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I. AFRICA

Zimbabwe Doctors Say Patients Dying Due to Drug, Equipment Shortages

(Reuters) - Doctors said on Wednesday that patients in Zimbabwe's biggest state hospital were dying due to a lack of medicines and basic supplies, brought on by a cash crunch that has crippled the economy. [FN1]

In a rare protest by senior medical staff, dozens of doctors picketed outside Parirenyatwa Hospital. They said they were only able to treat emergency cases and urged the government to provide the equipment they needed to do their jobs.

“I am just seeing patients, make a diagnosis and send them away to die,” said gynecological oncologist Bothwell Guzha, adding that the hospital had no cancer drugs left.

The southern African nation is acutely short of dollars, the currency it has used since in 2009, causing price spikes and shortages of basic goods, medicines and fuel.

Plans to float a new transitional local currency introduced last month, the RTGS dollar, have been delayed.

In a subsequent meeting with Health Minister Obediah Moyo, the doctors described shortages of painkillers and syringes and said nurses had to wash and re-use bandages, which increased the risk of infection.

Azza Mashumba said the theater in the maternity unit she heads had not been working for some time, forcing doctors to delay caesarian operations, sometimes with fatal results.

“I come to work to certify dead (baby) bodies, that's not why I am here... We are not working, we are not helping patients,” she told the health minister.

The doctors said Moyo had told them the government would speed up the purchase of equipment and other medical supplies.

At the turn of the year, junior doctors held a 40-day strike for better pay and conditions that crippled public hospitals. It ended without a deal being reached and with doctors threatening further stoppages.

South Africa's Life Healthcare Warns on Earnings after Disposal

(Reuters) - South Africa's Life Healthcare said on Wednesday half-year earnings could fall as much as 55 percent due to costs related to the disposal of its stake in India's Max Healthcare, impairments and other investments. [FN2]

Shares in the company fell 5.30 percent to 26.27 rand after the private hospital operator predicted headline earnings per share (HEPS) for the six months ended March 31 of between 24.1 cents and 29.5 cents, down from 53.7 cents a year earlier.

HEPS is the main profit measure used in South Africa and strips out certain one-off items.

In September, Life Healthcare said it would sell its 49.7 percent stake in Max Healthcare to KKR-backed Radiant Life Care Pvt Ltd for 4.3 billion rand ($300 million).

Life Healthcare also cited a 256 million rand marked-to-market valuation loss related to the disposal, as one of the factors impacting HEPS, along with an increase in contingent consideration relating to past company acquisitions.

Marked-to-market accounting is a way of valuing assets based on how much they could sell for under current market conditions.

Group revenue is expected to rise by between 8.6 percent and 10.4 percent, while normalized earnings before interest, tax, depreciation and amortization (EBITDA) will increase as much as 4.8 percent.

Life Healthcare competes with listed rivals Mediclinic International and Netcare Ltd.

Last Wednesday Mediclinic hit a more than three-month high on after it reassured investors with a forecast for net profit that was in line with market expectations despite a tough business backdrop.

South Africa's Aspen sells Australian prescription portfolio to Mylan

(Reuters) - Aspen Pharmacare said on Monday that Mylan NV had exercised an option to buy the South African drugmaker's portfolio of prescription and over-the-counter products in Australia for 188 million Australian dollars ($130 million). [FN3]

In December, Aspen said its wholly owned subsidiary incorporated in Mauritius, Aspen Global Incorporated, and its Australian subsidiaries had entered into a distribution arrangement with Alphapharm, a subsidiary of Mylan in respect of the portfolio commercialized in Australia and New Zealand.

That deal included an option for Mylan to buy the portfolio.

“The divestment is in line with the group's ongoing portfolio management approach and its stated intention to not only acquire value enhancing products, but to also divest of non-core assets, thereby ensuring enhanced operational focus,” Aspen said in a statement.

Aspen added that 93 million Australian dollars will be payable by May 29, 30 million in January 2020 and up to 65 million will be payable in September 2020.

The proceeds will be used to reduce Aspen's gearing, which has worried investors and caused a sharp decline in the drugmaker's shares.

The company's net debt to EBITDA (earnings before interest, tax, depreciation and amortization) stood at 4.4 times at the end of June, at the upper end of a threshold of 4.75 times negotiated with its creditors in December.

It also sold its infant formula business to French dairy giant Lactalis to bring borrowing down.

On Friday the company said it has received confirmation from Lactalis that the New Zealand Overseas Investment Office has granted approval to Lactalis for the acquisition of its business in that country.

Collaboration with U.S. Med Schools Helps Rwanda Improve Women's Health Care

(Reuters) - Rwandan women have better access to obstetrics and gynecology services thanks to an international partnership to train more doctors, a new study finds. [FN4]

The yearly number of medical school graduates specializing in obstetrics and gynecology (OB-GYN) in Rwanda tripled from 2011 to 2016, and rural women's access to care improved, with more than 87% now having an OB-GYN-staffed public hospital within an hour's travel time, researchers report in the journal Obstetrics & Gynecology.

“In poor areas, access to care is a key issue that relates to maternal and infant death. Increasing access is known to improve the health of mothers and babies,” said lead study author Dr. Maria Small of the Duke University Medical Center in Durham, North Carolina.

The 1994 genocide in Rwanda against the Tutsi ethnic minority created profound structural, social and economic destruction, and many health professionals were either killed or forced to flee the country, Small and her colleagues write.

The Human Resources for Health Rwanda program - a partnership between the Rwandan government and 22 U.S. academic institutions - was initiated to rebuild medical education training and increase access to healthcare for all Rwandans.

U.S. faculty sign on to teach trainees at the University of Rwanda in Kigali and provide clinical support for anywhere from a couple of months to a year.

“Rwanda experienced complete decimation of its healthcare system during genocide, and one of our main goals was to train the next generation,” Small said in a phone interview. “This great group of new doctors is going to make a huge difference.”

The researchers evaluated the first five years of the OB-GYN training program and its effects on access to care.

Overall, the number of trained OB-GYNs in public hospitals rose from 14 to 49 during the program's first five years. And the rate of graduations tripled. In 2011, before the program started, 18 OB-GYN trainee doctors had graduated over the previous seven years, for an average of two per year. During the study years, 33 graduated: an average of six per year.

Rwandan faculty numbers also increased by 45%. Many graduates have taken on leadership roles as the only trained OB-GYNs in many hospitals.

Before the program, most OB-GYN doctors were in the capital city, Kigali, and the second-largest city, Butare, leaving many rural areas without local services. Between 2011 and 2016, the proportion of pregnant women living within 10 km, or about 6 miles, of an OB-GYN-staffed public hospital increased from 13% to nearly 32%, and those who lived within 25 km, or about 15 miles, increased from 28% to 83%.

“This shows the power that a government and healthcare system can have to make substantial change in a country if there's really a desire to do so,” Small said. “Rwanda is still poor, but the achievements made over the last decade have been inspiring to all of the healthcare providers who have worked there.”

“Every country is different. There is no way to copy and paste what has been working in other countries to our country,” said Dr. Joseph Niyitegeka of the University of Rwanda.

Niyitegeka, who wasn't involved with this study, has analyzed travel time and neonatal outcomes among pregnant women in Rwanda, especially when it comes to receiving emergency cesarean sections. He is also an international representative of the Global Anesthesia, Surgery and Obstetric Collaboration, which focuses on access to surgery and obstetrics.

“To find the best solutions, we must know the gaps so different people can discuss them by considering the country's context,” he told Reuters Health by email. “This increases the inclusion of people with different ideas, and of course, diverse solutions for a common goal of access to healthcare.”

South Africa Puts Initial Universal Healthcare Cost at $17 billion

(Reuters) - South Africa published its draft National Health Insurance (NHI) bill on Thursday, with one senior official estimating universal healthcare for millions of poorer citizens would cost about 256 billion rand ($16.89 billion) to implement by 2022. [FN5]

The bill creating an NHI Fund paves the way for a comprehensive overhaul of South Africa's health system that would be one of the biggest policy changes since the ruling African National Congress ended white minority rule in 1994.

The existing health system in Africa's most industrialized economy reflects broader racial and social inequalities that persist more than two decades after apartheid ended.

Less than 20 percent of South Africa's population of 58 million can afford private healthcare, while a majority of poor blacks queue at understaffed state hospitals short of equipment.

Anban Pillay, deputy director general at the health department, told reporters an initial Treasury estimate of 206 billion rand costs by 2022 was more likely to be 256 billion rand by the time final numbers had been reviewed.

The bill proposes that the NHI Fund, with a board and chief executive officer, also be funded from additional taxes.

“The day we have all been waiting for has arrived: today the National Health Insurance Bill is being introduced in parliament,” said Health Minister Zweli Mkhize at the briefing, adding that the pooling of existing public funds should help reduce costs.

The Hospital Association of South Africa (HASA), an industry body which represents private hospital groups including Netcare, Mediclinic and Life Healthcare, welcomed the release of the bill.

“We are committed to, and supportive of, the core purpose of the legislation, which is to ensure access to quality healthcare for all South Africans,” said HASA chairman Biren Valodia in a statement.

“TAX BURDEN”

The new bill is still to be debated in parliament with public input. It is unclear how long the legislative process will take, with the main opposition party Democratic Alliance suggesting the NHI, which has been in the works for around a decade, would strain the nation's coffers.

“The DA is convinced that instead of being a vehicle to provide quality healthcare for all, this Bill will nationalize healthcare ... and be an additional tax burden to already financially-stretched South Africans,” said Siviwe Gwarube, the DA's shadow health minister, in a statement.

Successful implementation of NHI would be a boon for President Cyril Ramaphosa following May's election the ANC won, but its cost comes at a tricky time in a struggling economy.

South Africa's rand fell to touch an 11-month low on Wednesday, rocked by deepening concerns about the outlook for domestic growth with unemployment at its highest in over a decade and the economy skirting recession.

New taxation options for the Fund include evaluating a surcharge on income tax and small payroll-based taxes.

“There is no doubt that taxpayers will find the additional tax burden a bitter pill to swallow,” said Aneria Bouwer, a partner and tax specialist at Bowmans law firm.

The NHI is due to be implemented in phases before full operation by 2026. The government is looking to eventually shift into the new Fund approximately 150 billion rand a year from money earmarked for the provincial government sphere.

II. AMERICAS

Brazilian Doctors Fail to Report for Duty to Replace Cubans

(Reuters) - Brazil has failed to replace nearly one third of the thousands of Cuban doctors who exited the country after a diplomatic spat, as many new recruits failed to turn up for work, the Health Ministry said on Wednesday. [FN6]

Brazil's President-elect Jair Bolsonaro had criticized Cuba's involvement in a government healthcare program, saying that Cuban doctors were being used as “slave labor” because Havana took 75 percent of their salaries.

Cuba's government in response pulled out of the cooperation agreement, which provided medical care for millions of Brazilians in poor and remote areas, leaving more than 8,000 doctor positions vacant.

While Brazil said last month it had filled more than 90 percent of the vacancies, 2,439 out of 8,411 new recruits had failed to report to their work locations by a Tuesday deadline, a Health Ministry spokeswoman said. The positions will be opened up for new applications on Dec. 20 and 21, she said.

The information was earlier reported by news portal G1.

Cuba generates major export earnings by dispatching more than 50,000 health workers to more than 60 countries. The money the doctors earned in Brazil under the program was considered good by Cuban standards, even after the government took its portion.

Bolsonaro, who takes office on Jan. 1, has positioned himself as a fervent anti-communist and plans to align Brazil more closely with the United States. On Tuesday, he said that he would take all action “within the rule of law and democracy” to oppose the governments of Venezuela and Cuba.

Canada Budget to Include Limited Coverage for Prescription Drugs - Sources

(Reuters) - Canada's Liberal government will propose a limited expansion to the country's universal healthcare system in the spring budget to cover part of the cost of prescription drugs, two sources with direct knowledge of the matter told Reuters. [FN7]

The modest broadening of the healthcare program is set to become one of Prime Minister Justin Trudeau's key campaign promises ahead of the October election, which is shaping up to be a close fight.

The government would not commit to meeting 100 percent of the cost of prescription drugs for those who have no insurance through their workplace, the sources said. That suggests the government is leaning toward a narrower, more insurance industry-friendly model of pharmacare, as it is called, than that recommended by a government health committee last year.

A spokesman for Finance Minister Bill Morneau declined to comment.

Officials have yet to decide how much detail to provide about the pharmacare system in the budget, which is expected in the week of March 18, the sources said. They may release a general commitment to boost coverage and leave the specifics for the campaign, they added.

But new information on pharmacare's inclusion in the spring budget and its limited scope gives a first glimpse of the government's blueprint for what has been called the “unfinished business” of Canada's publicly funded healthcare system, called medicare.

The sources, who spoke in recent days, requested anonymity because they were not authorized to speak to the media.

Canada's health system covers care provided in hospitals and doctors' offices, but prescription medication remains largely the purview of private insurance, often offered through employers, and a patchwork of public plans geared primarily toward the old and the very poor.

Opinion polls consistently show strong popularity for Canada's public healthcare system.

There have been calls for Canada to extend medicare to include prescription drugs since medicare came into existence in the late 1960s, and multiple studies have recommended its inclusion.

Surveys have found 20 percent of Canadians are either uninsured for prescription drugs or under-insured, and one in 10 Canadians goes without prescription medications because of an inability to afford them, according to the standing committee on health's pharmacare report released in April 2018.

Manulife Financial Corp, Sun Life Financial Inc and Great West LifeCo are among the major insurers in Canada.

FILLING IN GAPS

The Liberal-dominated government health committee strongly recommended Canada adopt a universal, national pharmacare program that covers drug expenditures for all Canadians for a wide range of drugs.

That would not only improve equity and access, advocates said, but lower drug costs because there would only be one buyer negotiating with pharmaceutical companies.

The government's budget watchdog estimated that would cost about C$20.4 billion ($15.5 billion) a year - a hefty price tag for the government, but offering an overall saving of C$4.2 billion compared with the total now spent on prescription drugs.

What the government is likely to include in its budget is a much more targeted plan aimed at filling the gaps in coverage not already filled by private insurance or existing public plans, the sources said.

That matches with the government's finance committee recommendation late last year, which Morneau, himself a former benefits industry executive, has said he would prefer.

It is also in line with what the insurance industry has been asking for. Standing to lose business to a universal government plan, the insurers have argued that most Canadians have good private coverage and that pharmacare changes need only affect a small uninsured minority.

But the Liberals will likely face criticism from policy advocates and left-leaning political opponents for not pursuing a more comprehensive plan. Without a universal system overhaul, advocates argue, people will continue to slip through costly cracks in the coverage system.

An advisory council appointed to study the implementation of pharmacare is expected to come out with recommendations this spring.

Facing Crackdown in Canada, Drugmakers Offered Billions in Price Cuts

(Reuters) - Canadian pharmaceutical industry lobby groups, in an effort to head off a planned crackdown on prescription drug prices, offered to give up C$8.6 billion ($6.6 billion) in revenue over 10 years, freeze prices or reduce the cost of treating rare diseases, according to interviews and documents seen by Reuters. [FN8]

Those industry offers did not impress federal officials, coming last year as Canada prepared to expand the powers of a little-known federal watchdog called the Patented Medicine Prices Review Board (PMPRB) to reduce the cost of prescription drugs.

The government proposals would change the countries Canada compares its prices to, dropping the United States where they are highest, and set a formula to assess cost-effectiveness of medicines.

Announced in 2017, the new rules were scheduled to come into effect last month but have been delayed as the government reviews feedback, which has some wondering if they will ever be implemented.

The delay is a setback for supporters of the changes. But documents detailing counter offers from lobby groups Innovative Medicines Canada and BIOTECanada show an industry struggling to win over federal officials.

Unlike other countries with universal healthcare, Canada's government-funded healthcare system does not cover prescription drugs. Most Canadians rely on an expensive patchwork of public and private insurance plans for that. Among industrialized nations, only the United States and Switzerland spend more on prescriptions per capita.

Declan Hamill, a vice president at Innovative Medicines Canada, said the proposed regulations go too far and could hurt patient access to new drugs in Canada. But his group recognizes that the Canadian government wants to make drugs more affordable, he said.

