# REGULATORY INTELLIGENCE

# YEAR-END REPORT - 2022

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### I. AFRICA

# Doctors Say Lives Are Lost in Hospitals in Ethiopia's Tigray Due to Dwindling Supplies, Blame Blockade

(Reuters) - In the largest hospital in Ethiopia's Tigray region, a child wounded in an air strike bled to death after doctors ran out of gauze and intravenous fluids. A baby died because there were no fluids for dialysis. [FN2]

Doctors at the Ayder Referral Hospital in the regional capital Mekelle, which is under the control of Tigrayan forces fighting the central government, told Reuters by phone the lack of supplies is largely the result of a months-long government aid blockade on the northern region.

'Signing death certificates has become our primary job,' the hospital said in a Tuesday presentation prepared for international aid agencies and shared with Reuters.

Notes and documents in the presentation included case summaries, lists of missing drugs and medical supplies, and photographs of wounded and malnourished patients. Reuters also interviewed three doctors, who asked not to be identified for fear of retribution by Ethiopian officials.

The doctors identified 117 deaths and dozens of complications, including infections, amputations and kidney failure, which they said were linked to shortages of essential medicines and equipment. They did not provide dates for most of them.

War erupted in November 2020 after relations nosedived between Prime Minister Abiy Ahmed and the Tigray People's Liberation Front (TPLF), the party that dominated national politics until Abiy's appointment and controls most of the region. The conflict has killed thousands of people and driven millions more from their homes.

Government spokesman Legesse Tulu on Monday reiterated Ethiopia's position that no blockade had been imposed. He did not respond to questions about the shortages reported by Ayder.

'What is happening in Tigray currently is the sole responsibility of TPLF,' Legesse told Reuters.

He accused the TPLF of looting equipment and medicines at more than a dozen hospitals and 100 health centres when its forces invaded the neighbouring regions of Amhara and Afar last year before being pushed back in December.

Ethiopia's health minister and a TPLF spokesman did not respond to requests for comment. The TPLF has previously denied looting health facilities and blamed the government for shortages of humanitarian supplies.

The United Nations first sounded the alarm about lack of access to Tigray in December 2020, when government forces took control of Mekelle after battling rebellious forces loyal to the TPLF for three weeks.

Access for its trucks has ebbed and flowed since then but declined significantly after government forces withdrew from most of the region at the end of June, according to reports by U.N. humanitarian agency OCHA.

Abiy's government has repeatedly rejected accusations by the United Nations and other aid organizations that it is preventing humanitarian supplies from reaching Tigray.



The government has restricted media access since July. Some aid agencies have been barred, and most communications to the region are down.

Two international aid agencies reached by Reuters did not respond to requests for comment about the Tuesday presentation, which was issued on behalf of all of Ayder hospital's staff.

# 'DE FACTO BLOCKADE'

A senior doctor at Ayder told Reuters that about 80-90% of Tigray's hospitals and clinics were not functioning. The United Nations says more than 90% of the region's 5.5 million people need humanitarian assistance and 400,000 are living in famine-like conditions.

Some supplies reached Tigray's main cities during the first eight months of the conflict, when the region was under government control. But little food and almost no medical supplies have arrived since the government pulled back in late June, doctors said.

They blamed what U.N. and U.S. officials have described as a de facto government blockade. The United Nations estimates at least 100 trucks of aid must enter Tigray each day to keep up with needs. Less than 12% of that has arrived since July, OCHA said last week.

There are three main routes into Tigray, but bridges along two of them were blown up as the Ethiopian military withdrew, OCHA reports said. Convoys attempting to use the remaining land route, through Afar, have faced lengthy security checks and bureaucratic delays that can last weeks. Authorities often do not allow fuel and medication to get through, according to OCHA reports.

At the end of December, Afar authorities unloaded and distributed aid supplies from five of 20 trucks that had been waiting at the Afar border town of Abala for two weeks for clearance to enter Tigray, an OCHA report said.

The World Food Programme told Reuters it would run out of food and fuel in Tigray by mid-January.

Afar regional government spokesman Ahmed Koloyta did not respond to requests for comment. Government spokesman Legesse said trucks that entered Tigray had not returned and were being used by Tigrayan forces.

### **FAMINE**

Ayder has not received a resupply of medicine or equipment since June, the three doctors told Reuters. The 500-bed hospital is running out of everything from oxygen to antibiotics to therapeutic food for malnourished children, they said. Its scanners no longer work.

The percentage of children under 5 admitted with severe malnutrition nearly doubled to over 41% in October.

Three-month-old Surafeal Mearig weighed 3.4 kg at birth but is now 2.3 kg, hospital records show. A photograph shared by his parents shows his ribs protruding, eyes sunken in his skull.

A paediatrician said the boy's parents earned a good living before the war. The father worked as a construction company cashier and his mother in a bank. Neither is working now, according to the case notes.

The mother's milk has dried up and they cannot afford formula, the paediatrican said. The hospital will run out of food soon.

About 82% of essential drugs were available at the hospital a year ago, compared to 17.5% by the end of 2021, the documents state. Among those that have run out - insulin, oxygen and most cancer drugs.

A malnourished baby girl arrived from the town of Abi Adi with pneumonia and kidney disease, the notes show. The hospital could not give her dialysis because it had run out of intravenous fluids. She was one of 35 deaths recorded among dialysis patients since the war started. The dialysis department said it was reusing equipment meant for one patient between five.

One doctor described to Reuters seeing trauma patients succumb to deadly infections because most antibiotics had run out. He recounted the case of an 8-year-old girl who arrived with a head wound on Dec. 12 after the emergency department had run out of gauze, gloves and pain medications.

Staff first used their bare hands to try to staunch her bleeding, and finally scrounged some sutures from another department, but there were no intravenous fluids or blood supplies for a transfusion. She died in her mother's arms, case notes show.

The girl's mother told hospital staff she was injured in a government airstrike on Mekelle as she was watching cartoons at home, a doctor said in the notes.

Reuters could not independently confirm the account. Military spokesman Colonel Getnet Adane did not respond to requests for comment but has previously denied that the government is targeting civilians.

# Somali Doctors Open War-scarred Nation's Only Public Blood Bank

(Reuters) - When Somalia's biggest bomb blast killed more than 500 people in 2017, Dr. Ahmed Abdikadir Mohamed watched helplessly as many of the injured bled to death. <sup>[FN3]</sup>

Exactly one year later, in October 2018, Mohamed opened Benadir Blood Service, Somalia's first public blood bank since 1991.

The bank, run by a team of 20 volunteer doctors, nurses, and lab technicians, delivers life-saving donations to most Mogadishu hospitals.



'We are happy to work at this blood bank...the country has no other blood bank and there is a dire need,' said 32-year-old Mohamed. While private hospitals have their own small banks, Benadir is the only public one.

'Those who die due to lack of blood are more than those who are killed by bullets,' he estimates.

Lack of access to safe blood is a major cause of maternal death. Each year, 5,000 Somali women die from childbirth complications, according to 2017 data from the United Nations Children's Fund, the latest year for which data was available. That same year, there were 740 terror-related deaths, according to the Global Terrorism Index.

In addition to pregnant women and victims of violence, recipients of donated blood include people with chronic disease.

'I have had kidney problems for a long time... my kidneys undergo dialysis. This place helps me... they give me free blood. Thank God,' Moalim Rage Ali Irole told Reuters.

One challenge is convincing people to donate. Some of the stigma around donation decreased in the wake of the Oct. 2017 bombings when the government called on citizens to donate, but misconceptions remain, said Mohamed.

One man who brought his sick mother told Mohamed that he would die if he donated blood.

'This is something strange within the community; they think one will die if one donates,' said Mohamed. But the team explained its safety and eventually convinced him to donate.

But for 20-year-old Mohamed Haji Hussein, donating has become a source of pride.

'I donate my blood for the Somalis... I understand there is lack of blood: that is why I donate it. To save people,' he told Reuters.

Mohamed said other challenges include equipment shortages and scraping together the \$700 monthly operating fees.

The bank stores about 100 units of blood. One unit can save up to three lives, according to WHO.

### Moderna to Build mRNA Vaccine Manufacturing Facility in Kenya

(Reuters) - Moderna Inc said on Monday it would set up a manufacturing facility in Kenya, its first in Africa, to produce messenger RNA (mRNA) vaccines, including COVID-19 shots. [FN4]

Moderna said it expects to invest about \$500 million in the Kenyan facility and supply as many as 500 million doses of mRNA vaccines to the continent each year. It also has plans to start filling doses of its COVID vaccine in Africa as early as 2023.

Africa has lagged sharply behind other regions in vaccinating its citizens through the pandemic and there have been several efforts in recent months to help the continent produce its own mRNA COVID-19 shots.

'We all know the challenges that Kenya and the entire continent of Africa went through in the earlier stages of this pandemic that resulted in Africa being left behind. Not because of want but because of lack and Moderna has come to fill that space,' Kenya's President Uhuru Kenyatta said in a statement.

The World Health Organization last year set up a tech transfer hub in South Africa to give poorer nations the know-how to produce COVID-19 vaccines and has been trying to get Moderna and Pfizer to join in its efforts.

However, in September, a senior WHO official said there had not been much progress in talks with Moderna.

