Ensure quality of medical devices for better healthcare

MAJOR GENERAL MD MUSTAFIZUR RAHMAN

HEALTH is the primary concern of people, and even the government. It is also directly linked to productivity. When a person becomes sick, he needs standard, safe and effective medical care. To ensure medical care, good quality medicine and medical devices at affordable prices are needed. Keeping this in mind, the Directorate General of Drug Administration (DGDA) and concerned experts have formulated a robust guideline to regulate medical devices in Bangladesh.

The Registration Guidelines for Medical Device, Bangladesh 2015 have been formulated based on the guidelines from the Global Harmonisation Task Force, which comprises of regulatory affairs experts to harmonise the regulation of medical devices internationally.

The newly framed guidelines categorised the medical devices based on the level of risk – 'A' for low risk like surgical retractors, tongue depressors, dressing, gauge and bandage; 'B' for low-moderate risk like hypodermic needles and suction equipment; 'C' for moderate-high risk like lung ventilators and bone fixation plate; and 'D' for high risk like heart valves and implantable defibrillator.

The guidelines comply with a set of essential principles so that supply of safe, effective and quality medical devices can be ensured.

The instruction has implemented conformity assessment procedures to ascertain manufacturer's quality management system for the medical devices in accordance with ISO 13485:2003.

The guidelines stipulate that conformity assessment procedures shall be the responsibility of manufacturers and notified bodies for carrying out conformity assessment on the basis of the type of devices intended to be manufactured.

All the rules that follow in order to establish the proper classification for the device should be taken into consideration.

Under the guidelines, locally manufactured or imported medical devices shall mention the date of manufacture and date of expiry. In case of medical devices imported to the country, the importer can carry out further labelling of the product for conforming to the labelling rules and maximum retail price of the individual item in the label before release for sale in the market.

Major General Md Mustafizur Rahman

The guidelines maintain the proper implementation of regulatory controls for manufacturing processes in order to safeguard the health and safety of patients, users and other persons. It aims to ensure that manufacturers of medical devices follow specified procedures during design, manufacture and marketing. The guidelines further suggest that regulatory controls should be proportional to the level of risk associated with a medical device. In general, the classification rules are intended to accommodate new technologies.

Registration for all medical devices of class B, C and D has been made mandatory before they are imported or manufactured in the country. Medical devices, already being imported or manufactured into the country, requires application immediately from the issue of this guideline.

For medical devices which are to be imported or manufactured for the first time, the applicant has to apply for registration before such import or manufacture. A local authorised person of the manufacturer of the foreign supplier or authorised agent will apply to the DGDA for registration in prescribed form with a due amount of fees.

The guidelines also affirm implementation of post-marketing surveillance systems, adverse incident reporting and vigilance activities, through which DGDA will monitor and take action as per Drug Act 1940, Drug Control Ordinance 1982 and Drug Policy against counterfeit and unregistered item.

If DGDA considers that any product should be withdrawn from the market, or its placing on the market and putting into service should be prohibited, restricted or subjected to particular requirements, the authorities concerned may take any necessary measures.

All the relevant stakeholders are subjected to adhere to these guidelines for manufacture, import, distribution and sales of medical devices in Bangladesh. The decision to refuse or restrict the placing on the market or the putting into service of a device or the carrying out of clinical investigations; or to withdraw devices from the market will state the exact grounds on which it is based.

Such decisions can be informed to the party concerned, who will at the same time be informed of the remedies available to him under the Drugs Act.

It is expected that this guideline will enable DGDA and other stakeholders to ensure that Bangladeshi citizens can avail themselves of medical devices conforming to internationally acceptable standards of quality, safety and performance at affordable price.

All stakeholders should do the following -- they have to submit relevant paper along with product for registration according to the checklist attached with the Medical Device Registration Guideline. Unregistered medical devices found in the market will be seized by mobile court and drug superintendent as per Drug Act 1940 and Drug Control Ordinance 1982. Instructions have been given to all healthcare institutions by the ministry not to purchase unregistered medical devices through tender.

Regulation is necessary to ensure safe, effective and good quality medical devices at affordable prices, which will ultimately help ensure quality health care. Every person concerned should come forward to work together and ensure quality health care.