“We'd like to help the government out with that, and we've been trying to have discussions with them,” Hamill said.

Lower prices in Canada could eventually hit drugmakers in the most lucrative U.S. market, as Washington evaluates a proposal to base drug prices paid under the government's Medicare program on the cost of medicines in other developed nations, including Canada.

Global drugmakers, including Johnson & Johnson, Merck & Co, Amgen Inc and others, have argued against the Canadian proposal. They referred questions back to Innovative Medicines Canada.

'WOULD NOT ACHIEVE THE GOAL'

With major drugmakers united in their condemnation of proposed regulations to rein in prices, Health Canada hired former Bank of Canada governor David Dodge and health economist Åke Blomqvist to assess the government proposal. Their review, completed in August 2018, broadly endorsed the government's plan, documents seen by Reuters showed.

Prime Minister Justin Trudeau's senior ministers will eventually decide how to proceed. PMPRB Executive Director Douglas Clark told Reuters the new regime could be running by early 2020.

“People have a tendency to presume that the sky is falling,” Clark said. “I think it's a little early for people to panic and lament the demise of this policy initiative.”

Health Canada said the industry's offers do not address drug price problems created by outdated rules.

“The non-regulatory counter-proposals that Innovative Medicines Canada and BIOTECanada jointly submitted to the government would not achieve the goal of ensuring appropriate consumer protection in these circumstances,” the ministry said in an emailed statement.

One offer was to “secure a price reduction target of C$8.6 billion” in net present value terms, according to a letter from officials seen by Reuters.

Hamill said the C$8.6 billion figure was borrowed from a government estimate of how much the PMPRB reforms would reduce revenue and would have been spread over 10 years. He did not say exactly how it would have worked. Total patented medicine sales were C $16.8 billion ($12.8 billion) in 2017, according to the PMPRB.

Health Canada also rejected an offer to freeze prescription drug prices, saying it would not meet its objective of lowering prices.

Health Canada said the industry had also committed to improving access for patients with rare diseases, but that proposal would not help those who have drug plans.

Meanwhile, ahead of a fall election, Trudeau's government is preparing to announce a limited expansion of the nation's universal healthcare system to cover part of the cost of prescription medicines, as drug plans grapple with the extremely high cost of newer specialty drugs.

'WE DON'T WANT TO SHUT THAT DOOR'

The PMPRB caps prices of drugs still under patent protection. If new regulations are adopted, it would change the list of countries whose drug pricing it uses to decide whether costs are excessive, dropping the United States and adding countries with lower prices.

The regulator would also consider for the first time a type of value-based pricing, measuring how cost-effective drugs are in terms of quality-adjusted life years, and force drug companies to privately disclose some confidential discounts.

It is not entirely clear how the PMPRB would use its new powers. In documents posted online, the agency said it could apply new rules to drugs already on the market. But Health Canada said the regime would not apply to those.

Andrew Casey, president of BIOTECanada, would like “a more rigorous sit-down” with the government.

“I fear the consequences when you do something without really working with industry,” he said. “We don't want to shut that door.”

Canada Advisory Group Calls for New Prescription Drug Agency

(Reuters) - A Canadian advisory council studying prescription drug coverage said on Wednesday the federal government should create an arm's-length national drug agency to manage and oversee a new drug program. [FN9]

Finance Minister Bill Morneau said last month that the federal budget, set to be released on March 19, would outline ways to provide more access to prescription drugs, confirming a report from Reuters.

“I can tell you that I'm not going to announce the budget here this morning. So, sorry for the lack of details,” Morneau said at a news conference in Toronto. “We know that Canadians expect us to deal with what we see as the unfinished business of the Canadian healthcare system.”

The council's eight-page interim report contained few new details and was unveiled by two cabinet ministers on the same day that a former adviser to Prime Minister Justin Trudeau was set to testify about the government's handling of a corruption case, part of an escalating political crisis.

Unlike other industrialized countries with universal healthcare, Canada has no universal coverage for prescription drugs. Most Canadians rely on employer-funded insurance, while some are covered by government programs for the elderly or people with low incomes or very high drug costs.

About 20 percent of Canadians are uninsured or underinsured, according to government surveys.

The council's report said the patchwork system meant inconsistent access to drugs and that spending on drugs by patients and drug plans is unsustainable, in part because of the high cost of new drugs.

The proposed new national agency should evaluate clinical evidence on the effectiveness of new drugs and value-for-money, and negotiate with manufacturers, according to the report, as well as monitor safety and effectiveness. Those tasks are currently handled by several provincial and federal bodies.

It did not expand on what would make the agency arm's-length. In general, arm's length agencies have significant day-to-day independence from ministries led by elected officials, though politicians may choose their leaders or modify their powers.

The agency did not take a position on the central question of whether a new national program should replace or just augment existing drug plans. A final report is scheduled for “the coming months,” the council said.

Reuters reported in January that the federal budget would not propose a plan to cover the full cost of prescription drugs for those who have no insurance through their workplace, citing sources.

A more limited plan would benefit private insurers like Manulife Financial Corp, Sun Life Financial Inc and Great-West LifeCo.

U.S. Charges Chinese National in Hacks of Anthem, Other Businesses

(Reuters) - A federal grand jury charged a Chinese national in a 2015 hacking campaign that affected large U.S. businesses including insurer Anthem Inc, where the breach affected a computer system containing data on nearly 80 million people, according to an indictment unsealed on Thursday. [FN10]

Fujie Wang, 32, and others including one individual charged as John Doe, conducted intrusions into Anthem and three other American businesses, according to the four-count indictment in federal court in Indianapolis, where Anthem is based. It did not identify the other companies by name.

The hackers used sophisticated techniques to hack into the businesses' computer systems and installed malware, then identified information of interest including personally identifiable information (PII) and business information.

“The allegations in the indictment unsealed today outline the activities of a brazen China-based computer hacking group that committed one of the worst data breaches in history,” said U.S. Assistant Attorney General Brian Benczkowski.

Wang and Doe were charged with conspiracy to commit fraud in relation to computers and identity theft, conspiracy to commit wire fraud, and intentional damage to a protected computer, the Justice Department said.

The “extremely sophisticated hacking group” ultimately stole data concerning nearly 80 million people from Anthem's computer networks, the Justice Department said in a statement.

The information accessed included names, birthdays, Social Security numbers, street addresses, email addresses and employment information, including income data, it said.

In July 2017, Anthem agreed to settle litigation over the breach for $115 million, which lawyers said would be the largest settlement ever for a data breach.

U.S. Imposes Sanctions on Argentina-based Online Pharmacies for Opioids

(Reuters) - The U.S. Treasury Department on Thursday placed sanctions on Goldpharma, an Argentina-based network of online pharmacies that it said contributed to the opioid crisis by selling clandestinely produced narcotics to customers in the United States. [FN11]

The Treasury's Office of Foreign Assets Control also designated eight Argentine nationals and nine entities located in Argentina, Colombia, Canada, Britain and the Netherlands for their roles in Goldpharma, the agency said in a statement.

“The Goldpharma network illustrates the sophisticated tactics drug traffickers and money launderers use to capitalize on the Internet and online pharmacy sites to sell highly addictive illicit narcotics around the world,” said Sigal Mandelker, Treasury undersecretary for terrorism and financial intelligence.

Goldpharma websites sell both legitimate and clandestinely produced narcotics, including oxycodone, hydrocodone and tramadol, without a prescription, the statement said. They sell the vast majority of their illicit opioids to customers in the United States, it said.

The move was the latest effort by the Trump Administration to tackle the U.S. epidemic of abuse and overdoses linked to prescription painkillers and other opioids like heroin.

Opioids were involved in a record 47,600 overdose deaths in 2017 in the United States, according to the U.S. Centers for Disease Control and Prevention.

Five of the Argentine designated individuals have been indicted in the U.S. District Court for the Eastern District of Wisconsin for their role in Goldpharma, the statement said. Three others were involved in Goldpharma's money laundering activities, it said.

Seven U.S. companies owned or controlled by designated members of Goldpharma have also been blocked, the statement said.

Goldpharma was identified as a drug trafficking and money laundering organization under the Foreign Narcotics Kingpin Designation Act, the statement said.

Any property of the designated persons in the United States would be blocked and U.S. persons would be prohibited from business dealings with them, it said.

Lopez Obrador Says Will Shop Abroad If Necessary to Fix Medicine Shortages

(Reuters) - Mexican President Andres Manuel Lopez Obrador vowed on Monday to alleviate a medicine shortage in public hospitals, pledging to shop abroad for essential drugs if necessary and blaming the situation on companies upset about his crackdown on overpricing. [FN12]

The government promised on Friday to release about $126 million (2.4 billion pesos) to help alleviate shortages at Mexican public hospitals. The head of the largest public health system resigned last week citing budget cuts, a complaint echoed by several hospital directors.

In its first budget in December, the government reduced funding for several ministries as it sought to centralize spending, fight public sector corruption and honor a campaign pledge to implement fiscal austerity.

Lopez Obrador argues that the problems in healthcare are the result of his clampdown on overpricing that he says was rife in the health system under the last government, with a small group of companies benefiting from government purchases and charging excessive prices.

Health Minister Jorge Alcocer said at Lopez Obrador's regular morning news conference that the problem was not a shortage of money to pay for pharmaceuticals, but that some companies, which he did not name, had not responded to government tenders for drugs.

Previous governments acquired medicines through ten suppliers that provided 80% of the country's total drugs at premium prices, Lopez Obrador said at the news conference.

Last month, he said three Mexican companies would be excluded from future public tenders for medicine. Critics say that decision hit patient care.

“I ask citizens to help us, because we are cleaning the house, the pigsty that they left. It can be an inconvenience that some medicines are really unavailable, but the problem will be resolved, and the health service will be improved.”

“We apologize for the inconvenience,” he said.

Lopez Obrador said if shortages continue, the government could seek medicines directly from overseas pharmaceutical companies, rather than from Mexican intermediaries.

Under the veteran leftist's administration, which took office in December, purchases have been centralized through the Finance Ministry, as part of a broader push to combat corruption, he said.

Alcocer backed up his points by saying that Mexico previously paid the most of any country in Latin America for antiretrovirals to treat almost 100,000 patients living with the HIV virus.

Canadian Panel Calls for Universal Public Drug Coverage

(Reuters) - A Canadian advisory council studying prescription drug coverage said on Wednesday the federal government should create a C$15.3 billion ($11.5 billion) universal, single-payer public pharmacare system, and warned that the current system requires a major overhaul. [FN13]

The council said the plan should be implemented no later than Jan. 1, 2027, with coverage for essential medicines in place by Jan. 1, 2022.

Canada is the only country with a universal health care system that does not include universal coverage for prescription drugs. Most prescriptions are paid for through employer-funded drug plans, while some are covered by government programs for the elderly, or people with low incomes or very high costs.

“We can't tinker with what exists. We have to transform it,” council chair Eric Hoskins, a former Ontario health minister, said at a news conference.

The report said public and private drug providers had told the council the system is “near the breaking point.”

Canadian Prime Minister Justin Trudeau's Liberal government has promised some kind of national pharmacare program, and its approach may be a key issue in the country's October election.

Minister of Health Ginette Petitpas Taylor said in a statement that the government would “carefully study” the recommendations “over the coming months.”

The council estimated the national pharmacare would cost the federal government an additional C$3.5 billion at its launch in 2022, and C$15.3 billion in 2027.

If implemented in full, the plan would likely cut into profits of insurers and drugmakers in Canada, while saving employers and patients money.

Shares of three major insurers listed in Canada, Manulife Financial Corp, Sun Life Financial Inc and Great-West Lifeco Inc, all dropped.

'SPACE' FOR THE PRIVATE SECTOR

Canada's drug insurance system is a patchwork of more than 1,000 public and 100,000 private plans, which can make it difficult for smaller payers to negotiate discounts with pharmaceutical companies.

The Canadian Life and Health Insurance Association (CLHIA)urged the government to work with private plans to negotiate lower drug prices. CLHIA president Stephen Frank said in a statement that all Canadians can have access to the medications they need “without putting at risk what's working today.”

Hoskins said costs associated with the proposed program are already being paid by Canadians. By 2027, total prescription drug spending would be about 10% lower with the proposed changes, Hoskins said. Canadians spent C$34 billion ($25.6 billion) on prescription medicines in 2018.

Hoskins said he envisions “space” for the private drug insurance sector after a universal public program is rolled out.

“The profit that insurance companies generate through drug insurance plans is modest, I would describe it, compared to other aspects of benefits provided,” he said.

Pamela Fralick, president of pharmaceutical industry group Innovative Medicines Canada, said whatever path the government chooses, “no Canadian should be worse off than they are right now.”

NEW DRUG PRICE RULES IN THE WORKS

Speaking after the report's release, Petitpas Taylor said work on the Canadian government's proposal to reduce patented drug prices is still underway, and “movement” would come in the very near future.

New regulations, set to go into effect in January 2019, were delayed amid heavy lobbying from drugmakers.

Patented drug prices in Canada are among the highest in the world. Government surveys show some 20% of Canadians are uninsured or under-insured.

In its most recent budget the Trudeau government promised modest changes, including new funds for expensive drugs that treat rare diseases.

Canada Warns U.S. Against Drug Import Plans, Citing Shortage Concerns

(Reuters) - Canada opposes any U.S. plans to buy Canadian prescription drugs that might threaten the country's drug supply or raise costs for its own citizens, officials have told U.S. authorities, in a new setback to the Trump administration's efforts to tackle high drug prices, according to documents obtained by Reuters. [FN14]

Canadian opposition is a problem for U.S. lawmakers, who have argued they can lower sky-high prescription drug prices by approving imports from Canada, where prices are lower.

At least ten U.S. states, including Florida, have passed or proposed laws to allow such imports, but actual shipments would not be legal without federal approval. The U.S. Health and Human Services secretary said last week the government was looking into ways to import cheaper prescription drugs from overseas.

“Canada does not support actions that could adversely affect the supply of prescription drugs in Canada and potentially raise costs of prescription drugs for Canadians,” reads an April briefing for Canadian officials obtained under freedom of information laws.

The talking points, prepared by Canada's foreign ministry for use by Canadian officials who speak with U.S. officials, cite research suggesting shipments to the United States could cause shortages in Canada.

Health Canada confirmed the government's position has not changed since the talking points were prepared. The ministry said officials have “made Canada's position clear” to both federal and state officials in the United States and it stood ready to “take action to ensure Canadians have uninterrupted access to the prescription drugs they need.”

U.S. drugmakers, keen to protect profits in the United States, their most important market where prices are generally much higher, have also argued against imports, saying they would put the safety of the U.S. drug supply at risk. Health Canada says the Canadian drug supply is safe.

The documents instruct Canadian officials to say that “importing drugs from Canada is probably not your silver bullet.” It suggests noting that “there are other solutions” and offering to share the ways Canada keeps healthcare costs low.

The issue may pose a fresh challenge to Canada's relationship with U.S. President Donald Trump, while disruptions in the drug market would be an unwelcome headache for Prime Minister Justin Trudeau's government, especially ahead of Canada's October election.

In 2005, an earlier Canadian government promised a bill that would restrict drug exports in response to similar U.S. proposals, but never followed through.

The Trump administration has promised to lower drug prices, but it has failed to push through several initiatives, including forcing drugmakers to disclose prices in TV ads and overhauling the system of drug discounts.

U.S. Democrats see Trump as increasingly vulnerable to criticism on healthcare costs. U.S. presidential contender Bernie Sanders has offered several bills and amendments that would allow drug imports, while Minnesota Senator Amy Klobuchar recently announced a drug price plan that would include letting patients order drugs from countries like Canada.

Sanders is set to join a group of U.S. patients traveling to Windsor, Ontario, to buy cheap insulin later this month.

The documents say the U.S. proposals have not been detailed enough to properly assess impact, but cite a study from 2010 which estimated that if 10% of U.S. prescriptions were filled from Canada, the drug supply would run out in 224 days.

They also note there are already barriers to shipping drugs from Canada to the United States. For example, many purchase agreements forbid the re-export of drugs.

Most of the entities that regulate Canadian pharmacists forbid filling prescriptions written by foreign doctors, but some Canadian pharmacies do ship across the border. The U.S. Food and Drug Administration does not generally block small-scale imports for personal use.