WHO-backed South Africa's Afrigen Biologics said in February it would produce a version of Moderna's shot, though it has not yet managed to enlist the U.S. vaccine maker's assistance.

BioNTech, which teamed up with Pfizer to make the western world's most widely-used COVID-19 shot, has also announced plans to begin work on its mRNA manufacturing facility in the African Union this year.

Moderna's Kenyan facility would manufacture drug substance and could be expanded to include fill/finish and packaging capabilities, the company said.

Moderna's COVID vaccine brought in \$17.7 billion in sales in 2021 and has been cleared for use in over 70 countries.

The company is developing several other vaccines based on mRNA technology, including for respiratory syncytial virus, HIV and shingles.

### Main Hospital in Ethiopia's Tigray's Region Runs Out of Food

(Reuters) - The main hospital in Ethiopia's war-ravaged region of Tigray has sent home 240 patients after food supplies ran out last week, officials said. [FN5]

The decision by Ayder Referral Hospital in Tigray's capital Mekelle underscores how little food aid is reaching the region despite the government's declaration in March of a unilateral truce to allow aid deliveries.

One hospital official, who asked not to be named, said about 360 patients remained who were able to purchase their own food. New patients without food or money were being turned away, he said.

Those who had to leave included babies with meningitis and tuberculosis and a 14-year-old boy with HIV, two nurses told Reuters.



Tedros Fissehaye, a pediatrics ward nurse, said patients and their families went hungry on Thursday April 14. On Friday April 15, he had to tour the wards and tell them there would be no more meals. Ten patients left.

'Nobody cried. We have finished our tears for months now. But every nurse was so sad,' he told Reuters. 'The families said, pray for us, instead of dying here let's go home and die there.'

Another pediatric nurse, Mulu Niguse, said the hospital had run out of 90% of medication, but last month had received some HIV pills and tried to treat other diseases with any antibiotics they could scrounge. The discharged children would likely die, she said.

Ethiopia's Minister of Health Lia Tadesse and Mitiku Kassa, head of the National Disaster Risk Management Commission, didn't respond to requests for comment.

Conflict erupted in November 2020 between the central government and Tigray's rulers. Since the military pulled out of Tigray in July following months of bloody battles, only a tiny trickle of food aid has entered. The United Nations has said 100 trucks of aid are needed daily. But convoys have struggled to pass, partly due to fighting and partly due to bureaucratic delays.

Since the government's ceasefire announced on March 25, 71 trucks have made it in, said Michael Dunford, regional head of the United Nations' World Food Programme. A third convoy had been cleared by federal government and WFP is negotiating with regional authorities for safe passage, he said.

'It's essential that these convoys move and that they move now. If not, then we ... will see a spike in hunger related deaths,' he told Reuters.

More than 90% of Tigray's people need food aid. Staff in Ayder have not been paid since July and were themselves relying on the hospital for food. Nurse Mulu said her children ate once a day.

One doctor said that since the food ran out, he'd discharged two cancer patients waiting for operations; he'd operated on a third this Tuesday who had only been able to afford milk.

The hospital has no cancer drugs, the doctor said, sharing pictures of a 2-year-old girl, her eye disfigured by a bulging tumour, and a 14-year-old boy hooked up to a drip because nothing else was available.

'If you come to the hospital it is so empty,' he said sadly.

### Zimbabwe Blames Measles Surge on Sect Gatherings after 80 Children Die

(Reuters) - A measles outbreak has killed 80 children in Zimbabwe since April, the ministry of health has said, blaming church sect gatherings for the surge. [FN6]

In a statement seen by Reuters on Sunday, the ministry said the outbreak had now spread nationwide, with a case fatality rate of 6.9%.

Health Secretary Jasper Chimedza said that as of Thursday, 1,036 suspected cases and 125 confirmed cases had been reported since the outbreak, with Manicaland in eastern Zimbabwe accounting for most infections.

'The ministry of health and child care wishes to inform the public that the ongoing outbreak of measles which was first reported on 10th of April has since spread nationwide following church gatherings,' Chimedza said in a statement.

'These gathering which were attended by people from different provinces of the country with unknown vaccination status led to the spread of measles to previously unaffected areas.'

Manicaland, the second-most populous province, had 356 cases and 45 deaths, Chimedza said.

Most reported cases are among children aged between six months and 15 from religious sects who are not vaccinated against measles due to religious beliefs, he added.

Bishop Andby Makuru, leader of Johanne Masowe apostolic sect, did not immediately respond to a request for comment.

In Zimbabwe, some apostolic church sects forbid their followers from taking vaccinations or any medical treatment. The churches attract millions of followers with their promises to heal illnesses and deliver people from poverty.

With a low vaccination rate and in some cases, no record keeping, the government has resolved to start a mass vaccination campaign in areas where the outbreak was recorded.

The measles outbreak is expected to strain an ailing health sector already blighted by lack of medication and intermittent strikes by health workers.

### Dozens of Child Deaths Prompt Gambia to Suspend Paracetamol Syrup Sales

(Reuters) - Gambia on Tuesday ordered importers and shops to suspend sales of all brands of paracetamol syrup while the government investigates a suspected link between the medicine and the deaths of dozens of young children. [FN7]

Last Thursday, the head of the West African country's health service said it had launched the probe after a spike in cases of acute kidney injury among children under the age of five was detected in late July.



The medicines regulator, known as the Medicines Control Agency (MCA), said there was insufficient data to warrant a general ban on paracetamol syrups, a painkiller often used to treat fevers in children.

The children suffered symptoms including an inability to pass urine, fever and vomiting that quickly led to kidney failure.

It did not name any specific brands, but said some samples had been sent abroad for quality control testing.

Last week, World Health Organisation officials said the evidence pointed not to paracetamol but to an infectious origin such as polluted water, but emphasised there were many unanswered questions.

### Uganda Says Ebola Caseload Rises to 16 as Outbreak Grows

(Reuters) - Uganda said on Sunday its Ebola caseload had jumped to 16 people while a further 18 people also likely had the disease, fuelling fears of a spreading outbreak that involves a strain for which a vaccine has not yet been found. [FN8]

In a tweet, the ministry of health also said the death toll of confirmed cases remained four while 17 others classified as probable cases had also died. The outbreak had also now spread to three districts, all in central Uganda.

The east African country last week announced the outbreak of Ebola, a haemorrhagic fever whose symptoms include intense body weakness, muscle pain, headache and sore throat, vomiting, diarrhoea and rashes among others.

The current outbreak, attributed to the Ebola Sudan strain, appears to have started in a small village in Mubende district around the beginning of September, authorities have said.

The first casualty was a 24-year old man who died earlier this week.

The World Health Organization says the Ebola Sudan strain is less transmissible and has shown a lower fatality rate in previous outbreaks than Ebola Zaire, a strain that killed nearly 2,300 people in the 2018-2020 epidemic in neighbouring Democratic Republic of Congo.

# Africa CDC Hoping to Send Team Back to Ethiopia's Tigray Region After Peace Deal

(Reuters) - Africa's top public health body is hoping to send its team back to the Tigray region 'as soon as the situation allows' following a peace agreement in Ethiopia, its acting Director Ahmed Ogwell Ouma said on Thursday. [FN9]

The Ethiopian government and regional forces from Tigray agreed on Wednesday to cease hostilities, a dramatic diplomatic breakthrough two years into a war that has killed thousands, displaced millions and left hundreds of thousands facing famine.

Ouma said the Africa CDC -- which is headquartered in Ethiopia's capital Addis Ababa -- had pulled out its team from Tigray when the conflict intensified, but would consider sending it back once peace is restored on the ground.

'As soon as the situation allows, we will be sending back our teams to the ground because there's a lot of the public health emergency issues to deal with at the moment,' Ouma told an online briefing.

The United Nations says the war has led to a de facto blockade of Tigray that has lasted close to two years, with humanitarian supplies of food and medicines unable to get through most of the time.

# II. AMERICAS

# Canadian Hospitals Strain as Omicron Hits Health Workers

(Reuters) - After a year as an emergency department nurse at a busy Toronto hospital in the middle of the coronavirus pandemic, Aimee Earhart called it quits last week. She is moving to Florida for a short contract before getting work as a travel nurse for what she hopes will be double the salary. [FN10]

'We're just burnt out all the time,' Earhart said. She says she will miss her colleagues, and might have stayed if working conditions were better.

The COVID-19 pandemic and its highly contagious Omicron variant have made a challenging staffing situation in Canada's hospitals worse.

Interviews with a dozen health care workers, including eight current and former nurses, reveal a health system strained by a pandemic wave that hit at the worst possible time - sickness sidelining staff as more COVID-19 patients than ever need hospitalization, forcing health workers exhausted by two unrelenting years to take on more work.

Hospitals have been asking staff to forego holidays or take on overtime shifts.

Canadians take pride in their public health system. But by failing to adequately invest in it, critics say, governments left it vulnerable to the ravages of a years-long public health emergency. If health workers leave and are not replaced - thanks to training and certification backlogs, capped wages or the perception of a punishing profession - that could hurt health system capacity.

Job vacancies in Canada's health and social assistance sector increased by 78.8% between the third quarter of 2019 and the third quarter of 2021, according to Statistics Canada.