The writer is the director general of Directorate General of Drug Administration.

Tobacco giant BAT targets US with $47b Reynolds bid

AFP, London

British American Tobacco on Friday launched a vast $47 billion bid for full control of Reynolds American, as it seeks expansion into the United States -- the second largest market after China.

The deal, worth the equivalent of 43 billion euros for the 58 percent of Reynolds that BAT does not yet own, would cement its status as one of the world's largest tobacco companies.

The news sent BAT's share price surging on the London stock market, but it lost momentum and finished it closed down 2.9 percent.

BAT said the move would give it "a leading position in the US tobacco market" as well as "a significant presence in high growth emerging markets."

"The main reason for the deal is for BAT to be in the United States," a company spokeswoman told AFP, noting that the company did not have a direct presence there.

She added that building on the popularity of e-cigarettes was also a motivation behind the deal.

The blockbuster proposal would bring together BAT brands Dunhill, Kent and Lucky Strike cigarettes with Reynolds American's Camel and Newport.

The combined group would have a "world class pipeline" of so-called next generation products like e-cigarettes, in a fast-growing part of the market, the statement added.

Most global tobacco firms are looking to emerging markets to offset sliding demand in Western Europe, where high taxes, public smoking bans and health concerns have persuaded many people to give up or turn to e-cigarettes, battery-powered devices that heat a nicotine liquid.

Reynolds issued a brief statement, saying its board will evaluate the offer.

"Reynolds American Inc. acknowledges that it has received a non-binding proposal from British American Tobacco p.l.c. (BAT) to purchase the approximately 58 percent of RAI common stock that BAT does not currently own. The RAI board of directors, consistent with their fiduciary duties, will evaluate the offer from BAT and respond accordingly," the statement said.

Reynolds share price was up more than 13 percent at $53.35 midday. Half of BAT's sales are in developed nations and the rest in emerging markets.

"We are not concerned by the decrease in tobacco consumption in developed countries as the consumption is rising on a global scale," the spokeswoman added.

Indian regulator recommends $456m fine on telecoms firms

REUTERS/FILE

A rickshaw puller speaks on his mobile phone as he waits for customers in front of advertisement billboards belonging to telecom companies in Kolkata.

REUTERS, Mumbai

India's telecoms regulator on Friday recommended the top three network operators be fined a combined 30.5 billion rupees ($455 million), saying they were denying new entrant Reliance Jio sufficient interconnection points.

Jio is part of Reliance Industries Ltd, controlled by India's richest man, Mukesh Ambani. It began offering 4G services in September, triggering a war over network points that connect Jio customers with Bharti Airtel Ltd, Vodafone Plc's India subsidiary and Idea Cellular Ltd.

Responding to Jio's complaints over the denial of points of interconnection (POI), the Telecom Regulatory Authority of India (TRAI) recommended a fine of 500 million rupees per telecom zone for each of the three operators.

Airtel and Vodafone India were fined for 21 zones each while Idea was fined for 19 zones. India has 22 telecoms zones or circles.

The denial of POI to Jio "appears to be with ulterior motive to stifle competition and is anti-consumer", TRAI said in a statement.

Reliance Jio did not respond to an email seeking comment while Vodafone and Idea declined comment.

"We are continuously augmenting the POIs provided to Reliance Jio and the pace of augmentation has been the fastest ever done by us," a spokesman for Airtel said.

'Crazy' hike in Saudi visa fees could impact business ties

AFP, Riyadh

A seven-fold hike in visa fees to do business in Saudi Arabia risks deterring the foreign investment needed to transform its oil-dependent economy, diplomats and other sources say.

But a senior Saudi business leader has dismissed such concerns, insisting the country's most sought-after business partners could easily afford the new charges.

"It's incredibly short-sighted," a Riyadh-based diplomat said of the changes which took effect this month.

"They're obviously bleeding and they want to put the cost on foreigners as much as they can," he said, asking for anonymity. "It'll end up costing them a lot more than what they gain in visa payments."

Higher visa fees are one of many moves adopted by the kingdom to cover a loss in oil revenue which has slumped by 68 percent over the past five years, according to official data cited by Bloomberg News.