Innovative Medicines Canada, which represents drugmakers including the major U.S. manufacturers, said it is concerned about the import proposals, and raised the issue with Health Canada.

“Canada cannot supply medicines and vaccines to a market ten times larger than its own population without jeopardizing Canadian supplies and causing shortages,” the organization said in a statement.

Canada Enacts Drug Price Crackdown, in Blow to Pharmaceutical Industry

(Reuters) - The Canadian government announced final regulations on Friday that should cut billions of dollars from patented drug prices that are among the highest in the world, overcoming heavy opposition from pharmaceutical companies who may eventually challenge the new rules in court. [FN15]

The biggest reform to Canada's drug price regime since 1987 would save Canadians C$13.2 billion ($10 billion) over a decade. The rules will save money for patients, employers and insurers including the government at the expense of drug company profits. They also could eventually cut the earnings of drugmakers in the United States, the world's largest pharmaceutical market.

The Canadian Life and Health Insurance Association called the regulations “a crucial step to lower prescription drug costs for all Canadians.” The province of British Columbia also applauded the move, saying in a release: “People in B.C. and across Canada are now better protected against excessive drug prices set by manufacturers.”

The new rules were largely in line with a December 2017 draft. They came after months of delay prompted speculation the government would back down in the face of industry lobbying or simply run out of time before Canada's October election.

“We are taking the biggest step in a generation to lower the price of drugs in Canada by moving forward with these regulations,” Minister of Health Ginette Petitpas Taylor said in an interview.

Petitpas Taylor said the new rules would lay the foundation for a new national drug program. Prime Minister Justin Trudeau's government is expected to announce a program to cover the cost of prescription drugs for some or all Canadians, but the program's scope is not yet clear.

Canada will change the list of countries the federal drug price regulator, the Patented Medicine Prices Review Board (PMPRB), compares domestic prices to, dropping the United States and Switzerland where prices are highest. It will also let the agency consider cost-effectiveness of new medicines.

It will require drugmakers to disclose some confidential discounts to the PMPRB, which sets maximum prices.

Initially expected to take effect in January, the regulations were delayed so the government could review feedback. They will now go into force on July 1, 2020.

The new features of the regulations, which take into account cost-effectiveness of medicines and their impact on government budgets, apply only to drugs approved by Health Canada after the rules are officially published later this month. Changes in the list of comparison countries could affect prices for some drugs already on the market.

POTENTIAL FOR COURT CHALLENGE

Canada's approach to drug pricing is unusual. Rather than bargaining prices down, the PMPRB declares that some prices are an illegal abuse of patent rights.

Drugmakers base their list prices on the agency's published guidelines. When there is disagreement, PMPRB staff can challenge drugmakers at an internal tribunal. Most cases are settled, but appeals go to federal court and beyond.

In the past, drug companies have gone as far as the Supreme Court of Canada to challenge PMPRB guidelines. With new regulations come new guidelines, and the potential for fresh court challenges.

“We anticipate a considerable uptick in litigation, at least initially, as the industry patentees test the boundaries of the new regime,” said Douglas Clark, executive director of the PMPRB, on a call with reporters. “That's to be expected any time you substantially change rules.”

University of British Columbia professor Steve Morgan, who studies access to drugs and has advocated for a new national drug program, called the rules “a bold step forward”.

“Now the tricky part: implementation, with all the specifics concerning how rules will apply; and, no doubt, legal challenges from industry,” he wrote in a tweet.

REFORMS COULD AFFECT U.S. MARKET

Global drugmakers, including Johnson & Johnson (JNJ.N), Merck & Co (MRK.N) and Amgen Inc (AMGN.O), argued against the draft plan.

While the government's focus is on reducing domestic patented drug prices that are among the highest in the world, the new policy could eventually have consequences south of the border.

The Trump administration in July said it would allow U.S. states and other groups to start pilot programs related to importing drugs from Canada. It has also said it may start determining what the U.S. government healthcare program Medicare pays for certain medicines based on prices in some other countries, including Canada.

Reuters reported in February that pharmaceutical lobby groups had tried to head off the Canadian reforms with an offer to give up C $8.6 billion in revenue over 10 years, freeze prices or reduce the cost of treating rare diseases.

Drugmakers argue the reforms could limit Canadians' access to new medicines.

“The industry does take a lot of risk on in creating these products. It does cost money,” said Pamela Fralick, president of industry group Innovative Medicines Canada. “Our fear is that globally, decisions will be made that products will not be launched in Canada.”

The government said many countries with lower prices have more pharmaceutical industry investment and access to drugs that meets or exceeds Canada's.

Drug Industry Urges Canada to Act Early on U.S. Import Plan

(Reuters) - Canada's main pharmaceutical lobby group has urged the government not to wait for drug shortages before responding to U.S. plans to import Canadian drugs, according to documents seen by Reuters. [FN16]

The talking points were prepared last month by Innovative Medicines Canada (IMC) for its staff and member companies, before the Trump administration announced on Wednesday that it would allow U.S. states and other groups to start pilot programs importing cheap drugs from Canada in an effort to lower drug costs.

In one early version of its talking points, the IMC proposed the Canadian government ban all drug exports “unless otherwise permitted by regulation.”

“Wholesalers should not be permitted to export drugs in bulk from Canada, and there should be strict and significant penalties for exporting drugs where their export is prohibited by law,” a document prepared in May said.

It warned that “reliance on reactive measures after shortages occur may pose a risk to Canadian patients.”

Asked about the possibility of an export ban, IMC said in a statement: “This is not part of our current positioning shared with our members. That said, we believe the government has tools that could be used to prevent shortages.”

The lobby group's efforts so far suggest industry is eager to derail the Trump administration's plan. IMC's members include major drug companies based in the United States and abroad, and large-scale shipments of cheap drugs from Canada could lower their profits.

The group works closely with PhRMA, the Pharmaceutical Research and Manufacturers of America, the industry's U.S lobbying group.

“Our government's priority is ensuring that all Canadians can get and afford the medications they need,” Alexander Cohen, a spokesman for Canada's health minister, said in a statement.

“All statements and decisions surrounding Canada's drug supply are made based in the best interest of Canadians, and we are examining all options to ensure it remains secure.”

In the position papers reviewed by Reuters, the IMC warned it may not be possible for drug manufacturers to enforce contract terms with Canadian buyers that forbid the re-export of drugs.

“Although purchasing agreements with suppliers may contain clauses that would prevent bulk export to the US, many Canadian pharmaceutical companies are subsidiaries of US corporations and may become obliged to do so through US legislation,” the group warned in July.

Even if the U.S. plan proceeds as the administration has promised, shipments could be a year or more away, because of consultations required to pass new regulations.

The IMC documents suggest that a “first step” for the Canadian government would be to state publicly that it will act to protect drugs intended for Canadian patients in the event of any shortages.

Prime Minister Justin Trudeau delivered something like that message personally on Thursday, at an event in the Arctic city of Iqaluit.

“We recognize the new situation brought on by American announcements, and Health Canada will continue to ensure that our priority is always ensuring that Canadians have access to the medication they need at affordable prices,” he said.

Reuters reported last month that Canadian officials had privately warned the United States they oppose any import programs that might threaten Canada's supply or raise costs for Canadians.

Philips, Under Investigation in U.S. and Brazil, Fired Whistleblower Who Warned of Graft

(Reuters) - Healthcare giant Philips was warned of suspicious sales of its medical equipment to the Brazilian government, and failed to halt them, nearly a decade before an alleged bribery racket was exposed in the company's Brazil operations last year, Reuters has learned. [FN17]

Claims of malfeasance reached the highest levels of the Dutch conglomerate as early as 2010, according to court records filed by federal prosecutors, internal company documents and Reuters interviews with a former manager at a Philips subsidiary in Brazil who says he told superiors of the suspected scheme and was later sacked.

That ex-employee, Jose Israel Masiero Filho, a former supply-chain executive with Dixtal Biomedica Industria e Comercio Ltda., spoke extensively with Reuters in his first interview with foreign media. He said in January 2010 he spotted irregularities in three deals to sell Philips and Dixtal equipment to an obscure Brazilian middleman who had landed big contracts with Brazil's Ministry of Health. Masiero said he suspected payoffs had been used to secure that government business, allegations now at the heart of a burgeoning graft probe in Brazil, court records show.

Masiero emailed an internal Philips hotline immediately to report his suspicions, met soon after with the company's top compliance officer, and alerted at least three other senior executives during 2010. Among them was Steve Rusckowski, former chief executive of

Philips Healthcare, the company's largest division. Masiero's warnings were detailed in emails, internal company memos and court records viewed by Reuters.

“Philips should consider that by approving and accepting these sales, it will be involved in illegal activities if discovered,” Masiero wrote to Rusckowski in an email dated October 14, 2010.

Still, Koninklijke Philips, as the company is formally known, continued to sell to the Brazilian intermediary to fulfill the Health Ministry contracts, invoices show.

Rusckowski, who served as Philips Healthcare's chief executive until April 2012, did not respond to requests for comment. He is now CEO of New Jersey-based Quest Diagnostics.

In an emailed statement to Reuters, Philips said it is cooperating with Brazilian authorities investigating the nation's medical device industry. The company said it launched an internal investigation in 2010 in response to an “anonymous complaint” but “did not identify direct evidence of wrongdoing.” The company said it did, however, tighten up its internal control processes in Brazil.

Philips would not discuss ex-employee Masiero or the circumstances surrounding his dismissal.

Brazil's Health Ministry did not respond to requests for comment.

HEALTHCARE IN THE CROSSHAIRS

Philips is now among the targets in a widening investigation into medical contracting graft in Brazil that authorities say is still in its early stages, and which has sparked additional probes by U.S. law enforcement.

Masiero is cooperating with Brazilian prosecutors. They allege Philips and other multinationals conspired with intermediaries to pay bribes for public contracts, charging Brazil's state healthcare system inflated prices to recoup the cost of the kickbacks. Twenty-four people were charged last year in connection with the alleged scheme. All are currently on trial in Rio de Janeiro.

Germany's Siemens AG and the American firms Johnson & Johnson, General Electric Co. and Stryker Corp., all major manufacturers of medical devices, have been swept up in the probe.

Johnson & Johnson, Siemens and GE declined to comment. They previously denied wrongdoing and said they were cooperating with the investigation. Stryker said it was committed to working in an ethical manner and that it was unable to comment further.

In the United States, the FBI, Department of Justice and the Securities and Exchange Commission have launched their own investigations into suspected corruption in sales of medical equipment in Brazil as well as China, according to people with knowledge of the matter.

The whistleblower Masiero said he is cooperating with all those agencies, an assertion confirmed in emails viewed by Reuters. The Justice Department, SEC and FBI all declined to comment.

Philips told Reuters it is “reviewing” inquiries from the Justice Department and SEC in connection with the Brazil probe.

MYSTERIOUS MIDDLEMAN

Now 52, Masiero was hired in 2006 to be Dixtal's exports manager, rising to become the top logistics and supply chain executive for the Sao Paulo-based medical device firm in early 2009. Philips purchased Dixtal in 2008.

In early 2010, Masiero noticed what he considered irregularities with three large contracts awarded by Brazil's Health Ministry. The deals, one for 750 Philips heart defibrillators, the others for a total of 3,972 Dixtal vital-signs monitors, were worth a combined 68.9 million reis (about $40 million at the time), government records show.

Masiero said he found it odd that Philips did not compete directly for such a major piece of business. Neither Philips or Dixtal submitted bids, according to government records of tender competitors viewed by Reuters.

Instead the contracts were won by Rizzi Comercio e Representacoes Ltda., a little-known Brazilian medical supply firm. Masiero, tasked with getting the equipment to Rizzi Comercio, was surprised to find its billing address was a tiny storefront with peeling purple paint in a dilapidated Sao Paulo neighborhood.

“It was an immediate red flag for me,” Masiero told Reuters.

In addition, the Health Ministry was paying well above market prices for the equipment, Masiero said, unusual for a large customer with buying clout. On February 12, 2010, for example, Masiero allegedly received an email from a Philips' sales executive, Frederik Knudsen, directing him to deliver the first shipment of 60 defibrillators to Rizzi Comercio, which marked up those devices an additional 67%, according to correspondence included in court records.

“The value that should be on the order is what was agreed to with the Health Ministry” – $16,700 per unit – “and not what we sold them to Rizzi for ($9,991),” according to the email allegedly from Knudsen, which was seen by Reuters.

Prosecutors say Philips and Rizzi Comercio conspired to disguise and recoup the cost of bribes through inflated prices, fleecing Brazilian taxpayers in the process.

Knudsen, whom Philips confirmed still works for them, is now among those on trial in Rio. So is Daurio Speranzini, who led Philips Healthcare's operations in Latin America for seven years before joining GE in 2011. He left that firm last December. Both men were charged last August with racketeering and fraud.

Knudsen's lawyers did not respond to requests for comment. In a written defense filed with the court, they said Knudsen did not set Philips' prices and that he is innocent. In a separate court filing, they also questioned the veracity of the emails their client allegedly sent to Masiero.

Speranzini's lawyers referred questions to their written defense, which contends he had no knowledge of the alleged bribery scheme or of Masiero's warnings.

Also on trial for racketeering and fraud are two brothers who own Rizzi Comercio, Wlademir and Adalberto Rizzi.

Their lawyer, who did not respond to requests for comment, said in court filings that her clients engaged in no illegal activities.

SOUNDING THE ALARM

Uneasy about the deals with Rizzi Comercio, Masiero on January 20, 2010, notified Philips' global compliance team in Amsterdam through an email hotline.

Philips sent Caroline Visser, then-chief of Philips' global compliance, to Brazil to meet with Masiero in March 2010. She promised a swift investigation, according to emails the pair exchanged.

Two months later, Masiero was transferred from Dixtal to a logistics post within Philips in Sao Paulo, a move he considered a demotion and an effort to silence him. The shipments continued, invoices show.

Frustrated, Masiero on October 14, 2010, sent an email to Rusckowski, the head of Philips' healthcare division.

Masiero expressed concern about Rizzi Comercio and its use of an unfamiliar intermediary, Moses Trading American, to purchase the U.S.-made Philips heart defibrillators on its behalf for export to Brazil. Far more typical, Masiero told Reuters, would be for Philips to sell directly to Rizzi.

Masiero's uneasiness only increased when he traced Moses Trading American's address on Philips' invoices to a private home on a golf course in suburban Phoenix.

“Moses Trading selling operation is clearly suspicious,” Masiero wrote to Rusckowski.

According to emails reviewed by Reuters, Rusckowski forwarded Masiero's message to Clement Revetti, Jr., the chief legal officer for Philips Healthcare. Revetti thanked Masiero and asked him not to contact the CEO again.

Masiero defied that order. On November 9, 2010, he again emailed Rusckowski and Revetti of his concerns.

On March 4, 2011, Masiero says he discussed his suspicions once more in person in Sao Paulo with Visser, the compliance head. He was fired later that day. Masiero said he was given no reason for his dismissal. Paperwork required under Brazilian labor laws shows Philips sacked Masiero “without cause,” meaning the company made no claims that it was performance-related.

Visser and Revetti did not respond to requests for comment.

As for Moses Trading American, Brazilian prosecutors say that operation is run by a Peruvian named Oscar Moses whom they are investigating in connection with a string of allegedly fraudulent medical equipment deals in Brazil. He has not been charged with a crime.

Moses did not respond to requests to comment sent to his Linkedin and Facebook profiles.

TALKING TO PROSECUTORS

Discouraged after his firing, Masiero dropped the matter.

Then in 2014, Brazil was engulfed by a corruption scandal centered on contracting graft at state oil company Petrobras <PETR4.SA>. That blockbuster probe, known as Car Wash, ultimately toppled leaders at the highest levels of Brazilian business and politics.

Masiero got in touch with federal prosecutors.

“His information was key to helping us break up this scheme,” said Marisa Ferrari, a lead prosecutor on the case.

Masiero, meanwhile, is unemployed. He said he has been blacklisted in Brazil.

He and his family recently left Brazil for a country Masiero does not want to name.