Ontario's government, which has come under fire for capping the salaries of some public employees, including nurses, before the pandemic, said in a statement it added 6,700 health care workers and staff since the pandemic began and planned to add another 6,000 by March. It did not clarify whether this was a net increase.

### 'I JUST DIDN'T HAVE ANY MORE TO GIVE'

Lindsay Peltsch knew she had to quit when she stopped wanting to bathe her patients.

'I still did that but I didn't get the same sense of satisfaction anymore,' she said. 'It seems small but it's a big deal because people's dignity is a big part of what we do.'

Peltsch worked for 12 years as a pediatric nurse, 10 of them at SickKids hospital in Toronto. She fell in love with nursing but the strain became too much, she said.

Fully staffed shifts became a rarity. One of her last ER shifts was 10 nurses short. She also feels there is a lack of respect for the profession.

'I just got to a point where I just didn't have any more to give.'

A SickKids spokesperson said that the hospital 'has experienced challenges related to staffing' but was not aware of critical care unit shifts being short 10 nurses.

Praveen Nakesvaran and his respiratory therapist colleagues at Humber River Hospital have taken on roles normally filled by nurses when they prone COVID-19 patients - rolling them, tubes and all, gingerly onto their stomachs in hopes that will boost lung function.

'Usually we're just at the head of the bed: We make sure the tube is secure,' Nakesvaran said. 'Now we're kind of doing the nursing jobs, as well.'

Suzi Laj an intensive care unit manager at the hospital says she knows morale has been an issue and has sought to address it through everything from daily huddles to bringing in chaplaincy staff. They are 'trying to keep them hopeful and, you know, supporting them ... but their resilience is really wearing,' she said.

Public health experts say Omicron's peak may be approaching in Canada, and Ontario announced plans last week to loosen restrictions. But for now the health worker crunch remains.

Some provinces have made provisions for health care workers to return to work soon after testing positive for COVID-19; Ontario is letting internationally trained nurses, who often face hurdles and long waits before being able to practice in Canada, get on-the-job experience in hospitals.

Manitoba, meanwhile, said it will send hundreds of patients to get procedures in North Dakota because its hospitals lack capacity.

# 'WE ARE NOT ASKING FOR AN EASIER JOB'

When one Montreal ER nurse came down with a bad case of laryngitis during a shift, she felt torn between staying at work to help her colleagues and going home to rest and wait for COVID-19 test results, she told Reuters. The young nurse, who spoke on condition of anonymity for fear of work reprisals, said she was encouraged to complete her shift since her co-workers badly needed the help.

'It was really more guilt than anything,' she said.

'You feel like you're leaving those who are working in a really tough spot.'

Doris Grinspun, CEO of the Registered Nurses' Association of Ontario, gets calls from nurses across the province wondering how they will cope. 'All the hospital are scrambling.'

It translates, she said, to 'unsafe care.'

When Peltsch talks to her former co-workers, 'they're like, 'Don't come back.' — A resilient group of people is starting to crumble,' she said.

'We are not asking for an easier job. We are asking to be able to do the hard job we signed up for safely.'

# Proposed Language Law Sends Chill Through Some of Quebec's Hospitals

(Reuters) - A planned change to French language laws in Quebec could see understaffed hospitals in the Canadian province wrestling with hiring headaches during a labor shortage while battling the ongoing COVID-19 pandemic, critics say. [FN11]

Language remains a sensitive issue in the mostly French-speaking province, where unhappiness over the dominance of English helped fuel the rise of the separatist Parti Quebecois (PQ) in the 1970s.

The sweeping legislation proposed by the nationalist Coalition Avenir Quebec (CAQ) government would, among other things, make it harder for hospitals to hire staff that speak languages other than French, complicating efforts to serve patients, said Eric Maldoff, chair of a coalition of healthcare institutions that supports the use of French but wants the sector exempt from the law.

Under the proposed Bill 96, administrators, for example, would need to take 'reasonable means' to avoid including other languages as a job requirement.

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'If you cannot recruit the people who can deliver the service, then it's hard to have the service even if it is permitted,' said Maldoff, who served as an adviser to former Canadian Prime Minister Jean Chretien.

Quebec, the country's second-most populous province, has one of Canada's highest job vacancy rates, with unfilled positions in the health and social assistance network especially worrisome, the non-profit Institut du Qu?bec wrote in 2021.

The proposed law, which also would toughen French usage in smaller companies and colleges, is under review by lawmakers. It's not clear when or if it would be approved by the province's legislature.

Changes to Quebec's language laws are tricky as they have sometimes triggered constitutional challenges. Quebec's government, however, has embedded language in Bill 96 in an effort to bypass such legal issues.

Elisabeth Gosselin, a spokesperson for Quebec Justice Minister Simon Jolin-Barrette, said there was no need for worry. She said the law would not change rights set out in the province's existing health law.

'There is nothing in the bill that will prevent a citizen from receiving adequate care,' she said.

### 'VULNERABLE POSITION'

Quebec Premier Francois Legault's government, which faces an October election, proposed the bill following concerns over a decline in French usage among downtown businesses in Montreal, the province's largest city, and among top executives.

On Thursday, Montreal-based Canadian National Railway Co came under pressure from pension fund Caisse de depot et placement du Quebec, and Prime Minister Justin Trudeau over a lack of native French speakers on the company's board.

Last year, the chief executive officer of Montreal-based Air Canada apologized after suggesting he did not need to speak French, one of Canada's two official languages.

'It's important to understand that French will always be in a vulnerable position in North America,' Legault, who was a PQ member of Quebec's legislature from 1998 to 2009, said on Wednesday.

While exceptions are cited for health and public safety, the bill has created confusion over who is entitled to health services in English and other languages, raising alarm for new arrivals including refugees, Maldoff said.

It also allows healthcare workers' decisions and French language skills to be challenged through anonymous complaints, which would have a chilling effect, he said.

Quebec's justice department did not answer requests on who would be able to get services in English under the proposed law.

# British Columbia Reaches \$116 million Settlement with Purdue Pharma over Opioid Crisis

(Reuters) - Canada's British Columbia province said on Wednesday it reached a C \$150 million (\$116.50 million) settlement with OxyContin maker Purdue Pharma Canada over healthcare costs related to the opioid crisis. [FN12]

Purdue had been named as one of more than 40 defendants - drugmakers and distributors - in a proposed class-action lawsuit brought by British Columbia in 2018 on behalf of all provincial and federal Canadian governments. The lawsuit aims to recover healthcare costs for the 'wrongful conduct of opioid manufacturers, distributors and their consultants.'

'The proposed settlement with Purdue Canada has been agreed to by all federal, provincial and territorial governments and totals C \$150 million in monetary benefits, plus additional benefits including access to information and documents relevant to the lawsuit,' British Columbia said in a statement on Wednesday.

It added that this is the largest settlement of a governmental health claim in Canadian history.

Purdue Pharma Canada told Reuters it agreed to pay the sum and provide access to information sought by prosecutors for which the company 'will be released from all past and present government opioid-related claims and liability.'

Canada had a total of 29,052 apparent opioid-related deaths between January 2016 and December 2021, with a total of 7,560 such deaths occurring in 2021, according to government data.

During the first year of the COVID-19 pandemic, there was a 96% jump in such deaths, the data showed.

'We know that no amount of money can bring back those who have died, but we are committed to holding corporations and others accountable for acts of alleged wrongdoing committed in the manufacturing and distribution of opioid products,' British Columbia's Attorney General David Eby said.

The settlement includes no admission of wrongdoing or liability on the part of Purdue Pharma Canada or any of its related parties, the company said in an emailed statement.

# U.S. Declares Monkeypox Outbreak a Public Health Emergency

(Reuters) - The United States has declared monkeypox a public health emergency, the health secretary said on Thursday, a move expected to free up additional funding and tools to fight the disease. [FN13]



The U.S. tally topped 6,600 on Wednesday, almost all of the cases among men who have sex with men.

'We're prepared to take our response to the next level in addressing this virus, and we urge every American to take monkeypox seriously,' Health and Human Services Secretary Xavier Becerra said at a briefing.

The declaration will improve the availability of data on monkeypox infections that is needed for the response, U.S. Centers for Disease Control and Prevention Director Rochelle Walensky said, speaking alongside Bacerra.

The U.S. government has come under pressure for its handling of the outbreak.

The disease began spreading in Europe before moving to the United States, which now has the most cases in the world. Vaccines and treatments have been in short supply and the disease often left for historically underfunded sexual health clinics to manage.

The World Health Organization declared monkeypox a 'public health emergency of international concern,' its highest alert level. The WHO declaration last month sought to trigger a coordinated international response and unlock funding to collaborate on vaccines and treatments.

Governments are deploying vaccines and treatments that were first approved for smallpox but also work for monkeypox.

The U.S. government has distributed 600,000 doses of Bavarian Nordic's Jynneos vaccine and deployed 14,000 of Siga Technologies' TPOXX treatment, officials said, though they did not disclose how many have been administered.

Walensky said the government aims to vaccinate more than 1.6 million high-risk individuals.

U.S. Food and Drug Administration Commissioner Robert Califf said the agency was considering freeing up more Jynneos vaccine doses by allowing doctors to draw 5 doses of vaccine from each vial instead of the current 1 dose by using a different subcutaneous method of inoculation.