But the higher cost of entry permits has left people "scratching their heads", a second diplomat said.

"We are expecting to see business reconsider Saudi as a market," said the Western envoy. "It's certainly happening already," though not in a major way.

Starting in October, a six-month business or work-visit visa allowing multiple entries costs 3,000 riyals ($800), compared with 400 riyals before, said Ala Siyam, general manager of Gulf Consulting House.

The consultancy, in Khobar on the Gulf coast, assists clients from more than 40 countries in securing visas to Saudi Arabia, which requires all foreigners to have a local sponsor, whether to visit on holiday or business.

Siyam told AFP the changes do not apply to the European Union or United States, while fees for British nationals have only slightly increased.

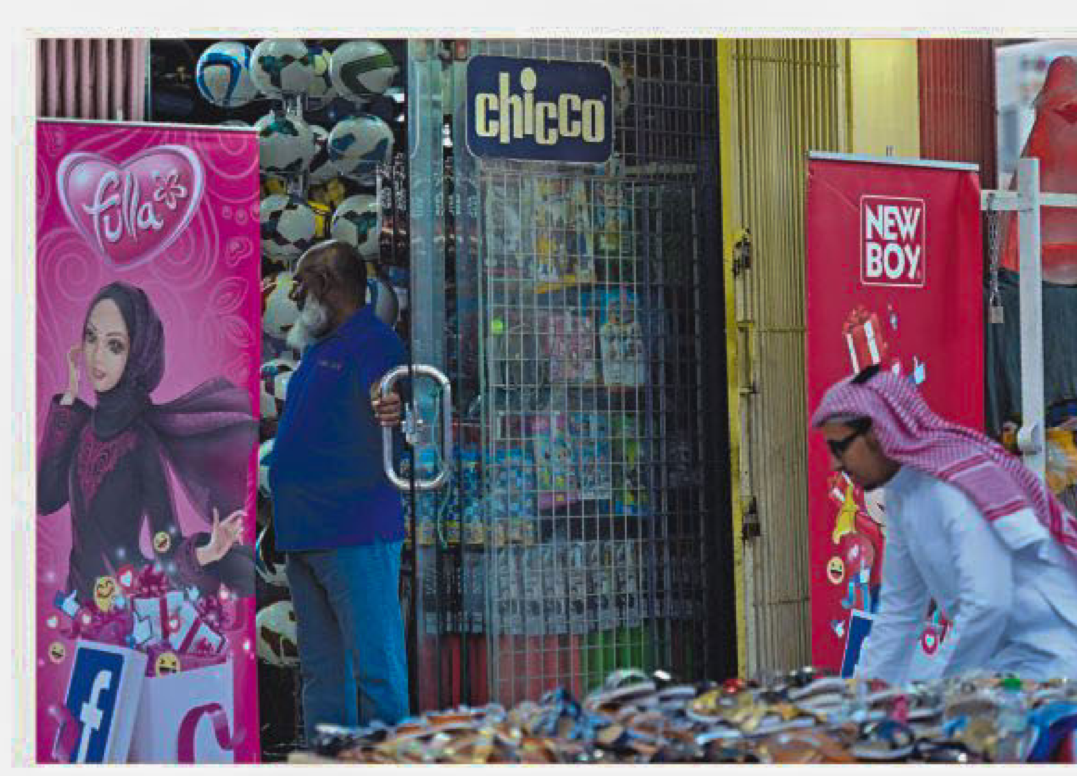
Most other countries face the higher charges but also have a new option of applying for one or two-year visas. Those cost 5,000 riyals and 8,000 riyals each.

Single-entry business visas are now priced at 2,000 riyals, several times higher than before.

An oil industry source called the new tariffs "crazy" and a "complete mistake" if Saudi Arabia was seeking foreign partnerships.

Since 2014, global oil prices have collapsed by about half, accelerating Saudi efforts to move away from petroleum which still accounts for the bulk of government income.

In April, Deputy Crown Prince Mohammed bin Salman, 31, announced a "Vision 2030" reform programme to transform the world's biggest oil exporter into a private-sector powerhouse with diverse industrial interests and major international investments.