Companies File Suit in Canada Challenging New Rules to Lower Drug Prices

(Reuters) - Five pharmaceutical companies said on Friday they have filed a complaint in a Canadian court challenging the constitutionality of new Canadian regulations meant to lower patented drug prices, setting up a fight with the federal government ahead of an Oct. 21 election. [FN18]

The complaint was filed in Quebec's Superior Court by the Canadian arms of U.S.-based Merck & Co and Johnson & Johnson's Janssen Inc, Germany's Bayer AG and Boehringer Ingelheim, and France's Servier Inc.

The filing ratchets up a confrontation between the pharmaceutical industry and the Liberal government of Prime Minister Justin Trudeau, which has vowed to make affordability a key plank of its election campaign.

Prescription drug insurance coverage in Canada is provided through a patchwork of public and private plans, with the federal, provincial and territorial governments offering varying levels of coverage and determining what the plans and patients pay.

The new rules will save patients, employers, insurers and government drug plans money, at the expense of drug company profits in Canada. They could eventually have consequences in the United States, the world's largest pharmaceutical market.

The regulations give new powers to the Patented Medicine Prices Review Board (PMPRB), which sets maximum drug prices. The new rules were published in an official register on Wednesday after being announced earlier this month and are to go into force on July 1, 2020.

All five firms said in separate news releases on Friday that in Canada, the 10 provinces have always had the authority to regulate the prices of medicines, not the federal government.

The new rules “will slow and limit Canadians' access to new breakthrough medicines,” Merck Canada said in a release.

Janssen echoed Merck Canada's concerns, adding that the provinces had already adopted policies to control costs of patented medicines.

Health Canada, Canada's federal health department, said it could not comment given that the matter was now before the courts.

The new regulations expand the information the PMPRB can consider when setting drug price caps, among other things, giving it the ability to consider cost-effectiveness, measured in quality-adjusted life years, for the first time.

The Trump administration, which has repeatedly said that it wants to address the high cost of prescription drugs in the United States, said in July it would let U.S. states and others start pilot programs importing drugs from Canada. It has also said it may base what Medicare, the government healthcare program for the elderly, pays for certain medicines based on prices in other countries, including Canada.

Drugmakers, represented in Canada by lobby group Innovative Medicines Canada, have argued that lower prices would delay drug launches, reduce investment in life sciences and drive new drug trials out of the country.

Ottawa says other countries with lower drug prices have investment and drug access that are as good as or better than Canada's.

Drugmakers File Second Court Challenge to Canada's New Drug Price Rules

(Reuters) - Canada's main pharmaceutical industry lobby group, along with 16 of its member companies, filed a lawsuit on Friday to block new regulations meant to lower patented drug prices, the second legal challenge to a new regime that could eventually reduce prices in the United States as well. [FN19]

Canada published the final regulations in August, despite heavy lobbying from drug companies, which stand to lose revenue as prices drop. The federal government estimates the new rules will save Canadian patients, employers and insurers, including governments, C $13.2 billion ($10 billion) over a decade.

Friday's lawsuit was filed in federal court and led by Innovative Medicines Canada (IMC), which represents major drugmakers in Canada. It is separate from a lawsuit filed last month and focuses on federal patent law, arguing that Canada cannot use regulations to “fundamentally alter” the role of its federal drug price regulator.

IMC was not a plaintiff in a Quebec Superior Court challenge filed in August, which argued that price regulation falls within provincial jurisdiction.

“We would not enter into this lightly. The industry lives and breathes saving lives, but it does require a viable business model to do so,” IMC President Pamela Fralick said in an interview. “Canada is not creating a sustainable environment for innovative medicines.”

Fralick said industry had been trying to work with Health Canada to find policy alternatives to the proposal for nearly two years.

IMC has argued that new drugs may launch late or not at all in Canada if prices fall, and that the policy will discourage investment in Canada. The government says other countries with lower drug prices have investment and drug access that are as good as or better than Canada's.

Lower prices in Canada could spill into the United States, the world's largest pharmaceutical market, since the Trump administration said in July it would allow U.S. states and other groups to start pilot programs importing drugs from Canada. The administration is also considering linking what it pays for drugs under Medicare, which provides federal health insurance for Americans 65 or older, to prices abroad, including in Canada.

The new regulations, which go into force July 1, 2020, change the list of countries with which Canada's federal drug price regulator, the Patented Medicine Prices Review Board, compares domestic prices, dropping the United States and Switzerland, where prices are highest. It will also let the agency consider the cost-effectiveness of new medicines for the first time.

Plaintiffs in the new case include Canadian subsidiaries of AbbVie Inc, Astellas Pharma Inc, AstraZeneca PLC, Bristol-Myers Squibb Co, Eli Lilly and Co, Novartis Pharmaceuticals, and Pfizer Inc.

Canadian Election Clears Path for Universal Drug Plan

(Reuters) - Canada's Liberal government is more likely to pass a universal prescription drug plan after losing its majority in Monday's election, setting the stage for what would be the biggest shakeup of the country's public healthcare system since it was created in the 1960s. [FN20]

The Liberals won the most seats in the election but fell short of a majority, which means Prime Minister Justin Trudeau will need the support of rivals like the left-leaning New Democratic Party (NDP) to govern. Both the Liberals and NDP have promised a new national drug plan.

Canada is the only developed country with a universal health care system that does not cover prescription drugs for all, though a patchwork of provincial programs support the elderly and people with low income or very high drug costs. Most Canadians rely on employer-funded drug plans.

Steve Morgan, a University of British Columbia health economist and leading advocate for a universal drug plan, or pharmacare, said the election results created a “window of opportunity” to change the system.

Universal drug coverage has been proposed before, but the rise of high-cost drugs has given the idea new urgency, as some patients struggle to pay for medication, and employer-funded plans shift high-cost patients to provincial plans, straining budgets without creating the negotiating power that a single federal buyer could wield against drugmakers.

“I think this is our best chance, the best opportunity we've ever had to bring pharmacare into the healthcare system,” said Eric Hoskins, who led a federal advisory council on the issue. “I feel even more strongly about that today. I am confident that the Liberals will follow through on their commitment.”

Speaking to supporters after the election, NDP leader Jagmeet Singh outlined his party's goals in the next parliament.

“If you need medication in our country, we want to make sure you use your health card, not your credit card,” he said. “That means a national, publicly-delivered single-payer pharmacare program.”

Universal drug coverage would shake up the country's C$39.8 billion ($30.4 billion) prescription drug market, and cut drugmakers' revenue by some C$4.8 billion a year by 2027. It may draw opposition from drugmakers, and from private insurers, who could also lose revenue, as well as deficit hawks.

“We believe that any national pharmacare program must ensure Canadians maintain access to at least the same range of cutting-edge medicines they rely on today to survive and maintain their quality of life,” pharmaceutical industry group Innovative Medicines Canada said in a statement.

The Canadian Life and Health Insurance Association said it looks forward to working with the government.

“We continue to believe strongly that any reform should use government resources wisely and build on what works well today,” Canadian Life and Health Insurance Association President Stephen Frank said in a statement.

A DEAL WITH PROVINCES?

The Liberals promised a new national plan ahead of the election, but only committed a total of C$6 billion for all health initiatives. The NDP and the Green Party of Canada were more aggressive.

Earlier this year, the advisory council led by Hoskins, a former provincial Liberal minister, recommended a universal, single-payer public pharmacare system, to be implemented no later than 2027 and costing C$15.3 billion a year in new government spending.

But it said cost-saving measures, including new negotiating power with pharmaceutical companies, would reduce overall spending by an estimated C$4.8 billion by 2027, saving provincial governments, employers and individuals money at drugmakers' expense.

The Liberals' platform stopped short of pledging a single-payer system, which left some advocates unsure whether Trudeau was fully endorsing the Hoskins' recommendation.

The NDP pledged to implement pharmacare for all as soon as possible.

To follow the Hoskins model, the federal government would need to strike a deal with provincial governments, to fund prescription drug plans as long as the provinces run plans that meet certain minimum standards.

The negotiations may be difficult, as key provinces are led by rival parties. But the promise of billions in new federal funding could make a deal possible. It is possible that some provinces would opt out, weakening the program, as lower participation means less bargaining power in buying drugs.

Morgan, of the University of British Columbia, expects pharmaceutical lobbyists to mobilize against the plan.

“I think we are going to see a lobbying effort by the pharmaceutical industry in Canada the likes of which we've never seen,” he added.

Canadian Ambassador Says Drug Imports Would Not Lower U.S. Prices

(Reuters) - Canada does not have a large enough supply of prescription drugs to meet U.S. demand, and importing medicines from Canada would not significantly lower U.S. prices, Ottawa's acting ambassador told U.S. officials in recent meetings, according to a statement published on Friday. [FN21]

Kirsten Hillman, Canada's acting ambassador to the United States, said her country is “sympathetic to U.S. concerns regarding affordable prescription drugs.”

“Not only are we too small of a market, Canada cannot increase its domestic pharmaceutical drug supply to meet U.S. demand,” the statement said. “Canada remains dedicated to working with the U.S. to improve our citizens' health and well-being, recognizing that Canada's priority is to ensure a steady and solid supply of medications at affordable prices for Canadians.”

The statement summarized a meeting between Hillman and Trump advisor Joe Grogan on Friday, as well as discussions with other officials on Oct. 22.

It cited a 2019 study that projected that if 40% of U.S. prescriptions were filled from Canada, the Canadian drug supply would run out in 118 days. It noted that the U.S. state of Florida spends more on prescription drugs than all of Canada.

Last week, U.S. President Donald Trump called on the head of the Department of Health and Human Services, Alex Azar, to speed up the administration's efforts to allow cheaper medicines to be imported from Canada.

Trump and Democratic rivals looking to run against him in the November 2020 election have made lowering the cost of prescriptions medicines for U.S. consumers a high priority.

The United States, which does not negotiate drug prices with manufacturers, has much higher prices for prescription medicines than most other developed nations.

In July, the Trump administration announced that it would allow U.S. states and other groups to start pilot programs importing cheaper drugs from Canada in an effort to lower drug costs.

Reuters previously reported that Canada had privately told U.S. federal and state officials that the country would not support any plan to buy Canadian prescription drugs that might threaten its own drug supply or raise costs for Canadian citizens.

III. ASIA

Chinese Police Begin New Probe into Expired Vaccines

(Reuters) - Police in China's eastern province of Jiangsu have begun an investigation after at least 145 children received expired polio vaccines, the Global Times said on Monday, a new blow to a sector hit by a series of scandals last year. [FN22]

Residents, including the children's parents, blocked traffic and disrupted public order as they gathered outside Jinhu county offices on Friday, said the paper, which is published by the ruling Communist Party's People's Daily.

Three have been arrested, police said in a statement.

The vaccine was administered on Jan. 7, despite an expiry date of Dec. 11, the paper said, adding that local government authorities have set up a special investigation team to look into the matter. It said 17 people had already been punished.

China, which has repeatedly pledged to crack down on companies and officials involved in food and drug scandals, on Sunday said food safety and health would be a major priority of its anti-graft campaigns this year.

China vaccine maker Changsheng Bio-technology Co Ltd was embroiled in a scandal last year after it was found to have falsified data for a rabies vaccine. It faces penalties of 9.1 billion yuan ($1.35 billion).

China to Crack Down on Health Care Violations: State Media

(Reuters) - China will step up its fight against “irregularities” in the sale of healthcare products after a series of scandals in the industry in recent months, state media reported on Thursday, citing senior officials. [FN23]

Zhang Mao, minister at the State Administration for Market Regulation, told China Central Television in an interview that the country's health sector was “rampant with irregularities” and plans were underway to put it under greater scrutiny.

China launched a 100-day campaign at the start of the month to crack down on illegal advertising and other violations in the industry following a number of high-profile cases.

“Recently, serious problems involving the health products market have been exposed, such as fake promotions, illegal advertising and deceiving consumers,” the China Daily newspaper quoted Zhang as saying at the launch the campaign.

Earlier this month, police arrested the founder of Quanjian Nature Medicine Technology, a traditional Chinese medicine firm, amid allegations of fraudulent practice following the death of a seven-year-old girl who had used the company's products as part of her cancer treatment.

Market regulators are also investigating local branches of Infinitus, a multi-billion-yuan Chinese company, after it was accused of selling products that damaged a child's heart.

Many of the recent investigations have focused on “multi-level marketing” schemes in which members buy products from the company and then sell them on. Though this “direct selling” is allowed in China, “pyramid selling” - which uses income generated from new members to pay off older members - has been banned.

Police in northern China's Hebei province said last week they had launched an investigation into Hualin Acid-Base Technology, a local health product company accused of operating a pyramid selling scheme and misleading customers.

Last week, the Guangdong provincial government in southeastern China also summoned 32 locally registered “direct sales” firms - including Infinitus and the U.S.-based Amway - to issue a warning against malpractice.

The firms agreed to sign a pledge not to deceive consumers about the therapeutic benefits of their products, according to the official Xinhua news agency.

U.S. Citizen Leaks Data on 14,200 People in Singapore with HIV

(Reuters) - An HIV-positive American who had been deported from Singapore after serving a jail term has leaked online the personal data of 14,200 Singaporeans and foreigners diagnosed in the city-state with the virus. [FN24]

The disclosure by Singapore's health ministry late Monday, coming after last year's news of a major cyberattack on its national health database, could further dent the highly wired state's push to place itself as a data and health care hub.

U.S. citizen Mikhy Farrera Brochez lived in Singapore from 2008 and was convicted in 2017 on numerous drug-related and fraud offences, including lying to the Ministry of Manpower about his own HIV status.

Last week, Brochez disclosed online the personal information including the names, ID numbers, phone numbers and addresses of 5,400 Singaporeans diagnosed with HIV up to January 2013 and 8,800 foreigners diagnosed up to December 2011.

In response to the AIDS epidemics in the 1980s, many countries introduced restrictions on entry against HIV-infected travelers and foreign workers. Singapore remains among a small number of developed countries that maintain some restrictions on long-term visit passes and work visas.

The Health Ministry had become aware in May 2016 that Brochez was in possession of confidential information that appeared to be from the country's HIV Registry.

Last week, it learned that he could still be in possession of the data, the ministry said.

Brochez was HIV-positive and used his Singaporean doctor partner's blood sample to pass blood tests so he could work in Singapore, the ministry said in a statement. His partner previously had access to the HIV registry for his work, it said.

The ministry did not say how Brochez obtained the data or suggest a motive for leaking it online but said only that the partner was believed to have “mishandled” the information.

“I am sorry that one of our former staff who was authorized to have access to confidential information in our HIV registry appears to not have complied with our security guidelines,” Health Minister Gan Kim Yong said.

“This may have led to an unauthorized person gaining possession of the data and disclosing it online,” he said.

Brochez was deported after serving his jail term and was now overseas, according to the ministry statement, which did not say where.

Singapore-based advocacy group Action for AIDS said the case has the “potential of damaging the lives of persons living with HIV and their loved ones.”

“This is a criminal act that should be condemned and answered in the most severe terms possible,” it said.

Brochez is currently under police investigation, and the authorities are seeking assistance from their foreign counterparts, according to the ministry statement, which did not specify any country.

Reuters could not reach Brochez for comment.

The ministry said it had worked with the “relevant parties” to disable access to the information. It did not say where it was leaked online.

Last year, Singapore revealed that personal information of about 1.5 million people including the prime minister was stolen after hackers infiltrated the government health database. The HIV information leak was not related to the cyber breach.

Philippines to Charge Officials of Sanofi, Government Over Dengue Vaccine

(Reuters) - The Philippine Department of Justice on Friday said it had found probable cause to indict officials from French drugmaker Sanofi and former and current Philippine health officials over 10 deaths it said were linked to use of a dengue vaccine. [FN25]

It recommended charges be filed in court for multiple counts of reckless imprudence resulting in homicide, due to what it said were procedural lapses and irregularities in implementing a Philippine dengue immunization program using Sanofi's Dengvaxia.

The prosecutors said six Sanofi officials, mostly country representatives of the firm, and 14 current and former Philippine health officials should be charged, including former Health Minister Janette Garin.

Sanofi has repeatedly said Dengvaxia is safe and effective and, on Friday, rejected the justice department's recommendations.

“We strongly disagree with the findings made against Sanofi and some of its employees and we will vigorously defend them,” a spokesman said in an emailed statement, adding it was not appropriate to comment further as proceedings were ongoing.