U.S. President Joe Biden this month appointed two federal officials to coordinate his administration's response to monkeypox, following declarations of emergencies by California, Illinois and New York.

First identified in monkeys in 1958, the disease has mild symptoms including fever, aches and pus-filled skin lesions, and people tend to recover from it within two to four weeks, the WHO says. It spreads through close physical contact and is rarely fatal.

Anthony Fauci, Biden's chief medical adviser, told Reuters on Thursday that it was critical to engage leaders from the gay community as part of efforts to rein in the outbreak, but cautioned against stigmatizing the lifestyle.

'Engagement of the community has always proven to be successful,' Fauci said.

### III. ASIA

# Australia's Ramsay Health Care to Buy Mental Healthcare Group Elysium for \$1 billion

(Reuters) - Australia's Ramsay Health Care Ltd said on Monday it would buy Britain's Elysium Healthcare Ltd for 775 million pounds (\$1.03 billion) as it looks to expand its presence in mental healthcare services. [FN14]

The COVID-19 pandemic has put an even larger spotlight on mental health as lockdowns take a toll on people's wellbeing. With greater acceptance and less stigma, demand for mental health services has started to outstrip supply.

The British government plans to increase spending on mental health services by 2.3 billion pounds a year by 2023-2024.

'The acquisition of Elysium will expand Ramsay's patient pathways into the 15 billion pound UK mental health market at a time when more and more people are seeking support for mental health, learning difficulties and neurological issues,' Ramsay Chief Executive Officer Craig McNally said in a statement.

Apart from adding 72 sites to its portfolio, the deal will allow the Australian hospital operator to further build on Elysium's relationship with the state-run National Health Services.

The acquisition of Elysium, which is owned by private equity firm BC Partners, is expected to add to Ramsay's fiscal 2023 earnings in the mid-single digits and provide savings of 5 million pounds a year.

The British firm had reported revenue of 349 million pounds for the 12 months to June this year. It did not immediately respond to a request for comment.

For Ramsay, the deal came five months after it failed in its 1.04 billion pound attempt to buy Spire Healthcare after it was blocked by some shareholders of the British firm.

# No Exit from Zero-COVID: China Struggles to Find Policy Off-ramp

(Reuters) - China's 'zero-COVID' stance has put it at odds with the rest of the world and is exacting a mounting economic toll, but an exit strategy remains elusive as authorities worry about the ability of the healthcare system to cope and adapt to new strains. [FN15]

Chinese medical experts believed last year that higher vaccination rates would eventually allow China to relax tough rules on movement and testing as infection rates slow elsewhere.



The emergence of the highly transmissible Omicron variant dashed those hopes.

While some analysts have branded China's approach as 'unsustainable', many local health experts - and some from overseas - say the country has no choice but to continue given its less developed health system.

Some even argue China's economy could even emerge stronger than ever if it keeps Omicron at bay.

'For a large country with a population of 1.4 billion, it must be said that the cost effectiveness of our country's prevention and control has been extremely high,' said Liang Wannian, head of the expert epidemic prevention group at China's National Health Commission, at a Saturday briefing.

Kristalina Georgieva, managing director of the International Monetary Fund, called on China last week to 'reassess' its approach, saying it had now become a 'burden' on both the Chinese and global economies.

But China is concerned the cost of lowering its defences could prove even higher, especially with a healthcare system that has lagged its broader development.

'With a large population and high density the government is rightly concerned about impacts for the spread of the virus,' said Jaya Dantas, professor of international health at the Curtin School of Population Health in Perth, Australia.

China had 4.7 million registered nurses at the end of 2020, or 3.35 per 1,000 people, official data showed. The United States has around 3 million - around 9 per 1,000.

China is also wary of the risk of new variants, especially as it refuses to import foreign vaccines. Studies suggest China's vaccines are less effective against Omicron and it has not yet rolled out its own mRNA version.

Wu Zunyou, chief epidemiologist at the Chinese Center For Disease Control and Prevention, warned the 'insidious' Omicron could still lead to a rise in the absolute number of deaths even if it was proven to be less deadly, and China must remain patient.

'China's medical capacity and standards are not as good as Britain or the United States, but the results of China's coronavirus prevention and control are far, far superior,' he said in a weekend interview with the Beijing News.

### 'PREMATURE OPTIMISM'

China has stepped up its health warnings, urging citizens to ignore claims that Omicron is no more serious than the 'flu and to stay vigilant.

On Wednesday, the Global Times, published by the official People's Daily, also lashed out at overseas media for 'mocking' China's policies, saying they saved lives.

Foreign criticism was 'based on unfounded or premature optimism regarding the end of the pandemic', it added.

Experts in China and overseas have also cast doubt on the hope that Omicron represents the final stage of the pandemic.

'SARS-CoV-2 will not magically turn into a malaria-like endemic infection where levels stay constant for long periods,' said Raina MacIntyre, head of the Biosecurity Research Programme at the University of New South Wales' Kirby Institute.

'It will keep causing epidemic waves, driven by waning vaccine immunity, new variants that escape vaccine protection, unvaccinated pockets, births and migration,' she told Reuters.

# **END-GAME**

China's economy is expected to slow as a result of COVID related supply disruptions, while lockdowns to douse domestic outbreaks weigh on travel and consumption.

Hong Kong's 'zero-COVID' approach has put the Chinese-controlled city out of step with other global finance centres and is battering its economy.

Still, China's economy has remained resilient, with GDP growth at 8.1% last year, far exceeding expectations.

MacIntyre of the Kirby Institute said it wasn't a 'binary choice' between opening up and remaining isolated, adding there was 'no need to surrender to the virus, as Australia is doing at the moment.'

China could still emerge from the crisis in the strongest position, especially if COVID leads to widespread cognitive impairment, organ damage and other long-term conditions in other countries, she said.

'If China keeps the virus largely under control, their population will be fit and healthy into the future, while the United States and Europe will be groaning under an unprecedented burden of chronic disease.'

### Lacking Vaccines, N. Korea Battles COVID with Antibiotics, Home Remedies

(Reuters) - Standing tall in bright red hazmat suits, five North Korean health workers stride towards an ambulance to do battle with a COVID-19 outbreak that - in the presumed absence of vaccines - the country is using antibiotics and home remedies to treat. [FN16]

The isolated state is one of only two countries yet to begin a vaccination campaign and, until last week, had insisted it was COVID-free.



Now it is mobilizing forces including the army and a public information campaign to combat what authorities have acknowledged is an 'explosive' outbreak.

In an interview on state television on Monday, Vice Minister of Public Health Kim Hyong Hun said the country had switched from a quarantine to a treatment system to handle the hundreds of thousands of suspected 'fever' cases reported each day.

The broadcaster showed footage of the hazmat team, and masked workers opening windows, cleaning desks and machines and spraying disinfectant.

To treat COVID and its symptoms, state media have encouraged patients to use painkillers and fever reducers such as ibuprofen, and amoxicillin and other antibiotics - which do not fight viruses but are sometimes prescribed for secondary bacterial infections.

While previously playing down vaccines as 'no panacea,' media have also recommended gargling salt water, or drinking lonicera japonica tea or willow leaf tea three times a day.

'Traditional treatments are the best!' one woman told state broadcasters as her husband described having their children gargle with salted water every morning and night.

An elderly Pyongyang resident said she had been helped by ginger tea and ventilating her room.

'I was first scared by COVID, but after following the doctors' advice and getting the proper treatments, it turned out not a big deal,' she said in a televised interview.

#### 'LACK OF UNDERSTANDING'

The country's leader, Kim Jong Un, said on Sunday - when state news agency KCNA reported 392,920 more cases of fever and eight more deaths? that drugs reserves were not reaching people, and ordered the army medical corps to help stabilize supplies in Pyongyang, where the outbreak appears to be centred.

KCNA said the cumulative tally of the fever-stricken stood at 1,213,550, with 50 deaths. It did not say how many suspected infections had tested positive for COVID.

Authorities say a large proportion of the deaths have been due to people 'careless in taking drugs due to the lack of knowledge and understanding' of the Omicron variant and the correct method for treating it.

The World Health Organization has shipped some health kits and other supplies to North Korea, but has not said what drugs they contain. Neighbours China and South Korea have offered to send aid if Pyongyang requests it.

While not claiming that antibiotics and home remedies will eliminate COVID, North Korea has a long history of developing scientifically unproven treatments, including an injection made from ginseng grown in rare earth elements it claimed could cure everything from AIDS to impotence.

Some have roots in traditional medicines, while others have been developed to offset a lack of modern drugs or as 'made in North Korea' exports.

Despite a high number of trained doctors and experience mobilizing for health emergencies, North Korea's medical system is woefully under-resourced, experts say.

In a March report, an independent U.N. human rights investigator said it was plagued by 'under-investment in infrastructure, medical personnel, equipment and medicine, irregular power supplies and inadequate water and sanitation facilities.'

Kim Myeong-Hee, 40, who left the North for South Korea in 2003, said such shortcomings led many North Koreans to rely on home remedies.

'Even if we go to the hospital, there are actually no medicines. There was also no electricity so medical equipment could not be used,' she said.