AFP

A foreign worker stands inside a toy store in Riyadh, Saudi Arabia.

To promote job creation among Saudis and boost exports, Vision 2030 aims to foster small and medium-sized enterprises (SMEs) partly through "international partnerships".

"This will be achieved by attracting both regional and international retail investors", the Vision says.

But higher visa fees will be a "particular disincentive for SMEs", including those wanting to assess the market or meet potential partners, the first diplomat said.

He and the Western diplomat agreed that foreign companies will now be more likely to consider doing business, and even meeting, elsewhere. Abdulrahman al-Zamil, former chairman of the Council of Saudi Chambers, says the impact of the hike in visa fees is being exaggerated.

"Most of those who are interested in our market.. can afford it. These are giant companies," said the head of Zamil Group, which employs 21,000 people in a range of sectors including steel fabrication and shipbuilding.

"The Saudi market is not really attractive to small and medium" enterprises from abroad, Zamil added.

Azevedo says Britain's WTO terms will depend on nature of EU divorce

REUTERS, Oslo

The terms of Britain's future membership of the World Trade Organization will depend a lot on how it separates from the European Union, the director-general of the WTO said on Friday.

In the case of a "hard Brexit", including leaving the EU's customs union, some argue Britain can fall back onto WTO terms to govern its global trading relationships.

Britain is a member of the WTO but once it leaves the EU, the bloc's schedules of commitments -- a list of its tariffs, quotas and subsidy entitlements -- will no longer apply to Britain.

"Once they (the British) leave, legally the EU schedules no longer applies to them ... The other WTO members arguably could say: 'I don't like it. We should change this, or we should change that'," Roberto Azevedo told a business seminar in Oslo.

"A lot will depend on the terms of separation in the negotiations between the UK and the EU. That may have a positive impact on how the other WTO members view this or not.

"I don't think the global economy at this point in time can afford the luxury of more turbulence. The less turbulence we have the better. The quicker trade relations are established between the UK, the EU and other WTO members, the better."

US presidential candidate Hillary Clinton has criticised the TPP and TTIP trade deals concluded between the United States and the Pacific nations and the EU respectively, while her rival Donald Trump has spoken out against accords such as Nafta, enabling free trade between the United States, Canada and Mexico.

Azevedo said the anti-global trade rhetoric heard on the campaign trail may make it more difficult for the next US president to come back on those comments, if required.

"My concern is that if you step up your rhetoric it becomes harder and harder to backtrack," he said. He later told Reuters: "You need to bring rationality back in the conversation about trade. It cannot be an emotional conversation."

"It is very difficult because people are affected in their everyday lives by these shifts. But these shifts are not caused by trade," he said, citing that eight out of the 10 jobs lost are due to increased productivity, new technologies, automation, rather than jobs being delocalised to countries with cheaper labour costs.

Zimbabwe pays IMF arrears, first step to restoring lending

AFP, Washington

Zimbabwe has paid off 15 years of arrears with the International Monetary Fund, taking the first key step towards restoring its access to international loans.

The country paid off about $108 million due to the IMF, and "is now current on all its financial obligations to the IMF," fund spokesman Gerry Rice said in a statement late Thursday. Zimbabwe had been behind in its payments to the global crisis lender since 2001, Rice said.

The move is a positive first step for the country as it tries to stabilize its economy and finances, but does not automatically make it eligible for IMF lending.

It first must have a plan in place to clear arrears to other international financial institutions, the IMF said in a statement. This includes $1.1 billion it owes to the World Bank.

The IMF has applauded Zimbabwe's reform efforts under a fund-monitored advisory program that ended in December 2015, which began to restore confidence and stabilize government finances. But the commodity-dependent country has faced a decade-long crisis, and the IMF warns that without "bold reforms" the economic difficulties will continue.

Zimbabwe adopted the US dollar as its currency in 2009 to end hyperinflation. But the strong dollar has made its exports more expensive. Unemployment is about 90 percent in Zimbabwe, which spends more than four-fifths of its revenue in the salaries of civil servants and is ranked by Transparency International as one the most corrupt countries in the world.