Dengue is a mosquito-borne tropical disease that kills about 20,000 people a year and infects hundreds of millions.

Approved in late 2015 as the world's first vaccine to treat the condition, Dengvaxia has rapidly become Sanofi's most problematic program to date.

The company acknowledged two years ago its use could, in some cases, increase the risk of severe dengue in people who had not been previously exposed to the disease, limiting access to vaccine after deaths of children were reported in the Philippines.

“INEXCUSABLE”

The World Health Organization (WHO) advises the vaccine should only be used after testing individuals to assess whether they have ever been exposed to the disease.

Despite concerns around its use, the European Medicines Agency has approved Dengvaxia and the U.S. Food and Drug Administration has granted priority review with a decision expected in May.

However, the Philippines has permanently halted the sale, distribution and marketing of Dengvaxia, which was initially seen as a potential $1-billion-a-year-plus product.

Net sales of the vaccine stood at 3 million euros ($3.42 million) in 2017. Sanofi did not provide a figure for 2018.

The Philippines justice department statement did not say Dengvaxia had caused the deaths, but it quoted excerpts from a resolution by prosecutors that said the 20 individuals had exhibited an “inexcusable lack of precaution and foresight”.

It said the government registered and bought Dengvaxia for its immunization program with undue haste.

The Philippines started rolling out the vaccination program in 2016 in a bid to dramatically reduce as many as 200,000 domestic dengue cases a year. It spent 3.5 billion pesos ($67.7 million) on the program during which it immunized 800,000 children with Dengvaxia.

But that drive came under heavy scrutiny the following year, with critics and some lawmakers voicing concerns about the speed at which the government sought to register, procure and distribute Dengvaxia among schools and clinics.

SAFETY CONCERNS

A criminal investigation and two congressional inquiries have already taken place and the Philippines last month revoked the product's license after concluding Sanofi had failed to meet directives issued by regulators.

Justice undersecretary Markk Perete told Reuters that there were 35 deaths under investigation, 10 of which were the basis for the charges announced on Friday.

Perete said the 20 individuals faced up to six years in prison for each of the alleged offences. All but two officials could be charged with eight counts of reckless imprudence resulting in homicide, he said.

A Sanofi source with knowledge of the situation said the Philippine prosecutors' criticism was vague and they were mostly interested in the processes by which the product was approved.

Separately to the case announced on Friday, the Philippines has tasked a panel of medical experts to investigate the deaths of scores of children who received the vaccine, to establish whether or not Dengvaxia was a contributing factor.

The panel's head, Juliet Aguilar, told Reuters that medical records of 119 victims were being looked into as of Friday.

The 20 officials named by the justice department on Friday had shown neglect in having “totally disregarded the identified risks and adverse effects of the vaccine”, the resolution said.

The department said those risks “materialized with the death of the victims”.

It also said Sanofi had failed to closely monitor the recipients of Dengvaxia, nor did it extend medical assistance to victims or their families, even after reports of “serious adverse reactions” surfaced.

China's Ant Financial Amasses 50 million Users, Mostly Low-Income, in New Health Plan

(Reuters) - A mutual health aid plan launched by Ant Financial Services Group, the dominant fintech player in China, has amassed more than 50 million users and is aiming for 300 million within two years, the company said late on Thursday. [FN26]

The plan, dubbed Xiang Hu Bao or literally “mutual protection”, is marketed on Ant Financial's flagship mobile payment app Alipay and provides participants a basic medical coverage with the risks and expenses distributed across all members.

It has gained unexpected popularity among China's “low-end population”, poorer sections of society, who struggle to afford medical services due to the government's inadequate social healthcare system and are under-served by traditional commercial insurers as they cannot meet the premiums and advance payments required with commercial health insurance products.

About 47 percent of Xiang Hu Bao plan's 50 million participants are migrant workers and 31 percent are from rural areas and county-level regions, Ant Financial said.

Chinese billionaire Jack Ma's Ant Financial was spun off from e-commerce giant Alibaba Group Co Ltd, which went public in 2014, and has played a vital role in shaping the financial technology landscape in China, shaking up the state-controlled traditional banking, asset management and insurance sectors with disruptive new products.

The expansion of Xiang Hu Bao was even faster than Ant Financial's blockbuster online spare cash management platform Yu'e Bao, which took more than six months to reach the 50 million user milestone after launching in 2013 and has grown to become the world's largest money market fund with 1.13 trillion yuan ($168.2 billion) in net asset as of end-2018. China has a population of nearly 1.4 billion.

The Xiang Hu Bao health plan protects participants against 100 critical illnesses with a one-time payout of up to 300,000 yuan ($44,650). The cost is shared equally by all other participants, capped at 188 yuan per month for individual users in 2019, according to its description.

Despite its mutual insurance features, Ant Financial said the plan is “not a health insurance product”, indicating the product is not regulated by the country's insurance regulator.

Ant Financial has obtained a range of licenses to operate financial services, including payments, online banking, insurance, micro lending, and fund management in China's vast financial market. Its rapid expansion has propelled regulators to place it under increased scrutiny to prevent potential systematic financial risks.

China Draws Up Tighter Rules on Human Gene and Embryo Trials: Xinhua

(Reuters) - China's top legislature will consider tougher rules on research involving human genes and embryos, the first such move since a Chinese scientist sparked controversy last year by announcing he had made the world's first “gene-edited” babies. [FN27]

He Jiankui, associate professor at Southern University of Science and Technology in Shenzhen, attracted condemnation from the global scientific community when he said he had used a technology known as CRISPR-Cas9 to alter the embryonic genes of twin girls born in November.

Chinese authorities launched an investigation into He's work and said they had halted the kind of research he was undertaking.

Under the draft laws sent to China's legislature for review on Saturday, medical and human trials would face closer scrutiny and stricter requirements, such as ensuring human subjects are properly briefed, state media outlet Xinhua reported.

The rules would also require all future trials to be approved by administrative authorities as well as ethical committees, it said.

The report did not specify a timeline for the approval of the regulations, or make specific mention of He's research.

In videos posted online and at the November 2018 conference where He made his controversial presentation, He said he believed his gene editing would help protect the girls from infection with HIV, the virus that causes AIDS.

Chinese authorities and institutions, as well as hundreds of international scientists, condemned him and said any application of gene editing on human embryos for reproductive purposes was against the law and medical ethics of China.

Tencent-backed China Online Healthcare Venture Raises $250 million

(Reuters) - China's Tencent Trusted Doctor, a venture backed by tech giant Tencent Holdings, said it has raised $250 million in a fundraising round, as investors pile into China's online private healthcare sector. [FN28]

The fundraising marked the first investment since the entity was formed through a merger of Tencent Doctorwork and Trusted Doctors last year.

Tencent Trusted Doctor is among a number of technology-driven firms looking to shake up China's overburdened public healthcare market, with increasingly affluent consumers willing to pay for more convenient access to doctors and health services.

The investment was led by Country Garden Holdings, Tencent Holdings and Sequoia Capital, Tencent Trusted Doctor said in a statement.

It would value Tencent Trusted Doctor at more than $1 billion, according to one person with knowledge of the matter. Tencent Trusted Doctor did not immediately respond to a request for comment.

McKinsey & Co estimates Chinese healthcare spending will hit $1 trillion by 2020.

Tencent Trusted Doctor said it connects 440,000 certified doctors with more than 10 million patients online, offering services from online consulting to e-commerce to physical checks.

The company said in a statement it also aimed to have more than 500 medical institutions offline in China by 2021.

CEC Capital advised Tencent Trusted Doctor in the fundraising.

China Restricts Opioid in Tighter Painkiller Controls

(Reuters) - China has imposed new restrictions on the opioid oxycodone, its drug regulator said, as the country tightens control of its painkillers industry in the battle against drug addiction. [FN29]

Oxycodone, among the heavy-duty painkillers blamed for the deadly opioid crisis in the United States, will be classified as a psychotropic drug in some formulations and require more approvals to produce or prescribe them, the National Medical Products Administration said late on Tuesday.

Oral solid formulations with more than 5 mg of oxycodone per unit will be categorized as first-class psychotropic drugs from Sept. 1, the agency said.

Formulations with less than 5 mg of oxycodone per unit, as well as composite oral solid formulations with buprenorphine and naloxone, will be categorized as second-class psychotropic drugs at the same time, it said.

Under current laws, first class psychotropic drugs are banned from sale to retail customers, and second class products cannot be sold to minors.

The laws also require state approvals for pharmaceutical firms to use first-class psychotropic drugs as active ingredients in their products, and hospitals can only purchase these products from suppliers designated by authorities.

Chinese media have voiced concern over oxycodone addiction in the country. Financial magazine Caixin reporting in March that opioid users accounted for 38.1% of the 2.5 million people who were known to have abused drugs in China in 2016.

Liu Xiaodong, a professor at China Pharmaceutical University, said the tighter controls would help to reduce the illegal use of oxycodone.

“Many medicines are useful, but abusing them would turn them into (illicit) drugs,” Liu told Reuters.

Narcotics produced in China have become a contentious issue in relations with the United States.

This month, President Donald Trump accused his Chinese counterpart Xi Jinping of failing to meet promises to stop the flow of the synthetic opioid fentanyl into the United States.

China Adds 148 Drugs to Key Insurance List: State Media

(Reuters) - China on Tuesday added 148 drugs to its list of medicines covered by basic medical insurance schemes, part of a push to lower patients' out-of-pocket costs in one of the world's largest drug markets, state media reported. [FN30]

AstraZeneca's Kombiglyze and Merck & Co's Janumet diabetes treatments are among the drugs that will now be covered by national insurance, according to the updated list published by China's National Healthcare Security Administration.

Its last major overhaul in 2017 was seen at the time as a much welcomed fillip for drugmakers as many patients had opted not to try new drugs because of high costs. Prior to that, it had not been updated for 8 years.

As it published the updated list of 2,643 drugs on its website on Tuesday, the healthcare administration said the adjustment was crucial to improving the efficient use of the country's medical insurance funds.

State news agency Xinhua said 47 western drugs and 101 traditional Chinese drugs were added to the updated list, covering medicines for cancers, rare diseases, chronic diseases and children's diseases, as well as some basic drugs.

The administration also removed 150 drugs which were considered to be of low clinical value or which could be substituted by products with better therapeutic effects from the list, it said in statements issued alongside the list.

An additional list that includes costly drugs of high clinical value will be finalized later after further negotiation with pharmaceutical manufacturers, the administration said.

Local governments will subsidize between 50% and 100% of the costs of medicines on the list, which is expected to boost patients' willingness to use high-quality foreign brand-name drugs that would otherwise be unaffordable.

China has become a bright spot for global pharmaceutical companies as Beijing increases its healthcare spending and fast-tracks the approval process for new drugs.

Chinese sales for British drugmaker AstraZeneca soared 44% in the second quarter this year, accounting for over half of its sales in the developing world.

Chinese State Media Says Fentanyl Abuse Is Entirely U.S. Responsibility

(Reuters) - Chinese state media on Friday hit back at claims by U.S. officials that China was failing to crack down on the flow of fentanyl and fentanyl-related substances into the United States, saying that responsibility for opioid abuse lay with users. [FN31]

The United States was “pushing responsibility” for fentanyl abuse to China and ignoring that Beijing had implemented strict controls on the highly addictive synthetic opioid, reported The People's Daily newspaper, published by the ruling Communist Party.

U.S. officials say China is the main source of illicit fentanyl and fentanyl-related substances that are trafficked into the United States, much of it through international mail. Beijing denies that most of the illicit fentanyl entering the United States originates in China.

“Some people in the United States need to understand, the source of the illness lies within one's body,” the newspaper said in an article which bore the pen name “Zhong Sheng”, usually used to express its views on foreign policy.

“You can't be rushed to see the doctor, and you can't just scold others once you're ill,” it said, adding that the United States had not done enough to fight the epidemic of opioid abuse.

The U.S. Treasury on Wednesday imposed sanctions on three Chinese men accused of illegally trafficking fentanyl. U.S. President Donald Trump accused Beijing of reneging on pledges to stem a flood of the drug into the United States.

In Joint Case with U.S., China Jails Nine Fentanyl Smugglers

(Reuters) - A Chinese court on Thursday imprisoned nine people, one of whom received a suspended death sentence, on charges of smuggling fentanyl into the United States, in the first such case the two countries have worked on together. [FN32]

China has faced U.S. criticism for not doing enough to prevent the flow of fentanyl into the United States, and the issue has become another irritant in bilateral ties, already strained by a bruising trade war the two are now working to end.

The joint announcement of the successful action against smugglers, in front of a group of Chinese and foreign reporters invited by the Chinese government, comes as the two countries are expected to be close to signing an interim trade deal.

Fentanyl is a highly addictive synthetic opioid, 50 times more potent than heroin.

It is often used to make counterfeit narcotics because of its relatively cheap price, and it has played an increasingly central role in an opioid crisis in the United States.

Yu Haibin, a senior official with China's National Narcotics Control Commission, told reporters in the northern city of Xingtai, where the court case was heard, that Chinese and U.S. law enforcement had worked together to break up the ring. Members were accused of smuggling fentanyl and other opioids to the United States via courier.

The case originated in 2017 from the Department of Homeland Security's New Orleans office, which acted on a tip from an informant who provided contact information for a Chinese seller using the pseudonym “Diana,” Austin Moore, a regional attache with the department, told reporters.

One of the people sentenced by the court was given a suspended death sentence - which in practice is normally commuted to life in jail - and two got life sentences, Yu said.

He said the case should not be connected to politics or the trade war, and the timing of the sentencing was the result of the legal process. There are two other joint fentanyl cases ongoing, he said.

“This should not be linked to trade, or other policy-related matters, because there's nothing more important than a human life,” he said.

Jim Carroll, head of the White House Office of National Drug Control Policy, said the arrests were a “positive step.”

“We look forward to further cooperation to stop the flow of these deadly substances into the United States,” Carroll said in a statement.

More than 28,000 synthetic opioid-related overdose deaths, mostly from fentanyl-related substances, were recorded in the United States in 2017, according to the U.S. Centers for Disease Control and Prevention.

U.S. drug enforcement officials have pointed to China as the source of much of the fentanyl and related supplies. China denies that most of the illicit fentanyl entering the United States originates in China, and says the United States must do more to reduce demand.

Yu said that the issue of fentanyl was not something any one country could resolve.

“If illegal demand cannot be effectively reduced, it is very difficult to fundamentally tackle the fentanyl issue,” Yu said.

In August, U.S. President Donald Trump accused Chinese President Xi Jinping of not fulfilling a promise to crack down on fentanyl and its analogs.

Yu said China was willing to work with U.S. law enforcement authorities and all other international colleagues to fight narcotics and “continue to contribute China's wisdom and power for the global management of narcotics.”

Johnson & Johnson Loses Pelvic Mesh Class Action in Australia

(Reuters) - More than 1,350 Australian women won a seven-year-old class action lawsuit on Thursday against Johnson & Johnson (J&J) for misleading patients and surgeons about the risks of the pharmaceutical giant's pelvic mesh implants. [FN33]

The suit is one of many J&J has faced in the United States, Canada and Europe over the implants, used to treat urinary incontinence and pelvic organ prolapse, in which organs shift from normal positions. J&J in October agreed to pay nearly $117 million to resolve claims in 41 U.S. states and the District of Columbia.

Australia's Federal Court found that J&J subsidiary Ethicon had sold the devices without warning women about the “gravity of the risks,” and was negligent in rushing the products to market before proper testing. The judge in the case, Anna Katzmann, has set February for the next hearing in the case, where damages will be discussed.

Ethicon said it was reviewing the court's decision and would consider its options to appeal.

“Ethicon believes that the company acted ethically and responsibly in the research, development and supply of these products,” the company said in a statement.

Judge Katzmann ruled that much of the information the company provided about the devices was “inaccurate” and at times made “false representations.”

“The question is whether this conduct considered as a whole was misleading or likely to mislead. I believe it was,” Katzmann said in her judgment.

“The post-market evaluation of all the Ethicon devices was deficient,” she said. “It fell well below the level of care required of a reasonably prudent manufacturer.”