When she contracted acute hepatitis, she said she was told to take minari - a water parsley made famous by the 2020 film of the same name? every day, and to eat earthworms when afflicted by another, unknown illness.

Home remedies had sometimes failed to prevent loss of life during epidemics in the 1990s, Kim added.

# Indonesia to Investigate Cases of Fatal Kidney Injury Among Children

(Reuters) - Indonesia will investigate cases of acute kidney injury which has caused the deaths of more than 20 children in its capital Jakarta this year, health authorities said on Wednesday. <sup>[FN17]</sup>

The probe comes as authorities in Gambia said nearly 70 children died from acute kidney injury after taking a locally-sold paracetamol syrup used to treat fever.

Indonesia will coordinate with investigators from the World Health Organization (WHO) that have found 'unacceptable' levels of diethylene glycol and ethylene glycol, which can be toxic, in four products made by New Delhi-based Maiden Pharmaceuticals Ltd.

Indonesia's drug regulator (BPOM) said in a statement the syrups were not registered in the country.



Mohammad Syahril, a health ministry spokesperson, told Reuters 131 cases of acute kidney injury have been found nationwide since January, citing the country's paediatric association (IDAI) data. The total number of deaths nationwide is still being determined, he said.

Syahril added the cases in Gambia are not related to those in Indonesia.

Separately, the Jakarta health agency said there have been a total of 31 cases reported in the city since January, of which 68% have been fatal.

Separately, the Jakarta health agency said there have been a total of 31 cases reported in the city since January, of which 68% have been fatal.

The health ministry said it is talking to experts from the WHO that are investigating the case in Gambia and it has formed a team with IDAI and a Jakarta-based hospital to look into the matter.

The health ministry said early findings point to potential intoxication as a cause of the illness, but no definitive cause has been found yet. The ministry said further research was needed.

Indian authorities said on Wednesday they found 12 violations of good practices at a factory of Maiden and halted production of cough syrups at the plant.

# Indonesia Reports 99 Child Deaths from Acute Kidney Injury this Year

(Reuters) - Close to 100 children in Indonesia have died from acute kidney injury (AKI) so far this year, a health ministry official said on Wednesday, as a team of experts investigates the spike in cases. [FN18]

The rise in fatalities comes as Gambia's government probes the death of 70 children from AKI linked to paracetamol syrups used to treat fever, which contained excessive levels of diethylene glycol and ethylene glycol.

Officials at Indonesia's food and drug agency said those products were not available locally and the ingredients they were comprised of had now been banned from all child medicinal syrups sold in the country.

As of Oct 18. Indonesian authorities have identified 206 cases of AKI among children, with 99 fatalities, health ministry spokesperson Mohammad Syahril said on Wednesday.

'As a preventive measure, the ministry has asked all health workers in all health facilities to temporarily stop prescribing or providing any liquid or syrup medication until our research and investigation is completed,' he told a news conference, adding that 65% of cases had been treated in Jakarta.

The ministry has purchased specialist medicines for AKI to address the spike, he said, while an investigation into the cause continues.

Indonesia has formed an expert team to look into the AKI spike among children, comprised of local health and paediatrics officials and World Health Organization (WHO) representatives. WHO experts investigating cases in Gambia were being consulted.

A health ministry letter dated Oct. 18 and seen by Reuters requested hospitals collect all medicines that families had given to those children admitted with AKI, so toxicology tests could be conducted.

In the same letter, it said chemists should halt the sale of syrup-based medicine until further notice.

### **IV. EUROPE**

# Flow of Health Supplies Is Reaching Ukraine, WHO Says

(Reuters) - A flow of medical gear and equipment, including trauma kits, is reaching Ukraine to prop up a health care system grappling with a shortage of supplies amid Russia's invasion, the World Health Organization said on Monday. [FN19]

Supply chains have been severely disrupted, with many distributors knocked out, some stockpiles out of reach because of military operations, supplies of medicine running low, as hospitals struggle to care for the sick and wounded, it said.

'The current estimated number of people impacted in Ukraine is 18 million, of which 6.7 million are internally displaced,' the agency said in a statement. 'Nearly 3 million people have fled the country.'

WHO was working with partners to alleviate shortages of critical equipment and medication such as oxygen and insulin, surgical supplies, anaesthetics, and transfusion kits, it added.

Items being shipped included oxygen generators, electrical generators, defibrillators, monitors, anaesthesia drugs, rehydration salts, gauze and bandages.

WHO said supplies were being distributed in coordination with Ukraine's health ministry, backed by a support hub in neighbouring Poland.

'The coming days and weeks will see a constant flow of medical supplies, as part of an effort to ensure people's access to essential drugs and medical care,' it added.



The agency again condemned attacks on health care providers, saying it had verified 31 such attacks from the time Moscow invaded on Feb. 24 until March 11.

These led to 12 deaths and 34 injuries, with health workers accounting for eight of the injured and two of those killed. More attacks were being verified.

Russia denies targeting civilians in what it calls a 'special operation' to disarm and 'de-Nazify' Ukraine.

# Ukraine War Shutters HIV Clinics, Disrupts Drug Supplies

(Reuters) - In basement shelters and makeshift clinics, Ukrainian doctors are striving to keep treatment for HIV-positive people on track as Russia's invasion raises fears that years of progress to combat the virus could be undone. [FN20]

Russian bombing and fighting has shuttered HIV clinics in two Ukrainian cities and forced others to limit their services, a leading nonprofit said, while the supply and distribution of vital antiretroviral drugs is also at risk.

'(The war is) making people with HIV more vulnerable to everything,' Valeriia Rachynska, the head of human rights at the All-Ukrainian Network of People Living With HIV group, told the Thomson Reuters Foundation in a WhatsApp call.

Infectious disease experts say the war could unleash a public health crisis both in Ukraine and neighboring countries in HIV, tuberculosis (TB), hepatitis C, and opioid addiction.

Research shows interrupting antiretroviral treatment can give rise to drug-resistant strains of HIV, potentially narrowing future treatment options, and also undoes the protection the therapy provides against transmitting the virus.

'It's just heartbreaking, and it's so disturbing,' said Chris Beyrer, an epidemiologist at Johns Hopkins Bloomberg School of Public Health, referring to the war's impact on Ukraine's HIV prevention, care and treatment infrastructure.

Roughly 260,000 people were living with HIV in the nation of 43 million people in 2021, according to UNAIDS, with about 152,000 people of them receiving treatment.

'Whatever the outcome from a military and political perspective, this crisis will shake health and will generate a major health crisis across the region,' said Michel Kazatchkine, former executive director of the Global Fund to Fight AIDS, Tuberculosis and Malaria.

### AD HOC CLINICS

According to the AIDS Healthcare Foundation (AHF), military assaults and bombings have forced the complete closure of its clinics in the eastern city of Kharkiv and the seaport of Mariupol in the south.

The NGO, which provided treatment to about one in three people receiving antiretrovirals in Ukraine when the war broke out, said Russian military incursions have also limited the work of clinics in cities including Kherson, Mykolaiv, Severodonetsk, Slavyansk and Odessa.

Still, Martin C. Donoghoe, senior advisor for TB, HIV and hepatitis at the WHO's Ukraine office, said many of the nation's infectious disease physicians remain in the country, managing to care for their patients from basements and ad hoc clinics.

'There is an incorrect narrative that nothing is working,' Donoghoe said from Copenhagen, where he is in regular contact with colleagues in Ukraine, adding that many people are still receiving their HIV medications.

But as international NGOs mobilise to send new supplies to the country, distributing them could also prove difficult.

'The challenge will then be not only to bring them inside the country, but to dispatch these medicines in various areas of Ukraine,' said Kazatchkine.

Rachynska, who left the capital for the relative safety of western Ukraine after Russian troops invaded the country on Feb. 24, said she feared President Vladimir Putin would seek to enforce the same punitive policies in Ukraine as he has at home.

'Am I afraid of Russia? Yes. But not to fight with them or to have a war with them, but to live with them,' Rachynska said, adding that LGBTQ+ Ukrainians could be at particular risk.

In Russia, gay men and people who inject drugs are often persecuted by the police, with the names of HIV-positive people kept on a central registry.

HIV awareness programmes are often stymied by the effect of the country's 2013 'gay propaganda' law that outlaws discussion of LGBTQ+ matters with minors, Beyrer added.

Beyrer said he was concerned that prominent people working in HIV services in Ukraine could be targeted under Russian rule.

Ruslan, a 42-year-old bisexual man living with HIV who declined to give his surname or reveal his exact location, said he feared losing access to antiretroviral medication if drafted into the army.

'I am worried that I and people with HIV won't receive timely therapy, Ruslan said. 'I try not to lose heart and live in the hope that all will be well.'

'DISASTER'



Global NGOs are trying to help avert an infectious-disease crisis in Ukraine and across Europe, where some 3.6 million refugees have fled so far.

The Global Fund has committed an extra \$15 million to prop up prevention, testing and treatment of TB and HIV, as well as support opioid addiction treatment programmes in Ukraine.

The U.S. global HIV aid programme, PEPFAR, has contributed an additional \$6 million towards providing antiretroviral treatment in Ukraine.

A delivery of 209,000 90-day supplies of antiretrovirals is expected to arrive in Poland this week bound for Ukraine, which has made more progress against HIV than most of its neighbors in Eastern Europe and Central Asia in recent years.

