Medical device makers drop products as EU law sows chaos

• By MAGGIE FICK

LONDON (Reuters)-Nicola Osypka's German company has been selling medical devices for surgery on newborn babies in Europe for decades, but new European Union rules have forced her to make tough decisions.

Under the regulations designed to prevent another health scandal, such as the one in 2010 involving ruptured breast implants made by Poly Implant Prothese, companies must apply for new certificates for their medical equipment.

But Osypka says the small firm founded in 1977 by her father Peter cannot afford the process and it has withdrawn five lines of devices sold in the EU, some for over 30 years.

"A law created to stop one criminal company's actions 10 years ago now endangers patients' lives, inducting children, and European manufacturing sites," said Osypka.

"Is that what the EU wants for its citizens?"

Osypka AG is one of eight companies Reuters has spoken to, including Swedish medical equipment maker Getinge GETib.ST, that are withdrawing devices from the EU market, or have stopped making them due to the cost it takes to comply with the rules.

While some companies say the products they have cut have no impact on patients or profits, others say some of withdrawn devices are essential, and doctors agree.

Under the EU's Medical Devices Regulation (MDR), *which* came into effect in May 2021, all medical devices, from implants and prosthetics to blood glucose meters and catheters, must meet stricter safety criteria, sometimes with new clinical trials.

The eight manufacturers all said the requirements were stretching the time it takes to get a certificate for a product line to as much as two-and-a-half years, compared with a few months under the old system.

Costs have also surged, by anywhere from three to 10 times, the companies said. As a result, some are simply allowing their product certifications to lapse, which means hospitals in the EU can no longer use their devices.

The EU Commission, in response to Reuters' questions, said it was concerned about the pace of the implementation of the new rules and would do all it could to ensure patients have access to the medical devices they need.

Reuters also spoke to two medical associations, three doctors and two regulatory experts and, like the companies, they said the new rules were causing widespread. disruption and shortages of crucial equipment.

TiiE DOCTORS, in Austria, Belgium and Germany, said in some cases they were unable to provide their standard quality of care because devices for routine procedures were no longer available.

The Standing Committee of European Doctors (CPME), a group of national medical associations, *told* Reuters that hospitals in Austria and Denmark have reported shortages of critical devices.

France's national medical regulator (ANSM) told Reuters that the **coim-**

EUROPEAN HEALTH Commissioner Stella Kyriakides speaks during a plenary session on EU global strategy on COVID-19 vaccinations at the EU parliament in Brussels, Belgium January 19, 2021. Uohn Thys/Pool via REUTERS)

try's health system was being affected by shortages of various types of devices, partly because of the new law.

Nicola Osypka, a molecular biologist, said she sat down with staff to run the numbers on their niche products, such as a miniscule catheter used to keep newborns with non-functioning heart valves alive until surgery can be performed.

"These types of products are totally beneficial for these patients, but we cannot afford the half a million euros it takes to conduct a clinical study, even though these products have been on the market for 30 or 40 years," she said.

Just as painful is the fact Osypka cannot afford costs estimated at one million euros ($1.1 million) to prepare the application for an innovative product that has already been through clinical trials.

The company's new stent for babies was developed over eight years and doctors successfully used it on 19 babies during the trial in Germany, according to the results seen by Reuters.

John O'Dea, chief executive of Palliare, a small Irish medical equipment manufacturer, is so keen to get his firm's new Japaroscopic device for surgery in the abdomen or pelvis onto the market, he has swallowed the costs.

The process has taken a year and a half so far and O'Dea estimates the total cost will come to about 100,000 euros, for equipment approved two years ago by the US Food and Drug Administration.

Under the old system, it took about €15,000 and a few months to get a similar device approved, he said.

The costly approval process is the latest blow to the world's second-biggest medical device market, worth more than $150 billion, which 'Is already reeling from soaring energy bills and unpredictable supply chains following COVID-19 lockdowns.

An EU Commission spokesperson said in an emailed statement that there were currently not enough agencies, known as notified bodies, to do the work of recertifying products, though device makers had also not prepared sufficiently for the change.

Brussels has authorized 36 agencies and is considering 20 more applications, the spokesperson said.

Tom Melvin, an associate professor of medical device regulatory affairs at Trinity College Dublin, said there were nearly 100 such agencies a decade ago under the old system.

In a major concession, the EU Health Commissioner proposed on December 9 to delay the. May 2024 deadline for companies to comply with the new Jaw to 2028 to prevent shortages.

THE EXTENSION will require an amendment to the Jaw to be approved by the European Council and Parliament, which would not happen until next year.

While a delay would mean some devices will not be q1t in the short term, it would not address the log-jams and *high* costs putting firms off going through the process, executives such as Frank Matzek, vice president of regulatory and government affairs at Biotronil<, a cardiac devices maker in Berlin, said.

EU Commission data this month shows the scale of the problem.

Under the old system, there are about 25,000 certificates. So far, m_anufacturers have submitted applications under the new system for about 8,000, but less than 2,000 have been approved.

Certificates cover multiple deVICes and in some cases whole product lines, making it hard to estimate the number of products potentially affected. Industry experts say about 500,000 different devices are sold in the EU.

Even large companies with deeper pockets and more experience of handling tough global regulations say they have been astonished by the new system's complexity and expense.

Getinge, which makes products for surgery, intensive care and sterilization, has new certificates for about 20% of its portfolio and feels it is on track to meet the deadline, said Mikae)Johansson, an executive overseeing MDR implementation.

But that work started in 2018 required a full review of the company's portfolio and resulted in the removal of about a third of Getinge's products from its range of hundreds of devices.

He said the cull was "healthy" in that it removed products with little effect on profit, but recertification of the rest has been more demanding and taken much longer than expected.