“The risks were known, not insignificant and on Ethicon's own admission, serious harm could ensue if they eventuated,” the judge said in her ruling.

Patients said they had suffered chronic pain, bleeding and severe discomfort during sexual intercourse after having the mesh surgically implanted.

Dozens of women involved in the class action welcomed the court's decision.

Julie Davis, the original claimant in the case, said she was “incredibly pleased” with the judgment but said it would not take away the pain and damage done to women.

“They have treated women essentially like guinea pigs, lied about it and done nothing to help,” she told reporters at a televised media conference outside the court in Sydney.

India Asks States to Halt Online Drug Sales

(Reuters) - India's drugs regulator has asked all states to enforce a court directive prohibiting online medicine sales, a senior government official said on Wednesday, raising industry concerns it could disrupt some online businesses. [FN34]

India is yet to finalize regulations for online drug sales, or e-pharmacies, but the growth of several online sellers such as Medlife, Netmeds, Temasek-backed PharmEasy and Sequoia Capital-backed 1mg has threatened traditional drug-store businesses.

The Delhi High Court in December last year said the government must ensure online sales are prohibited for the time being, as it heard a petition from a doctor who alleged unregulated online sales could lead to abuse of medicines.

K. Bangarurajan, a senior official at the Central Drugs Standard Control Organisation (CDSCO), said the federal agency had asked states earlier this year to comply with the court's order, and a reminder had now been issued to all authorities.

“State drug controllers are the regulating authority, they have to implement this ... and if anyone is dealing (in online sales) they need to take action,” Bangarurajan told Reuters.

The CDSCO's directive was sent on Nov. 28 to all states, according to a copy seen by Reuters. It was not immediately clear what subsequent action states would take.

Sreenidhi Srinivasan, a senior associate at law firm Ikigai Law, said the Delhi court order had raised concerns in the industry and any bans by state drug controllers could hurt online sellers.

Trader groups have protested for years against e-pharmacies, saying they challenge their businesses and could allow medicines to be abused by being sold without proper verification. They also allege e-pharmacies make it easier to use one prescription to buy medicines multiple times.

Steep online discounts have also hit offline businesses, which according to industry estimates recorded $18.4 billion in retail sales in 2018-19. Sales growth has averaged only 8.2% a year since 2015-2016, when sales grew by 12.3%.

“Online retailers have been offering discounts more than our margins,” said Yash Aggarwal, legal head of South Chemists and Distributors Association in New Delhi.

Some are not worried, however. Pradeep Dadha, CEO and founder of online e-pharmacy Netmeds, said his firm was complying with all Indian laws and regulations and business was continuing as usual.

“All our partner pharmacies also have the required licenses,” Dadha said.

IV. EUROPE

Dutch Hospitals Warn No-Deal Brexit Will Put Patients in Danger

(Reuters) - Dutch hospitals warned on Wednesday that a no-deal Brexit would lead to a shortage of medicines and medical supplies in the Netherlands and could put patients at risk. [FN35]

The Dutch annually import around 2 billion euros worth of medicines and medical supplies from Britain, which is around 10 percent of all goods shipped from Britain to the Netherlands.

But, echoing concerns in other EU countries, the Dutch fears go beyond this direct import line, as a large number of medical supplies, from bandages to pacemakers, made in other countries receive an EU certification in Britain.

These certifications would become invalid in the EU in the event of Britain leaving the bloc on March 29 without a deal to facilitate trade in goods and services with countries with which it used to have seamless arrangements, meaning hospitals would have to find a replacement for the products involved.

“We foresee great risks for our daily operations if Britain leaves the EU without a deal”, the Dutch Federation of Academic Hospitals (NFU) said.

“This varies from medicines, tissues and medical supplies becoming unavailable, to problems with data storage and the registration of doctors. The safety of patients is at risk.”

Germany's drug safety regulator concluded this month that Brexit would not put its patients at risk of losing access to essential drugs, while Ireland has drawn up a list of 24 medicines whose supply would be most vulnerable if Britain fails to conclude a divorce deal.

An attempt by British lawmakers to prevent a no-deal Brexit was gaining momentum on Wednesday after the opposition Labour Party said it was highly likely to throw its parliamentary weight behind the bid.

But the EU, whose members are also worried by the prospect of a disorderly Brexit that would cost jobs in major economies in the bloc, cautioned that no-deal was still the default scenario until London proposed something else.

The Netherlands's Association for General Hospitals said it still had no clear idea of the scale of the problem.

“We have asked our suppliers to find out how much we are talking about”, said spokesman Wouter van der Horst.

The NFU has called for an emergency law permitting the use of UK certified medical goods for at least the rest of the year.

Dutch Health Minister Bruno Bruins said this month he had taken the issue up with his European colleagues, but has so far not given an update on progress on the matter.

“We will only take national measures when a European-wide solution is impossible,” a ministry spokesman said on Wednesday.

Novartis Urges Britain to Secure Drug Supplies before Brexit

(Reuters) - Novartis called on Britain to urgently guarantee the movement of drugs in the event of a chaotic Brexit and said it was stockpiling to maintain the delivery of the 120 million packs it exports to Britain from Europe each year. [FN36]

The Swiss company, one of the world's biggest drugmakers, said the risk of Britain leaving the European Union, its biggest trading partner, without a deal had risen after Prime Minister Theresa May failed to get her deal through parliament last week.

“Given the complex nature of the supply chain, government needs to implement a comprehensive continuity plan rapidly,” Novartis said in a statement.

Novartis's fastest-growing medicine is Cosentyx, the blockbuster medicine for psoriasis and other auto-immune disorders including ankylosing spondylitis. It also makes the cell therapy Kymriah, for young people with leukemia, and the multiple sclerosis medicine Gilenya.

Fellow Swiss drugmaker Roche, which makes the cancer drugs Herceptin, Avastin and Rituxan, has also built up stocks to prevent any shortages.

Britain is due to leave the EU on March 29, and with May still battling to get the accord she agreed with the rest of the bloc through parliament, businesses are having to spend millions of pounds to prepare for a “no-deal” exit.

The highly regulated drugs sector is one of the most vulnerable to a no-deal outcome due to its pan-European supply chains and need for regulatory oversight.

More than 2,600 drugs have some stage of manufacture in Britain and 45 million patient packs are supplied from the UK to other European countries each month, while another 37 million flow in the opposite direction, industry figures show.

Britain has called for drugmakers to produce an additional six weeks of medicines to cope with potential supply disruption in the event of a no-deal Brexit - a target the industry has said would be challenging.

“It is vital that government makes minimizing disruption to the medicines supply the highest priority as it prepares for a potential hard or disorderly Brexit and ensures cooperation over medicines regulation in this event,” Novartis said.

Novartis also urged Britain's health service and pharmacists to stick to the government's advice not to stockpile medicines, so the supply can be managed centrally and not risk shortages.

Britain's biggest drugmaker GlaxoSmithKline has said it is increasing inventory, updating packaging, amending importation licenses and securing warehousing to protect its supply chains before March 29.

It puts the cost of implementing such changes at 70 million pounds over the next two to three years, with ongoing costs of around 50 million pounds per year.

With parliament in deadlock, many major companies that normally avoid national politics have started to turn up the volume, with Airbus, the world's second-largest aerospace group, warning it could shift future wing-building out of the country in the absence of a smooth exit.

Airbus employs 14,000 people in Britain while Novartis, the maker of neurological, immunology and cancer drugs, employs around 1,500 in Britain.

Pharmacy Stocks Run Low as Turkey's Drug Price Policy Hits Supplies

(Reuters) - The shelf of heart disease drugs in Hulya Akpinar's Istanbul pharmacy is almost bare, and patients seeking medicine for blood pressure and diabetes leave empty-handed. [FN37]

For months Akpinar says she, and pharmacists across the city, have faced a shortage of critical stocks caused by a government decision to keep the prices it pays pharmaceutical firms for medicines artificially low.

“We have been calling the pharma warehouses several times a day to ask if they can deliver these drugs, but we can't find them,” she told Reuters in her pharmacy in the central Istanbul district of Sisli.

Medicine shortages are a regular problem in Turkey at the start of each year, when the government sets the exchange rate for all drug purchases. The state's Social Security Institution buys 90 percent of the drugs on the market, worth around 30 billion lira ($5.75 billion).

Just over half of medicines in Turkey are imported and most of the locally manufactured drugs use imported raw materials, making the exchange rate a crucial factor in cost.

This year, following the sharp depreciation of the Turkish lira, shortages have been even more acute. The exchange rate for pharmaceuticals in 2018 was 2.69 lira to the euro - barely half the current market rate.

This year the government, which is trying to cap spending, is expected to raise the rate by just 15 percent. Pharmaceutical companies are asking for a minimum of 35 percent.

Nezih Barut, head of the Pharmaceutical Manufacturers Association of Turkey (IEIS), said drugmakers could not operate properly if the government proposal is approved.

“In such a situation, drugs would be nowhere to be found because as drug companies, we are at a point where we are having a lot of difficulty even with raw materials supplies,” he said.

DRUGS SHORTAGES

Reuters spoke to 10 pharmacies around Istanbul this week. Nine said they did not have common medicines for high blood pressure or influenza. One pharmacy said it had only one pack.

Turkish Pharmacists' Association (TEB) head Erdogan Colak said 150 types of medicine were unavailable in the market in January, and Akpinar said drugs for cardiovascular diseases, high blood pressure and diabetes were particularly hard to find.

“These drugs are essential,” Akpinar said. “Our clients come in and ask for them but they are nowhere to be found from medical suppliers. We call our other pharmacist friends to find them.”

Last week Health Minister Fahrettin Koca appeared to blame the pharmaceutical industry for the shortages, saying his ministry had determined that 42 producers, 20 warehousemen and 32 pharmacists were hoarding drugs to sell after the price hike.

But on Tuesday the health ministry gave authorization for 41 drugs to be sold at prices higher than those set by the fixed exchange rate. “As of this week, the supply problem of 41 drugs will end,” Koca said.

Cancer, flu medicines and antibiotics were among medicines that would be affected by the price liberalization, Koca said.

Pharmacists and their patients are impatient for change. “We have been having this problem for three to four months,” said Engin Erdogan, at another pharmacy in Sisli. “I do not have anything left in my eye drop shelf and I cannot replace them.”

Brexit to Harm UK's Cherished Health Service, Experts Say

(Reuters) - A British exit from the EU without a deal would have “an immediate and drastic” impact on availability of medicines and vaccines as well as affecting health system funding and staffing, experts warned on Monday. [FN38]

Although a no-deal Brexit was the worst scenario, even a negotiated divorce from the European Union would also damage the National Health Service (NHS), the experts said in a review published in The Lancet journal.

Britain is scheduled to leave the bloc on March 29th, and Prime Minister Theresa May has yet to secure parliament's backing for her negotiated EU withdrawal agreement.

The Lancet review, led by three UK health policy specialists, found that even under this deal or potential variations of it before the deadline, Brexit's health impact would be only slightly less harmful than in a no-deal scenario.

“Some people will dismiss our analysis as ‘Project Fear’. But with just over a month to go to Brexit ... it just isn't good enough to keep saying that ‘something will work out’ without any details of exactly how,” said Martin McKee, a professor at London School of Hygiene & Tropical Medicine who co-led the review.

The analysis used available legal and political texts on four Brexit scenarios to assess likely impact on the state-funded NHS, a much-cherished though increasingly strained pillar of Britain's welfare services.

It found that one major problem from Brexit under all scenarios would be staff recruitment and retention - in part because few provisions have been made for immigration of health workers to the UK or for long-term recognition of professional qualifications.

It also said that “under a no-deal Brexit, the absence of a legal framework for imports and exports is expected to have an immediate and drastic effect on supply chains” for medicines, vaccines, medical devices and equipment.

Despite government assurances, the analysis said, shortages would be likely because stockpiling cannot cover more than a few weeks and some products - such as radioisotopes used in medical imaging for diagnosis - cannot be stockpiled.

The British government has asked UK drugmakers to build an additional six weeks' worth of stockpiles to prepare for any no-deal Brexit, a target the industry has said will be challenging.

The review said that as one of the largest areas of public spending, any negative impact on the economy - however short-term - would put extra pressure on health service financing.

Filling ‘Brexodus' Gap, Filipino Nurses Find English Tests Too Daunting

(Reuters) - Bracing for life after Brexit, British hospitals badly need more nurses like Filipino Jobie Escalona, but she twice flunked a mandatory English language test that asked her to write up the merits of immigration and computer education in school. [FN39]

The 23-year-old Escalona, with three years' experience in a private hospital in Manila, lost almost 3 months' salary paying nearly $600 to sit the tests.

Fed up, she was ready to give up on Britain and try Canada, one of several other countries short of nurses, until her father persuaded her to take the test a third time.

“I was already losing hope,” she told Reuters. Finally, in January last year, she passed, having at last got a subject she felt comfortable writing about in the tough written section of the test.

Asked to compare team and individual sports, Escalona had little trouble: “I was able to relate to it because I am a swimmer.”

But, her tortuous experience doesn't bode well for Britain's chances of adequately filling alarming staffing gaps in its healthcare services.

With Brexit looming, the supply of nurses from European Union countries has almost dried up, with lots going home. And of the many foreign nationalities employed in Britain, Filipinos made up the largest number, with 10,719, according to a parliamentary paper.

As of June last year, 16 percent of nursing jobs in hospitals and community health services were held by foreigners - nearly a quarter of whom were Filipinos.

Britain is already facing a shortage of 40,000 nurses, and once it leaves the EU, if it ever happens, the gap could widen to 50,000, enough to staff more than 40 small to medium-sized hospitals, according to a report commissioned by the Cavendish Coalition, a group of health and social care organizations.

OUT OF THEIR COMFORT ZONE

The staffing crisis is increasing Britain's dependency on hiring from low cost countries like India and the Philippines, where English is widely spoken, yet the language test has proved to be a major obstacle.

Philippine recruitment firm Louis International Manpower Services has received 1,000 job orders for nurses since 2015.

It has only filled a quarter of them.

“It is not because of the lack of applications, but the English test,” said Lilibeth Villas, documentation officer at the firm. “We have applicants who were interviewed in 2015, but they have not passed the test yet.”

Run by the British Council, IDP Education and Cambridge Assessment, the International English Language Test System (IELTS) gauges applicants' ability to speak, listen, read and write, and is used by employers around the world.

Questions in the academic written section asks candidates to write short essays on diverse subjects. Examples given on the IELTS website included interpreting graphs on changes in radio and television audiences, and gender variations between full and part-time students, and discussing the pros and cons of nuclear technology and of regulating car ownership.

Many candidates clearly find the weighty topics too daunting.

Febin Cyriac, a business development manager at Envertiz Consultancy, a British healthcare recruitment firm that specializes in bringing in nurses from overseas, started a petition in change.org in 2014 that asked UK regulators to relax their IELTS scores.

Working as a nurse himself, Cyriac said there are a good number of Indian or Filipino nurses with many years of experience working in Britain, but who are only working as assistant nurses in the National Health Service (NHS) and nursing homes.

“IELTS is the only barrier for them to practice as a nurse in the UK,” said Cyriac, himself a nurse working in Britain.

Still, the number of Filipinos in the NHS has risen by almost a third in the last two years, according to British government figures.

Late last year, the pass mark for the writing section was lowered, but there are no immediate plans to make further changes to the test standards, said Andrea Sutcliffe, Nursing and Midwifery Council (NMC) Chief Executive and Registrar.

“We will continue to carefully monitor the impact of the recent changes. This change is part of a wider review of our overseas registration processes aimed at making it more straightforward and user-friendly for people with the right skills and knowledge to join our register in a timely way”, Sutcliffe said.

There is an Occupational English Test (OET), more suited to medical professionals, that foreign nurses can take. If they pass that test they would still have to sit the IELTS, but they would be eligible for a lower pass mark. The OET is more expensive, however, making it unattractive for low paid nurses.

A London-based recruitment agency visited Manila recently to find nurses for Cambridge University, East Surrey and Royal Cornwall Hospitals, while there have also been recent hiring drives for hospital trusts in Oxford, Hull and Dudley.

Germany, Japan, the United Arab Emirates and Saudi Arabia are the other countries hiring Filipino nurses, said Bernard Olalia, head of the government's Philippine Overseas Employment Administration.