According to UNAIDS, this is the only global region to have seen a substantial rise - of 43% - in the estimated annual HIV transmission rate between 2010 and 2020.

In Russia, new HIV diagnoses have trended upward over the past decade, with nearly 1 million people testing positive, according to the European Centre for Disease Control and Prevention.

By contrast, Ukraine reversed annual HIV transmissions and deaths during the decade - achievements that are now threatened, Rachynska said.

If the Russians occupy Ukraine, 'it will be a disaster for the gay population, for people living with HIV', she said.

'We will have the same disaster in HIV and AIDS that (Russia has) right now.'

### Ukraine's Zelenskiy Says Russia Has Devastated Hundreds of Hospitals

(Reuters) - Russia's invasion of Ukraine has devastated hundreds of hospitals and other institutions and left doctors without drugs to tackle cancer or the ability to perform surgery, President Volodymyr Zelenskiy said on Thursday. [FN21]

Zelenskiy, in a video address to a medical charity group, said many places lacked even basic antibiotics in eastern and southern Ukraine, the focal points of the fighting.

'If you consider just medical infrastructure, as of today Russian troops have destroyed or damaged nearly 400 healthcare institutions: hospitals, maternity wards, outpatient clinics,' he told the gathering.

In areas occupied by Russian forces, he said, the situation was catastrophic.

'This amounts to a complete lack of medication for cancer patients. It means extreme difficulties or a complete lack of insulin for diabetes. It is impossible to carry out surgery. It even means, quite simply, a lack of antibiotics.'

The Kremlin says it targets only military or strategic sites.

In one of the most widely denounced acts of the war, a maternity hospital was all but destroyed on March 9 in the city of Mariupol. Russia alleged pictures of the attack were staged and said the site had been used by armed Ukrainian groups.

# **GSK's Consumer Arm Haleon Debuts with Lacklustre Valuation**

(Reuters) - British drugmaker GSK spun off its consumer health business on Monday in the biggest listing in Europe for more than a decade, but the unit's market value of 30.5 billion pounds fell well short of the price rival Unilever offered to pay earlier this year. [FN22]

The new company, Haleon, emerges as the world's biggest standalone consumer health business, home to brands including Sensodyne toothpaste and Advil painkillers.

Shares in Haleon started trading at 330 pence, giving the business a market valuation of around 30.5 billion pounds (\$36.4 billion) and ranking it in the top 20 companies by market cap in London's FTSE index.

Haleon's debut price was largely in line with market expectations, according to two bankers involved in the deal. However, its current valuation is lower than expected.

Even accounting for the roughly 10 billion pounds in debt, it is below the enterprise value of 50 billion pounds Unilever was prepared to pay for the business at the beginning of the year. GSK had rebuffed the offer on the basis it was too low.

'Investors might be wondering why GSK didn't accept the much higher bid from Unilever,' AJ Bell analyst Danni Hewson wrote in a note.

GSK shares rose in early trading, but started to slip later. At 1105 GMT, the stock was down 0.7%.

Meanwhile, Haleon's stock was trading down nearly 3% from the opening price, but it's difficult to draw conclusions without several days of trading, investors said.

'Generally, demerger prices take some time to settle as there is no 'normal' liquidity in them yet,' said Tineke Frikee, a portfolio manager at Waverton Asset Management with shares in GSK and Unilever.



The last major European company to list after being spun off was French drug ingredients business EUROAPI, which debuted in Paris in May after being spun off by Sanofi.

Those shares stayed above their reference price on their first day of trading on May 6, rising as much as 12.6% on the day.

### **GSK OVERHAUL**

Having made about 9.6 billion pounds last year, Haleon is forecast to bring in 10.7 billion pounds in 2022, according to Barclays analysts.

GSK's June forecast for Haleon's annual organic revenue growth of 4% to 6% over the next three to five years exceeded some analysts' expectations.

It was also met with a degree of scepticism among some investors given industry average of 3% to 5%, according to Barclays.

The Haleon separation is the result of a long-scripted overhaul of GSK, which will now focus solely on vaccines and prescription drugs.

The company has been buoyed by recent clinical trial successes, including its potential blockbuster RSV vaccine, and M&A activity.

However, the company has underperformed relative to its peers in recent years, triggered by a falling share of R&D spend, some clinical failures, and missing out on the lucrative market for the first set of COVID-19 vaccines.

As a result, activist investors pushed for an array of changes last year. Now, the company has momentum on its side - its shares have risen 5% this year despite sharp declines in global stock markets.

But there remain questions over its long-term prospects, with the loss of exclusivity of its key HIV drug, dolutegravir, expected by 2028.

However, GSK has a long runway to execute and find new drugs, including potentially using part of the 7 billion pounds generated via the Haleon spin-off to fund more deals.

### SHARE CONSOLIDATION

With the split complete, all GSK shareholders receive one Haleon share for each GSK share they own.

Pfizer will retain its 32% stake in Haleon, which it intends on selling off over time. GSK will hold up to 13.5% in Haleon, while the remaining 54.5% will be owned by GSK shareholders.

After close of trading on Monday, GSK will consolidate its share price to ensure the company's earnings per share and share price can be compared with previous periods, it has said.

### Climate Change Puts Lyme Disease in Focus for France's Valneva after COVID Blow

(Reuters) - With climate change spurring more cases of tick-borne Lyme disease, drugmaker Valneva is betting big on a vaccine as it looks beyond disappointing sales of its COVID shot. [FN23]

Although Valneva secured European Union and British regulatory approval, both walked away from contracts worth more than a billion dollars combined, wiping nearly 40% off the value of Valneva's share price in the past six months.

The French firm had touted its COVID-19 vaccine as a traditional alternative for people who had refused shots based on newer messenger RNA (mRNA) technology, which teach cells how to make a protein that will trigger an immune response.

But unlike the fierce competition with major international drugmakers such as Pfizer, Moderna and AstraZeneca to roll out vaccines to tackle the coronavirus pandemic, there are no established rivals for either Lyme disease or Chikungunya.

As climate change leads to longer summers and milder winters in many parts of the world, including Europe and North America, infections which spread through so-called vectors, such as ticks and mosquitoes, are escalating, according to the European Centre for Disease Prevention and Control.

Valneva Chief Executive Thomas Lingelbach said there has been a significant increase in the prevalence of disease-causing vectors. 'Global warming is certainly a key - if not the driving force,' he told Reuters in an interview.

The company, based in Saint-Herblain on the outskirts of Nantes in south-west France, is preparing to start a late-stage human trial for its experimental vaccine against Lyme disease and will soon submit its vaccine against Chikungunya for U.S. approval after a successful late-stage study.

The Lyme disease vaccine trial will start in the coming weeks, involving at least 5,000 people over the age of five.

Lyme disease is usually caused by poppyseed-sized ticks which carry the bacteria. While most bites do not lead to an infection and not every person infected has a characteristic rash, some find out later they have the disease.

But by this point, standard antibiotic treatment can become ineffective and if untreated, some patients can go on to develop serious complications, including brain inflammation.

Chikungunya is spread through the bite of an infected mosquito, largely in the developing world including Africa, Asia and the Indian subcontinent.



While rarely fatal, the viral disease is characterised by intense muscle and joint pain that can last months or years.

If approved, Valneva aims to sell its Chikungunya shot as a travel vaccine in the developed world, and to populations in low- and middle-income countries. Rx Securities analyst Samir Devani expects it to generate peak sales of \$250 million.

Valenva expects that, if successful, the Lyme disease vaccine, known as VLA15, will generate annual global sales of \$1 billion, given burgeoning tick populations, rising infection rates and the incidence of long-term complications.

That could prove transformative for Valneva, which generated 350 million euros in revenue last year.

### 'HUGE OPPORTUNITY'

The COVID-19 pandemic and recent outbreaks of monkeypox outside Africa, where it is endemic, have shored up interest in vaccines for infectious diseases among drugmakers and investors.

Endemic diseases which are either chronic or prone to acute periodic outbreaks are a major public health challenge for the developing world and a 'huge opportunity' for vaccine makers, David Pinniger, healthcare fund manager at Polar Capital, said.

This is reflected in the fund's portfolio, which includes shares in Valneva, AstraZeneca and Bavarian Nordic, which makes the main approved monkeypox vaccine.

In June, Valneva was given a major boost when Pfizer bought an 8.1% stake for 90.5 million euros (\$92 million), to co-develop the Lyme disease vaccine.

Valneva's VLA15 is not the first Lyme disease vaccine to be developed. SmithKline Beecham, which later became GSK, secured U.S. approval for its LYMErix shot in 1998.

But challenges including a lukewarm recommendation from a key U.S. advisory committee, unfounded safety concerns and growing anti-vaccine sentiment, led to paltry sales.

The vaccine generated just \$5 million in 2001 and it was withdrawn from the market a year later.

Valneva and Pfizer are banking on how much things have since changed, with infection rates now at half a million cases in Europe and the United States each year.

The hope is that VLA15 could help people who live in rural areas and other places where ticks are endemic, Lingelbach said.

VLA15 is designed to attack multiple strains of bacteria, rather than just one as was the case with LYMErix.

