH. Therefore, it is of the utmost importance that pharmacists review the medications used by patients with BPH. Last, but not least, pharmacists should counsel patients on possible adverse effects of drugs and on methods to cope with the adverse effects that they may experience.

To answer the quiz for your CPD points, please go to www.mims-cpd.com.my
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