In January alone, Olalia's office received 1,000 job orders for nurses from Saudi Arabia.

“There are a lot of markets for our Filipino nurses,” Olalia said, adding that it was understandable if they took jobs in places where the requirements were easier to fulfil.

Filipino nurses who were recruited in the 1990s did not have to take the language tests, yet they are still in the NHS and providing good service, said Reydeluz Conferido, who was until recently the labour attache to the Philippines embassy in London.

While there, Conferido called on British officials to review the requirements placed on overseas nurses to see whether they were serving the correct purpose or creating an artificial barrier.

“If you really want these nurses, you would do something about your standards,” he said.

French Drugmaker Sanofi, Google to Use Data Tech for Innovations

(Reuters) - French healthcare company Sanofi has teamed up with Google to work on innovations, aimed at using emerging data technologies to change how medicines and health services will be delivered in future. [FN40]

Sanofi and Google will use data sets to improve their understanding of key diseases and extract patients' insights and feedback, the companies said in a joint statement.

“Combining Sanofi's biologic innovations and scientific data with Google's industry-leading capabilities, from cloud computing to state-of-the-art artificial intelligence, we aspire to give people more control over their health and accelerate the discovery of new therapies,” said Ameet Nathwani, chief medical officer and executive vice-president, Sanofi.

This would enable Sanofi to research and develop a more personalized approach to treatment and identify accompanying technologies to improve results, the statement said.

No-deal Brexit Could Deepen Europe's Shortage of Medicines

(Reuters) - As the Oct. 31 deadline for Britain to leave the European Union approaches, health professionals are warning that shortages of some medicines could worsen in Europe in the event of a no-deal Brexit. [FN41]

Britain's food and drink lobby warned last week that the country would experience shortages of some fresh foods if there is a disorderly no-deal Brexit. Pharmaceutical companies have expressed similar concerns about medicines, and some have reserved air freight capacity to fly in supplies if needed.

But the impact on medical supplies will also be felt beyond Britain. About 45 million packs of medicines are shipped from Britain to the rest of the bloc every month, in trade worth nearly 12 billion pounds in 2016, according to a British parliament report.

Experts say some disruption is inevitable if Britain leaves the EU without a deal. British Prime Minister Boris Johnson has said he will lead his country out of the EU on Oct. 31 without a deal if the EU refuses to negotiate a new divorce agreement.

Some drugs might not have the required regulatory approval by then to continue being brought in from Britain. About 1 billion packs go in one direction or the other each year, industry data show.

Increased customs controls at ports and other borders between Britain and the EU could also disrupt supplies of drugs and the chemical compounds needed to produce them, regulators and industry representatives say.

“Despite intensive preparation by industry for every scenario, a no-deal Brexit risks disruption to the supply of medicines” throughout the EU, Andy Powrie-Smith, an official at the European Federation of Pharmaceutical Industries and Associations, told Reuters.

The EU drugs regulator, the European Medicines Agency (EMA), said the bloc is well prepared for Brexit and has finalised authorizations for nearly all the 400 drugs under its watch that required further clearing because of Britain's impending departure.

But authorization is pending for three medicines that need EU-wide licenses, an EMA official said without identifying them.

Other essential medicines could also be blocked because of supervisory hurdles because of Brexit, EMA data show.

The agency is the only body that can authorize sales in the 28-country EU of new drugs to treat the most common and serious diseases, including cancer, diabetes and flu.

WORSENING WOES

Many other medicines authorized at national level could also be at risk. Nearly 6,000 of these drugs need to go through a new licensing process after Brexit.

The EMA official said the agency did not have “a full picture” of the situation in all EU states for nationally authorized medicines.

The Netherlands said in February that 50 “critical” drugs were at risk of shortages in the event of a no-deal Brexit. Concerns about most of those drugs have since been resolved, a spokesman for the Dutch health ministry said, but problems could arise for less essential medicines.

In a report in June, the EU's executive European Commission included medicines and medical devices in a list of sectors for which “continued and particular vigilance” was needed.

Many EU states already face shortages of some medicines because of problems with production, regulators or distribution.

A survey of 21 European countries showed that all of them experienced shortages of medicines last year, according to the Pharmaceutical Group of the European Union, a pharmacists' trade body. Vaccines were among the drugs most frequently cited as being in short supply.

Britain will need to authorize hundreds of new medicines on sale now only thanks to EU-wide registrations. Britain imports about 37 million medicine packs every month from the EU, industry figures show.

Britain is also losing supervisory and clinical-trial capacities as many operations have already moved to the EU to remain able to test and approve drugs for the EU market after Brexit. This trend could shrink the local pharmaceutical industry and lead to tighter supplies and higher costs.

EU countries face the same logistical hurdles for their imports from Britain.

In the event of Brexit without a divorce deal, “there will be some problems and delays in the supply chain due to border protocols, but I think we will be able to manage,” said Eric Van Nueten, the chief executive officer of Febelco, Belgium's largest wholesale trader of medicines.

Lundbeck Buys Alder for $2 billion, Eyes ‘Blockbuster’ Migraine Therapy

(Reuters) - Denmark's Lundbeck has agreed to buy Alder BioPharmaceuticals in a deal valued at almost $2 billion, hoping to reap profits from a potential blockbuster migraine drug. [FN42]

The move comes as Lundbeck, which specializes in treatments for illnesses such as Alzheimer's and depression, is under pressure from patent expirations and competition from generics.

Alder, whose board unanimously approved a takeover pitched at a 79% premium to Friday's share price close, develops preventative treatments of migraine in adults.

It submitted a license application for its eptinezumab antibody to the FDA in February.

Lundbeck expects the drug, used in intravenous infusion therapy, to be launched in the United States in the first half of 2020.

“The acquisition will accelerate and diversify Lundbeck's revenue growth starting in 2020 as well as enhancing our antibody process development capabilities,” said Lundbeck Chief Executive Deborah Dunsire.

In a subsequent call with analysts, the CEO added that eptinezumab was a potential blockbuster drug, a term for popular drugs reaching annual sales of at least $1 billion.

Lundbeck shares fell 3% at Monday's market open, but were up 4.5% at 1020 GMT following the call with analysts.

It is offering an upfront payment of $18 per Alder share, plus an additional $2 per share contingent upon approval of eptinezumab by the European Medicines Agency.

Lundbeck said it expects the deal, to be funded through cash and bank financing, to close in the fourth quarter of this year.

Lundbeck, which bought U.S.-based research hub Abide Therapeutics in a $250 million deal May, will continue to look for new takeover and licensing opportunities as well as partnerships, Dunsire said.

Copenhagen-based Lundbeck, founded in 1915 as a trading company, began developing and producing pharmaceutical products in the 1930s. It is 70% owned by the Lundbeck Foundation, one of Denmark's biggest industrial foundations.

Roughly 39 million Americans suffer from migraine headaches, according to the Migraine Research Foundation.

Annual global drug sales to treat migraines could total $8.7 billion by 2026, according to the GlobalData analytics firm.

If the transaction, valued at up to $1.95 billion, is closed on Nov. 1, the company expects transaction costs of about 200 million Danish crowns ($30 million) and integration and retention costs of 400-500 million crowns.

In the same scenario, Lundbeck said it would pay two months of Alder's operating costs, seen at around 325-400 million crowns.

Lundbeck expects to submit the eptinezumab antibody for regulatory approval in the European Union during 2020, and later in China and Japan.

With a Backup to the Backup, Insulin Makers Say They're Primed for Brexit

(Reuters) - For two men trained as scientists, the bosses of Britain's major insulin providers have had to become experts in ferry schedules, trucking laws and warehouse capacity as they seek to guarantee the supply of life-saving drugs through a chaotic Brexit. [FN43]

With Britain set to leave the European Union within weeks, Pinder Sahota at the world's biggest insulin maker Novo Nordisk, and Sanofi's Hugo Fry have rebuilt operations to withstand the most turbulent of events.

The two companies told Reuters they had spent millions of pounds, which they cannot recoup, stockpiling millions of packets of insulin - used to treat diabetes - inside Britain and building new shipping and air freight routes.

Their plans, formulated over three years, show the lengths companies across the continent are having to go to overhaul long-standing supply chains that may not survive Britain's biggest trade upheaval in half a century.

“There is nothing comparable to this,” Novo Nordisk's UK General Manager Sahota told Reuters of the Danish company's preparation. “It's unprecedented from a logistics point of view. We're preparing for the worst-case scenario, the most extreme.”

With two Brexit deadlines already been and gone, Prime Minister Boris Johnson has vowed to take Britain out of the EU with or without a deal by Oct. 31 - increasing the chance of a sudden departure that brings trade tariffs and customs checks with the continent for the first time in decades.

The government's own planning shows that, in a worst-case scenario, lorries seeking to enter Europe at the French port of Calais could face delays of two-and-a-half days, creating supply disruptions that could last for months.

That poses a real risk for the pharmaceutical industry which imports 37 million packs of drugs from Europe a month. According to the government, three-quarters come via that route.

While Britain's GSK and AstraZeneca are world leaders in respiratory and cardiovascular treatments, Britain's insulin is imported.

“In the case of pharmaceuticals, you can't just throw things onto a boat or a lorry, you have to test and validate these routes into the country,” Fry told Reuters in his office to the west of London, adding they had backups to their backup plans.

Both Sanofi and Novo Nordisk have reserved space on ferries going the longer route to eastern English ports to avoid the main Calais-Dover crossing if needed, and also air freight if required.

“We anticipate that route is going to become congested so what we've done is open up other routes,” said Sahota. “So two other routes that we've opened up are Denmark to Immingham (in north-east England) and Netherlands to Immingham.”

SKY-HIGH STOCKPILES

Novo Nordisk, Britain's biggest insulin supplier, has tripled its warehouse capacity to hold 18 weeks' worth of stock - 3.8 million packs that piled high would stand 12 times the height of the London Shard skyscraper.

Eli Lilly of the United States and France's Sanofi, the country's second and third-biggest suppliers, have similar stockpiles.

Frustration is growing that while they dedicate huge resources to such preparation, they are spending less time on their normal jobs.

“When we're doing this, we're not doing other stuff,” Fry said. “We're not working on projects that will bring our most innovative products to the market.

”Although we are happy to do it, it is starting to weigh on our balance sheet, on our logistics, keeping all this additional stock in the country. It's not an ideal situation.”

The companies are confident they will be able to guarantee the British supply of insulin to the around 1 million diabetes patients who need it.

But some patients like Georgina from London, who was diagnosed with Type 1 diabetes more than 30 years ago, have become increasingly alarmed as the chances have grown of Britain leaving the EU without a deal to govern their trading relationship.

“For me, I can't tell you how worried I am about that. It's life-threatening for me,” she said, declining to give her last name. She added that she also worried about older patients she encountered at clinics.

The British government is organizing a regular freight service reserved just for drugs as part of its preparations alongside industry for Brexit on Oct. 31.

“We are doing everything we can to help ensure the supply of medicines and medical products remains uninterrupted, including insulin,” said the department of health and social care.

The two drug companies did not say how much their Brexit preparations had cost, beyond many millions of pounds. With fixed contracts with Britain's health service, they cannot raise prices.

Both Fry and Sahota have had to delve into arcane areas of transport.

As part of their planning, for example, they have had to factor in how many drivers are needed to avoid breaking legally mandated rest laws, how long refrigerated lorries can operate in one stretch, and what happens in the event of fuel shortages.

“We're doing everything we can,” said Fry. “I know more about ferry crossings now than I ever thought I would.”

Croatia Doctors, Nurses to Get 7% Wage Hike; Strike Averted

(Reuters) - The Croatian government and the major healthcare unions agreed on Friday an average 7% wage increase, averting a strike doctors and nurses threatened to stage in the coming weeks. [FN44]

The agreement has been reached after a series of protests in recent weeks that the medical workers staged in front of their hospitals during their daily breaks at work.

“Both sides have had to step back a bit from initial positions,” said Health Minister Milan Kujundzic. The 7% increase “may not be enough for them, but it was really not easy for the government to set aside 400 million kuna ($60.05 million) annually.”

The unions initially demanded increases of at least 10%.

The Croatian government has faced demands for higher wages in recent weeks from education and public transport unions.

Last week, teachers protested and threatened to strike if their demand for a wage increase averaging around 6% was not met. Prime Minister Andrej Plenkovic promised to consider their demand and continue talks next week.

Croatia has considerably improved its public finances, posting a slight surplus for two years running after almost two decades of regular deficits. Critics say that was largely based on higher revenues rather than on cutting public spending.

In the first six months of this year, Croatia posted a general budget surplus of 0.3% of gross domestic product.

Drug and Medical Suppliers Say Brexit Freight Plans Needed Urgently

(Reuters) - Makers and suppliers of life-saving drugs and medical devices say they have still not been told by British authorities how their goods will be handled if the UK leaves the European Union without a deal at the end of October. [FN45]

Some larger pharmaceutical companies have opted to make their own plans to replenish supplies of critical medicines in the event of a “no deal” Brexit, industry groups said on Friday, while others are aiming to book slots in the government's air and ferry freight plan.

Despite repeated and urgent requests to the government for details, medicines suppliers still don't know which ports such shipments will depart from, the timings and lengths of the journeys or where they will arrive in the UK.

With some cross-channel trips taking as little as an hour, and others taking six or more, this heightens the potential risk for some medicines that may need refrigeration, the groups said, and raises questions about the number of drivers needed and the length of their working shifts.

“The industry doesn't know which ports will be available, which ferries will be available. So we don't know which ferries are coming from where to where,” said Steve Bates, chief executive of the UK BioIndustry Association.

“We have been repeatedly asking for this,” he said, adding that with fewer than six weeks to go before the Oct. 31 Brexit deadline “everything is become increasingly urgent.”

The Department for Transport on Friday said that it had shortlisted eight companies that could bid to bring in drugs, using ports away from areas that are likely to face disruption.

It said the contracts - awarded to ferry companies, Eurotunnel and an aircraft charter company - would provide capacity equivalent to thousands of trucks per week.

Two Brexit deadlines have already been and gone, but Prime Minister Boris Johnson has now vowed to take Britain out of the EU with or without a deal by the end of October - increasing the chance of a sudden departure that will bring trade tariffs and customs checks with the continent for the first time in decades.

The risk is particularly acute for the pharmaceutical industry, which imports 37 million packs of medicines into the UK from the rest of Europe every month.

Briefing reporters on Friday, leaders of drug industry groups and medical research charities said they have been working for three years on contingency plans and are broadly confident that UK doctors, hospitals and patients will not face immediate or dangerous medical shortages.

“This is all about managing risk,” said Mike Thompson, chief executive of the Association of the British Pharmaceutical Industry. “The scale of this means that we have to be sensible and prepare for shortages, but the system is well geared up for managing that.”

Responding to the concerns, a government spokeswoman said in an emailed statement that “comprehensive plans” are in place to ensure that vital medicines are brought into the UK after Brexit.

“We want to alleviate any fears by stressing that the government is doing everything we can to make sure patients receive the medicines they need,” she said.

Brexit May Have ‘Gravest of Consequences' for Health

(Reuters) - Britain's looming exit from the EU carries real risks that medicines and healthcare supplies will be delayed, the UK's public spending watchdog said on Friday, and an influential lawmaker said a no-deal Brexit may have the “gravest of consequences.” [FN46]

While Prime Minister Boris Johnson's government has taken some steps to manage the risks, the National Audit Office (NAO)said in a report, there is still significant work to be done.

Lawmaker Meg Hillier, who chairs parliament's public accounts committee, said the report was “deeply concerning.”

The health ministry “still doesn't know whether all stockpiles are in place”, she said, has no idea whether social care providers such as nursing homes for the sick and elderly are ready, and is not sure whether freight capacity needed for medical imports will be in place on time.

“If (the) government gets this wrong, it could have the gravest of consequences,” Hillier said in a statement about the NAO report. She added that as head of the committee, she had already seen “countless examples of deadlines missed and government failing.”

Johnson has vowed to take Britain out of the EU with or without a deal by Oct. 31 - increasing the chance of a sudden departure that will bring trade tariffs and customs checks with the continent for the first time in decades.