There is also a greater scientific understanding of Lyme disease, while celebrities including Justin Bieber and Amy Schumer have made their struggles with it public.

'Their word carries some weight,' Sam Telford, a professor at Tufts University who helped run the LYMErix clinical trial, said.

#### V. GLOBAL ISSUES

# WHO Urges Manufacturers to Provide COVID-19 Vaccine Data

(Reuters) - A World Health Organization committee urged COVID-19 vaccine manufacturers on Tuesday to provide it with the data it requires in order to list their shots for emergency use, saying the delays were affecting equitable vaccine access. [FN24]

An emergency use listing with the U.N. agency means shots can be shipped to multiple developing nations that rely on WHO guidance for their regulatory decisions. It also allows them to be used by the COVAX vaccine-sharing programme that aims to ramp up vaccinations in poorer countries.

'The Committee recognized the challenges posed by some manufacturers' delayed submission of vaccine data to WHO,' its Emergency Committee said in a statement, urging vaccine producers to supply the data as soon as possible.

The statement, the outcome of a closed-door meeting held last week, did not clarify which manufacturers had not yet submitted data.

A WHO document dated Dec. 23 listed the Sputnik V vaccine, produced by the Gamaleya Institute, as having submitted incomplete data.

The Emergency Committee, made up of independent experts, meets every three months and makes policy recommendations on key issues relating to the coronavirus pandemic, such as international travel measures and COVID-19 vaccines.

It is also the body within the WHO that first declared COVID-19 a global health emergency, or 'PHEIC' (Public Health Emergency of International Concern) in WHO jargon, nearly two years ago. Its members unanimously agreed last week to maintain the current state of emergency.

### Dozens of Firms to Make Cheap Version of Merck COVID Pill for Poorer Nations

(Reuters) - Nearly 30 generic drugmakers in Asia, Africa and the Middle East will make cheap versions of Merck & Co's COVID-19 pill, under a landmark U.N.-backed deal to give poorer nations wider access to a drug seen as a weapon in fighting the pandemic. [FN25]



Merck's early greenlight to production of its anti-viral pill molnupiravir by other companies during the pandemic is a rare example in the pharmaceutical sector, which usually protects its patented treatments for longer periods.

However, there are questions about molnupiravir which has shown low efficacy in trials and has raised concerns for side-effects, and lengthy procedures for approvals may delay supplies in many poorer nations for months.

Under the deal, negotiated by the U.N.-backed Medicines Patent Pool (MPP) with Merck, the U.S. company will not receive royalties for the sale of the low-cost version of the pill while the pandemic continues.

The MPP said the deal stipulated the pill would be distributed to 105 less-developed nations.

A molnupiravir course of 40 pills for five days is expected to cost about \$20 in poorer nations, an MPP official involved in the talks with drugmakers told Reuters, citing initial estimates from drugmakers, which are subject to change.

That is far below the \$700 per course the United States agreed to pay for an initial delivery of 1.7 million courses, but twice as high as first estimated by the World Health Organization (WHO)-backed programme to procure COVID-19 drugs and vaccines for the world.

The new agreement allows 27 generic drugmakers from India, China and other countries in Africa, Asia and the Middle East to produce ingredients and the finished drug.

An MPP spokesperson said deliveries from some firms covered by the deal could start as early as February. However, that will be subject to regulatory approval.

While molnupiravir is in use in the United States after approval in December, some other Western countries have cancelled or are reconsidering orders after the drug showed low efficacy in trials.

Molnupiravir has also not been approved by the World Health Organization, which makes its sale at the moment not possible in most developing countries with limited regulatory resources for national authorisations.

The drug can already be sold in India, after it received emergency approval by the national regulator, but it is not currently recommended for use because of safety risks.

### NO ROYALTIES, FOR NOW

The developers of molnupiravir, which alongside Merck are U.S. firm Ridgeback Biotherapeutics and Emory University, will not receive royalties for the sale of the low-cost versions made by generic drugmakers while COVID-19 remains classified as a Public Health Emergency of International Concern by the WHO.

Bangladesh's Beximco Pharmaceuticals, India's Natco Pharma, South Africa's Aspen Pharmacare Holdings and China's Fosun Pharma are among generics firms that will produce the finished product.

Other companies, including India's Dr Reddy's Laboratories, had struck earlier deals with Merck for the production of molnupiravir. Dr Reddy's will sell molnupiravir at 1,400 rupees (\$18.8) per course.

The MPP spokesperson said there was no firm estimate yet of the likely output from generics makers covered by the deal, but that poorer nations' demand was expected to be largely covered.

The MPP works to increase access to life-saving medicines for poorer countries. It also has an agreement with Pfizer for the sub-licensing of its COVID-19 pill paxlovid to generics drugmakers.

# WHO Says Quarantine Can Be Shortened in Places with High COVID Cases

(Reuters) - The World Health Organization said on Thursday countries struggling with surging COVID-19 infections may shorten the recommended quarantine duration of 14 days in some situations. <sup>[FN26]</sup>

The U.N. agency said its new guidelines may be helpful for places where essential services are under pressure.

For example, quarantine could be shortened to 10 days without a test, and to 7 days with a negative test? provided the person does not develop any symptoms, WHO said.

Where testing to shorten quarantine is not possible, the absence of symptoms could be used as a proxy for testing, the agency said in its new interim guidance.

WHO also said countries may consider relaxing their contact tracing measures in similar situations.

For contacts of people infected with COVID, those at highest risk of getting infected such as healthcare workers should be prioritised, as well as those at high risk of severe disease such as people with underlying ailments or the unvaccinated.

Some countries such as United States, Germany and Switzerland have already shortened the quarantine period to cope with a wave of Omicron-driven coronavirus infections.

# Long COVID a Global Issue for Patients and Healthcare Systems, UK Review Finds



(Reuters) - British researchers led by Oxford University said on Friday that the current understanding of long COVID and options to treat it is emerging as a major long-term issue for global healthcare systems after reviewing the illness' effects on patients. [FN27]

The review, published in the European Heart Journal, looked at direct impacts of a coronavirus infection such as myocardial infarction or inflammatory myocarditis - severe heart conditions - and long-term effects such as fatigue and mental wellbeing.

'Long COVID is, besides its huge impact for the affected individual, of great societal and economic importance as it leads to leave of absence from work, reduced work performance and hence unforeseen costs,' said Thomas L?scher from the Royal Brompton and Harefield Clinical Group.

### Over Two Thirds of Africans Infected by COVID Virus Since Pandemic Began - WHO

(Reuters) - More than two thirds of Africans have been infected by COVID-19 since the pandemic started, 97 times more than reported confirmed cases, according to a World Health Organization (WHO) study published on Thursday. [FN28]

The study found that by September 2021, 800 million Africans had been exposed to SARS-CoV-2, the virus that causes COVID-19, compared with 8.2 million cases reported at that time.

The WHO said that under-counting was happening everywhere, but to a lesser degree than in Africa. It said that on average globally, true infections were 16 times higher than confirmed cases.

The agency's regional director for Africa, Dr Matshidiso Moeti, said that the continent's high exposure to the virus and currently declining infection rates did not mean that Africa could declare victory against COVID-19.

'The risks of more lethal variants emerging which overwhelm immunity gained from past infections cannot be brushed aside,' she said in a statement, calling for increased testing.

The study consisted of synthesising 151 previous studies on seroprevalence in Africa, the proportion of individuals with SARS-CoV-2 antibodies in their blood serum.

It found that exposure to the virus had rocketed from 3% in June 2020 to 65% in September 2021, with sharp rises after the emergence of the Beta and Delta variants.

Studies estimate that 45% of the global population had been infected by September 2021, but the WHO said comparisons were difficult as studies covered different time periods.

With routine diagnostic testing in Africa focused on travellers and people who come to hospitals with symptoms, seroprevalence studies provide data on asymptomatic cases that otherwise go undetected.

Africa has a higher proportion of asymptomatic cases than other parts of the world, with 67% of cases having no symptoms, the WHO said.

That is partly due to a smaller proportion of people with risk factors such as diabetes and hypertension, and partly due to the continent's youthful population.

So far, Africa has fully vaccinated 209 million people, or 16% of the population, against COVID-19.

The WHO and other agencies are trying to ramp up vaccination rates, but are struggling with low take-up, partly due to a perception that vaccination is less useful because the now dominant Omicron variant is less virulent.

The WHO says vaccination for those with prior infection results in better protection than that offered by infection-induced immunity alone.

# U.S. Will Share COVID-19 Vaccine Technology, Biden Tells Global Summit

(Reuters) - The United States will share technologies used to make COVID-19 vaccines through the World Health Organization and is working to expand rapid testing and antiviral treatments for hard-to-reach populations, President Joe Biden said on Thursday. [FN29]

Speaking at the second global COVID-19 summit, Biden called on Congress to provide additional funds so that the U.S. may contribute more to the global pandemic response.

'We are making available health technologies that are owned by the United States government, including stabilized spike protein that is used in many COVID-19 vaccines,' Biden said in his opening speech.

The summit, jointly hosted by the United States, Belize, Germany, Indonesia and Senegal, is being held virtually on Thursday for countries to discuss efforts to end the pandemic and prepare for future health threats.

It is set to build on efforts and commitments made at the first global summit in September, including getting more people vaccinated, sending tests and treatments to highest-risk populations, expanding protections to health-care workers, and generating financing for pandemic preparedness.

It has gathered more than \$3 billion in new funding to fight the pandemic, the White House said, including over \$2 billion for immediate response and \$962 million in commitments to the World Bank pandemic preparedness fund.



The contributions include the United States contributing an additional \$200 million to a global health fund for future pandemic preparedness at the World Bank, bringing its total contribution to \$450 million, it said.

The European Union said it was providing 300 million euros for vaccination support, and \$450 million for the preparedness fund. NGOs, philanthropies, and the private sector made over \$700 million in new commitments.

Several generic drugmakers that will produce versions of Pfizer's COVID-19 antiviral treatment Paxlovid have agreed to sell the medicine in low- and middle-income countries for \$25 a course or less, the Clinton Health Access Initiative (CHAI) said on Thursday.

At least 14 other countries as well as the WHO, European Commission, private-sector companies like Google, and non-governmental organizations, are attending the summit.

'This summit is an opportunity to renew our efforts, to keep our foot on the gas when it comes to getting this pandemic under control and preventing future health crises.' Biden said.

He called on world leaders to consider how their countries could contribute further to the global pandemic response.

'That is why I continue to call on Congress here at home to take the urgent action to provide emergency COVID-19 funding,' he said. 'The request also includes \$5 million to keep up our global partnership in the fight against COVID-19, to sustain our efforts to get shots in people's arms all around the world.'

Biden has asked Congress for over \$22.5 billion in additional COVID-19 response funds, including \$5 billion for international aid, but lawmakers have failed to pass any funding bill and those negotiating the package have been unable to agree on how to pay for the global response.

While additional U.S. funding may be stuck, the commitment to share 11 COVID-19 technologies with the UN-backed Medicines Patent Pool (MPP) should help improve access to vaccines, treatments, and tests in lower-income countries by allowing them to work on generic versions, the WHO said.

'It's through sharing and empowering lower-income countries to manufacture their own health tools that we can ensure a healthier future for everyone,' said WHO Director General Tedros Adhanom Ghebreyesus.

The technologies will be licensed by the U.S. National Institutes for Health to the WHO's COVID-19 Technology Access Pool (C-TAP) and the MPP, initiatives set up to share know-how with manufacturers all around the world, allowing them to work on generic versions of key COVID-19 tools.

Scientists at the NIH worked with Moderna to develop its COVID-19 shot.

The United States has delivered over 500 million doses of vaccines to over 100 countries as part of the 1.2 billion doses it pledged at the first summit in September and has already committed over \$19 billion in funding for vaccines, tests, treatments, and other forms of assistance, Biden said.

'There is still so much left to do. This pandemic isn't over,' said Biden. 'Today, we mark a tragic milestone here in the United States, 1 million COVID deaths, 1 million empty chairs around a family dinner table. Each irreplaceable.'

# Pfizer to Sell All Its Patented Drugs at Nonprofit Price in Low-income Countries

(Reuters) - Pfizer Inc will make all of its patented medicines including COVID-19 treatment Paxlovid and big-selling breast cancer drug Ibrance available at a not-for-profit price to 45 of the world's poorest countries, the drugmaker said on Wednesday. [FN30]

These countries lack good access to innovative treatments. It can take four to seven years longer for new treatments to become available in low-income countries, according to the Bill & Melinda Gates Foundation, if they become available at all.

Pfizer said its plan includes 23 wholly-owned, patented medicines and vaccines that treat infectious diseases, certain cancers, and rare and inflammatory diseases. In addition to Paxlovid and Ibrance, the list includes pneumonia vaccine Prevnar 13, rheumatoid arthritis drug Xeljanz and cancer treatments Xalkori and Inlyta.

The COVID-19 vaccine Comirnaty developed with BioNTech SE was also on the list.

Chief Executive Albert Bourla said in an interview that all the medicines being made available should be of use.

'But clearly the antiviral (Paxlovid) is going to be a very big deal for them - if they need it they can get it immediately,' he said.

When Pfizer launches new medicines and vaccines, they will also be included in the drug portfolio at a not-for-profit price, it said.

The 27 low-income countries and 18 lower-income countries included in what Pfizer is calling 'An Accord for a Healthier World' cover most of Africa and much of Southeast Asia. Five countries - Rwanda, Ghana, Malawi, Senegal and Uganda - have already committed to joining the accord, which was announced at the World Economic Forum in Davos.

Malawi President Lazarus Chakwera said in a statement the accord will allow the countries and the drugmaker to share 'the burden of costs and tasks in the production and delivery of supplies that will save millions of lives.'

Pfizer has been criticized for how it rolled out its COVID-19 vaccine, with some poorer countries waiting for months after the earliest doses arrived in wealthier countries.



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Bourla said the new accord has been informed by the difficulties of that rollout, particularly the lack of health infrastructure in some countries that made distributing the vaccine difficult.

'Instead of washing our hands and saying, 'I gave you the product, do whatever you want with them,' we're saying, 'We'll give you the products and we will sit with you to see how we can help organize a system that can utilize them." Bourla said.

# **VI. MIDDLE EAST/NORTH AFRICA**

Holding for future reports.

# VII. RUSSIA AND EURASIA

### Drugmakers, Device Companies Say Sanctions May Hinder Medical Supplies to Russia

(Reuters) - Western drugmakers and medical device companies warn their plans to keep selling products to Russia may be complicated by economic sanctions targeting the country and its major banks in punishment over Moscow's invasion of Ukraine. [FN31]

Sanctions levied by the United States, Britain, Europe and Canada against Russia do not apply to medicine and medical equipment, and the industry has a responsibility under international humanitarian law to continue supplying these products, industry trade groups, policy experts and company officials said.

International aid groups are pushing to keep critical medicines flowing into Ukraine, where Russian troops are seeking to wrest control of major cities, prompting more than 870,000 Ukrainians to flee their country and millions to seek shelter from air strikes. Already, pharmacies are reporting shortages of medical supplies.

Many Western companies said they will stop selling everything from cars to movies in Russia. Transactions related to medicine and medical devices, as well as food, have been authorized despite U.S. and EU sanctions.

But sanctions that have cut off Russian banks from the international financial system, as well as decisions by major shipping companies to suspend service to the country, could hinder the delivery of medical supplies as well.

The removal of seven Russian banks from the SWIFT international payment system - as well as the ongoing assault on Ukraine - could cause interruptions, MedTechEurope, the European lobby group for medical device companies, said. Without access to that payment system, it becomes more difficult to transact with Russia.

'The freezing of bank transfers could indeed have an impact on the export of medical devices from the EU to Russia, and we are actively looking into the extent of this and will see how the situation evolves,' the MedTechEurope spokesperson said.

The European Federation of Pharmaceutical Industries and Associations in a statement called for safe passage of medicines and vaccines to people in need in Ukraine, neighboring EU member states and Russia.

The U.S. drug industry group PhRMA said it supports the continued exemption from all sanctions of medicines and the materials needed to manufacture them.

Under international humanitarian law, everyone has a right to access essential medical services and supplies, including drugs and vaccines, Lawrence Gostin, a public health law expert at Georgetown University said.

'During times of conflict, this right of uninterrupted access to essential medical supplies has often been violated,' Gostin said. 'Governments that impose sanctions are also supposed to make an exception for medical supplies. Yet sanctions often disrupt medical services and supply chains.'

The United States in a general license issued last week authorized transactions related to the export or re-exportation of medicine and medical devices with Russia. It has also issued carve outs for energy-related payments and international organizations, among others.

The U.S. Treasury Department declined to comment on the issue.

The EU supplied Russia with 6.5 billion euros (\$7.23 billion) of pharmaceutical products in 2020, about 8.4% of the region's total exports to Russia, according to Eurostat data. It sent about 1.6 billion euros of medical equipment to the country in the 12 months ended September 2021, according to MedTech Europe.

U.S. government data shows that in 2021, pharmaceuticals and medical equipment represented about 8% of all U.S. goods exported to Russia. It sent \$355 million worth of medicines and \$157 million worth of medical equipment to the country.

Top shipping group A.P. Moller-Maersk on Wednesday warned that shipments to Russia, including medical supplies, risk being damaged or spoiled due to significant delays at ports and customs. read more

Drugmakers including Switzerland's Novartis, Denmark's Novo Nordisk and Lundbeck, Britain's GlaxoSmithKline and U.S.-based Eli Lilly said they are working to ensure patients have continued access to their medicines.



Novo Nordisk, the world's largest maker of diabetes medicines, said it would do 'all we can to maintain supply in Ukraine and Russia' but it anticipates sanctions will make that more difficult. It has been sufficiently supplied with medicine in Ukraine over the past week, but has faced issues delivering inside the country due to shortage of truck drivers.

'The supply of medicines may be indirectly affected by sanctions in other areas, and we will do whatever we can to ensure the citizens of Russia receive their life-saving medication,' Novo Nordisk said in an emailed statement.

Lundbeck, which specializes in treatments for depression, said it will continue to serve patients who need medicine in Russia.

'As long as we can supply medicine to patients in Russia within the current sanctions, we will do so,' chief commercial officer Jacob Tolstrup said in a written comment.

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