The risk is acute for health and social care services, as well as for the pharmaceutical industry, with 37 million packs of medicines imported into Britain from Europe every month.

STOCKPILE

The government's own reasonable worst-case view is that the flow of goods across the channel Europe could be reduced to 40%-60% of normal levels on day one after Brexit.

The Department for Health & Social Care has asked medical suppliers to build up stockpiles of medicines and other essentials and has found extra warehouse capacity for them.

A six-week stockpile of equipment such as gloves, syringes and other medical supplies is 88% complete, the NAO said, but information on other stockpiles is “incomplete.”

Drug industry and patient representatives said the report's findings were worrying.

“This report tells us ... that very little thought has been given to securing basic medical supplies such as bedpans and incontinence pads for people in social care in nursing homes,” said Alan Boyd of the Academy of Medical Royal Colleges.

“Bluntly, that means the frail, elderly and most vulnerable could be hit the hardest. That cannot be right.”

Aisling Burnand, head of the Association of Medical Research Charities, said the report would cause “anxiety and worry.”

“Anxiety for people who are seriously ill or living with a long term condition is unwanted. They have many other things to worry about,” she said in a statement.

The Department for Transport last week shortlisted eight companies that could bid to bring in drugs. The contracts would provide capacity equivalent to thousands of trucks per week.

But the audit report said the time was short and warned that not all that freight capacity might be available on Oct. 31.

Richard Torbett a spokesman for the Association of the British Pharmaceutical Industry, said his members urgently needed detail of how to access to access this medical freight capacity.

V. GLOBAL ISSUES

WHO Agrees to Watered-down Resolution on Transparency in Drug Costs

(Reuters) - Countries at the World Health Organization agreed on Tuesday to push for clearer drug pricing, after watering down a draft resolution that would have also required pharmaceutical firms to disclose the cost of making medicines. [FN47]

The deal calls on governments to share more information about the prices they pay for drugs, which can vary widely around the world and are often kept shrouded in secrecy.

It was hailed as a landmark by WHO chief Tedros Adhanom Ghebreyesus and “enthusiastically welcomed” by the United States, which had advocated making pricing clearer while allowing firms to keep their research costs secret.

However, Britain, Germany and Japan, which have healthcare systems that depend on negotiating steep discounts from drug companies to keep their costs down, said the debate had been rushed and called for the issue to be studied more closely.

An earlier draft of the text would have also given the WHO explicit powers to collect and analyze data on the costs of making and testing drugs. That wording was omitted from Tuesday's draft.

Activists say drug companies should be obliged to disclose how much their products actually cost to design and make. Drug companies argue that such data can be a commercial secret, and that prices should be set based on a drug's benefit to patients.

FIRST STEP

Gaelle Krikorian at medical charity MSF called the resolution a “welcome first step” but said it needed to go further to force drug companies to disclose more.

“We need to know the mark-ups corporations charge, production costs, the cost of clinical trials, how much investment is really covered by companies, and how much is underwritten by taxpayers and non-profit groups,” she said.

The International Federation of Pharmaceutical Manufacturers and Associations industry lobby group said the resolution's “single focus” on price fell short of the complexity needed to address issues about affordability and access to medicines.

The resolution, which was initially proposed by Italy, urges governments to publicly share information on net prices. WHO member states will also support dissemination of information about the costs from clinical trials, if it is already publicly available or voluntarily provided.

James Love, head of the transparency campaign group Knowledge Ecology International called the resolution a “solid start” in addressing the issue of opaque drug prices, but said the text made “tortured dances around R&D costs”.

“This will be seen by industry as language making costs data confidential information,” he said on Twitter.

The negotiations over the resolution showed how difficult the issue of drug pricing can be. In many countries, the government negotiates bulk discounts with companies in secret. In the United States, where drug prices are frequently far higher than in other rich countries, they are usually set commercially by insurance companies and benefits managers.

Germany's delegate Dagmar Reitenbach described the negotiations over the resolution as acrimonious, harmed “by leakage of perceived positions with a view to intimidate some delegations publicly, accompanied by incorrect information regarding (their) reasoning.”

United Nations Targets Universal Health Coverage by 2030

As part of its 2030 Agenda for Sustainable Development, all member countries of the United Nations (UN) agreed to try to achieve universal health coverage by 2030. This agreement included financial risk protection, access to quality essential healthcare services as well as access to safe, effective and affordable essential medicines and vaccines.

At a UN high-level meeting on Universal Health Coverage last week, all UN member nations joined a high-level Political Declaration reaffirming “the right of every human being, without distinction of any kind, to the enjoyment of the highest attainable standard of physical and mental health.” The declaration includes 83 specific agenda items as well as interim goals, including:

• to progressively cover an additional one billion people by 2023; and

• to “stop the risk and reverse the trend of catastrophic out-of-pocket” health expenditures.

The UN General Assembly endorsed a resolution on Global Health and Foreign Policy in 2012 to accelerate progress toward universal health coverage.

According to the World Health Organization (WHO), nearly $7.5 trillion is spent on healthcare globally each year. WHO estimates an increase of 3% or $200 billion a year could save 60 million lives.

Currently there are at least 32 countries that already offer universal health care, including nearly all developed nations except the U.S.

In 2017, the U.S. alone spent $3.5 trillion on healthcare, nearly 18% of GDP.

Although the U.S. was a key signatory to the declaration, Health and Human Secretary Alex M. Azar II, in a joint statement from 19 countries, also took issue with “ambiguous terms and expressions,” including “sexual and reproductive health and rights” in UN documents that might promote reproductive choices that do not enjoy “international consensus.”

Health coverage in the U.S. is currently a patchwork of private insurance and government-funded programs such as Medicare and Medicaid. However, 27.5 million or 8.5 percent of people in the U.S. did not have health insurance in 2018.

As part of his campaign in 2016, President Donald Trump promised to repeal and replace the Affordable Care Act (ACA). However, Republicans have yet to put forth a viable replacement place and have only been successful in chipping away at the ACA.

However, the Administration has taken steps to reduce healthcare costs to consumers, including increased healthcare cost and prescription drug price transparency.

Looking ahead to the 2020 elections, Democratic candidates have place health care coverage at the center of the discussion, with nearly every candidate proposing a plan to provide more coverage. These plans range from a “Medicare for All” strategy to a combination of a “public option” with the continuation of private employer-based insurance coverage.

Joe Biden, former vice president and current leader in the polls, focuses on expanding the ACA to reduce costs, increased assistance with health insurance premiums and a public option.

Senators Elizabeth Warren (D.-Mass.) and Bernie Sanders (I-Vt.) support Medicare for All to extend the existing program. Senator Warren co-sponsored Medicare for All legislation Senator Sanders introduced in April 2019.

VI. MIDDLE EAST/NORTH AFRICA

U.S. Sanctions on Iran Threaten Access to Certain Medicines: Report

(Reuters) - U.S. sanctions on Iran threaten access by some Iranians to medicines that treat diseases such as cancer and epilepsy, despite exemptions in the measures for imports of humanitarian goods, a report said on Tuesday. [FN48]

“There's no acute nationwide shortage of medicine in Iran at this point,” Tara Sepehri Far, a researcher at Human Rights Watch and an author of the report, said at the Atlantic Council think tank in Washington. “But people who are suffering from rare and special diseases are already seeing the negative effect of sanctions.”

If the situation does not change, “we expect the harm to be even greater,” Far said.

Iran's MAHAK Pediatric Cancer Treatment & Research Center lacked three key chemotherapy drugs - pegaspargase, mercaptopurine and vinblastine - in May, the report said.

Hundreds of people who have epidermolysis bullosa, or EB, a type of disease that causes fragile, blistering skin, had difficulty accessing medicine after the sanctions were imposed, it said.

Food, medicine and other humanitarian supplies are exempt from sanctions that Washington reimposed last year after President Donald Trump walked away from a 2015 international deal over Iran's nuclear program.

But the U.S. measures targeting everything from oil sales to shipping and financial activities have deterred several foreign banks from doing business with Iran, including humanitarian deals. Imports of grain have been slowed as well.

As oil exports fall, it could result in higher inflation and affect the affordability of medicine, the report said.

'CORRUPTION AND MISMANAGEMENT'

In response to the report, a U.S. Treasury Department official said exceptions to the sanctions allowed the sale of agricultural commodities, food, medicine and medical devices to Iran. “The people of Iran have long suffered from the regime's corruption and mismanagement,” the official said on condition of anonymity.

A mechanism the Treasury Department introduced last week will facilitate humanitarian exports to Iran, the official said.

A senior administration official told Reuters this month that any drug shortages represented the Iranian government's prioritization of its missile program and other initiatives.

The official conceded that slowdowns in some drug imports were possible, but put the onus on Tehran, which the official said must address corruption in the medicine trade. “To blame us for that is a little more than just disingenuous,” said the official, who spoke on condition of anonymity.

Last week, the Treasury and State departments said the administration's new humanitarian mechanism would ensure “unprecedented transparency” into food and medical trade with Iran.

It requires foreign governments and banks to provide Treasury an unprecedented amount of information on a monthly basis to ensure no funds are diverted by Tehran “to develop ballistic missiles, support terrorism, or finance other malign activities,” the administration said.

The move sparked a debate on whether humanitarian trade would be eased or gummed up as it requires banks to reveal large amounts of information.

Adam Smith, a lawyer who worked on sanctions under former President Barack Obama, said the new mechanism could enhance humanitarian trade if the banks find that the markets are big enough to go through the trouble.

“I actually don't think this could make things worse,” Smith said at the Atlantic Council. “But ... there's still more that needs to be released about how this will work and what the risks are if you get it wrong.”

VII. RUSSIA AND EURASIA

Holding for future articles.

[FN1]

. Philemon Bulyawayo, Zimbabwe doctors say patients dying due to drug, equipment shortages, Reuters (March 13, 2019).

[FN2]

. Nqobile Dludla, South Africa's Life Healthcare warns on earnings after disposal, Reuters (April 24, 2019).

[FN3]

. Nqobile Dludla, South Africa's Aspen sells Australian prescription portfolio to Mylan, Reuters (May 20, 2019).

[FN4]

. Carolyn Crist, Collaboration with US med schools helps Rwanda improve women's health care, Reuters (July 12, 2019).

[FN5]

. Onke Ngcuka, South Africa puts initial universal healthcare cost at $17 billion, Reuters (August 8, 2019).

[FN6]

. Jake Spring, Brazilian doctors fail to report for duty to replace Cubans, Reuters (Dec. 19, 2018).

[FN7]

. David Ljunggren and Anna Mehler Paperny, Canada budget to include limited coverage for prescription drugs - sources, Reuters (Jan. 31, 2019).

[FN8]

. Allison Martell and Anna Mehler Paperny, Facing crackdown in Canada, drugmakers offered billions in price cuts, Reuters (Feb. 6, 2019).

[FN9]

. Allison Martell, Canada advisory group calls for new prescription drug agency, Reuters (March 6, 2019).

[FN10]

. Doina Chiacu, U.S. charges Chinese national in hacks of Anthem, other businesses, Reuters (May 9, 2019).

[FN11]

. U.S. imposes sanctions on Argentina-based online pharmacies for opioids, Reuters (May 23, 2019).

[FN12]

. Diego Ore, Lopez Obrador says will shop abroad if necessary to fix medicine shortages, Reuters (May 27, 2019).

[FN13]

. Kelsey Johnson and Allison Martell, Canadian panel calls for universal public drug coverage, Reuters (June 12, 2019).

[FN14]

. Allison Martell, Exclusive: Canada warns U.S. against drug import plans, citing shortage concerns, Reuters (July 18, 2019).

[FN15]

. Allison Martell, Canada enacts drug price crackdown, in blow to pharmaceutical industry, Reuters (August 9, 2019).

[FN16]

. Allison Martell, Drug industry urges Canada to act early on U.S. import plan, Reuters (August 5, 2019).

[FN17]

. Brad Brooks and Marla Dickerson, Exclusive: Philips, under investigation in U.S. and Brazil, fired whistleblower who warned of graft, Reuters (August 21, 2019).

[FN18]

. Allison Martell, Companies file suit in Canada challenging new rules to lower drug prices, Reuters (August 23, 2019).

[FN19]

. Allison Martell, Drugmakers file second court challenge to Canada's new drug price rules, Reuters (September 6, 2019).

[FN20]

. Allison Martell, Canadian election clears path for universal drug plan, Reuters (Oct. 22, 2019).

[FN21]

. Allison Martell, Canadian ambassador says drug imports would not lower U.S. prices, Reuters (Nov. 1, 2019).

[FN22]

. David Stanway, Chinese police begin new probe into expired vaccines, Reuters (Jan. 13, 2019).

[FN23]

. David Stanway, China to crack down on health care violations: state media, Reuters (January 23, 2019).

[FN24]

. Aradhana Aravindan, U.S. citizen leaks data on 14,200 people in Singapore with HIV, Reuters (Jan. 28, 2019).

[FN25]

. Karen Lema and Matthias Blamont, Philippines to charge officials of Sanofi, government over dengue vaccine, Reuters (March 1, 2019).

[FN26]

. Shu Zhang, China's Ant Financial amasses 50 million users, mostly low-income, in new health plan, Reuters (April 12, 2019).

[FN27]

. Cate Cadell, China draws up tighter rules on human gene and embryo trials: Xinhua, Reuters (April 20, 2019).

[FN28]

. Pei Li and David Stanway, Tencent-backed China online healthcare venture raises $250 million, Reuters (April 23, 2019).

[FN29]

. China restricts opioid in tighter painkiller controls, Reuters (August 7, 2019).

[FN30]

. Roxanne Liu and Brenda Goh, China adds 148 drugs to key insurance list: state media, Reuters (August 20, 2019).

[FN31]

. Brenda Goh, Chinese state media says fentanyl abuse is entirely U.S. responsibility, Reuters (August 23, 2019).

[FN32]

. Huizhong Wu, In joint case with U.S., China jails nine fentanyl smugglers, Reuters (Nov. 11, 2019).

[FN33]

. Sonali Paul, Johnson & Johnson loses pelvic mesh class action in Australia, Reuters (Nov. 21, 2019).

[FN34]

. Aditya Kalra, India asks states to halt online drug sales, Reuters (Dec. 4, 2019).

[FN35]

. Bart Meijer, Dutch hospitals warn no-deal Brexit will put patients in danger, Reuters (Jan. 23, 2019).

[FN36]

. Kate Holton and Noor Zainab Hussain, Novartis urges Britain to secure drug supplies before Brexit, Reuters (Jan. 25, 2019).

[FN37]

. Ceyda Caglayan and Ezgi Erkoyun, Pharmacy stocks run low as Turkey's drug price policy hits supplies, Reuters (Feb. 6, 2019).

[FN38]

. Kate Kelland, Brexit to harm UK's cherished health service, experts say, Reuters (Feb. 25, 2019).

[FN39]

. Karen Lema, Filling ‘Brexodus' gap, Filipino nurses find English tests too daunting, Reuters (April 8, 2019).

[FN40]

. Sudip Kar-Gupta, French drugmaker Sanofi, Google to use data tech for innovations, Reuters (June 18, 2019).

[FN41]

. Francesco Guarascio, No-deal Brexit could deepen Europe's shortage of medicines - experts, Reuters (August 12, 2019).

[FN42]

. Nikolaj Skydsgaard, Lundbeck buys Alder for $2 billion, eyes ‘blockbuster’ migraine therapy, Reuters (September 16, 2019).

[FN43]

. Kate Holton and Paul Sandle, With a backup to the backup, insulin makers say they're primed for Brexit, Reuters (September 17, 2019).

[FN44]

. Igor Ilic, Croatia doctors, nurses to get 7% wage hike; strike averted, Reuters (September 13, 2019).

[FN45]

. Kate Kelland, Drug and medical suppliers say Brexit freight plans needed urgently, Reuters (Sept. 20, 2019).

[FN46]

. Kate Kelland, Brexit may have ‘gravest of consequences' for health - MP, Reuters (Sept. 26, 2019).

[FN47]

. Tom Miles, WHO agrees watered-down resolution on transparency in drug costs, Reuters (May 28, 2019).

[FN48]

. Timothy Gardner, U.S. sanctions on Iran threaten access to certain medicines: report, Reuters (Oct. 29, 2019).

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