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**Onderwerp:** FW: EU tries new role of chief drugs buyer

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**Onderwerp:** EU tries new role of chief drugs buyer

### **EU tries new role of chief drugs buyer**

-- By Helen Collis

March 1, 2021, 8:02 pm | [View in your browser](#)

Equal access to medicines across the EU has long been a pipedream of patient groups.

But the European Union — a patchwork of drugs markets, each with their own rules and capacities to assess, buy and deliver medicines to those who need them most — offers a stark reality check.

With the pandemic setting a landmark precedent in showing how the bloc can step in to purchase treatments for coronavirus patients — including remdesivir, analgesics, antibiotics, muscle relaxers, anesthetics and others — and provide equitable access to countries willing to participate, this patchwork approach could be set to change.

For its next deal, the European Commission is in talks with drugmakers about purchasing monoclonal antibodies to treat coronavirus. It would be the first agreement for a highly innovative COVID-19 therapy that also happens to be very expensive.

The issue has become all the more important since Friday, when the European Medicines Agency [backed](#) the first monoclonal antibody cocktail to treat COVID-19.

Advocates of the EU taking on a bigger role as drugs purchaser see an opportunity to exploit the successes of remdesivir and vaccines. They're lobbying for the expansion of the scheme to buy life-changing medicines, otherwise only available to countries in the bloc with deep pockets.

“The pandemic has shown that [EU procurement] is feasible ... not only for vaccines, but also for treatments,” said Simone Boselli, public affairs director at the EU rare diseases group EURORDIS. Buying rare disease therapies for the entire bloc would be the “next logical step.”

“We’ve done it for COVID-19, so why don’t we do this for other diseases?” he said. The rare disease community “would be very happy to ... be a guinea pig.”

The Commission wouldn't be starting from scratch: It already signed more than 60 contracts during the pandemic, allowing EU countries to order COVID-19 medicines using national budgets. These cover more than 500,000 treatment courses of remdesivir (despite [concerns](#) over its efficacy). They also secured over 100 million vials of 19 different intensive care medicines, including [dexamethasone](#), the cheap steroid used to treat hospitalized patients on respiratory support.

### Small-country power

The Commission, for its part, has embraced this new role. Despite [criticism](#) over its vaccines strategy, President Ursula von der Leyen continues to chalk it up as a big EU win and has stayed on-message throughout.

And the sentiment, especially from smaller countries, has been a resounding thumbs up and thank you. For countries like Malta, the small island nation of half a million people, the next question is, what can the EU buy next?

"Malta would favorably consider more joint procurement initiatives at the EU level, led by the Commission for certain categories of products," Prime Minister Robert Abela urged Council President Charles Michel on February 17. Abela has also written to von der Leyen asking for "concrete action" on this effort.

Such action is the push EURORDIS has called for since 2015. The group has long noted that therapies to treat rare diseases are often highly specialized and expensive — meaning they require modern health systems and are rarely available in lower-income EU countries.

A good case in point is the growing number of cell and gene therapies in the pipeline. They have the potential to treat or cure patients with severe or fatal diseases, but are complex to make and administer. Accordingly, they require specialist technical knowledge and skills to provide them to patients — a patient's sample is often used to develop a personalized therapy, for example, which must then be delivered back to the patient.

Buyers need to be clued into these treatments to be in a strong position, explains Martin McKee, professor of European public health at the London School of Hygiene & Tropical Medicine. Without technical knowledge, the supplier — often a multinational big pharma — has the upper hand in the sale.

"One of the things joint procurement does is redresses that power imbalance, particularly for smaller nations," said McKee.

In a 97-page report commissioned by the DG SANTE and DG GROW, dated January 8, co-rapporteur McKee and colleagues emphasize this advantage, concluding that "cooperative procurement, including joint procurement, should be encouraged at the appropriate level (regional, national, EU) whenever there is good evidence of its potential benefits."

### How would it work?

The report concludes that there's certainly a place for joint procurement, provided it's assessed on a case-by-case basis.

"There's always a trade-off to make," said Pedro Pita Barros, economics professor at Nova School of Business and Economics in Lisbon and co-author of the report. "Smaller groups move faster and agree more easily; larger groups will have more bargaining power."

"[There's] room for further EU joint procurement of medicines, without requiring every country to participate in every procedure," he added.

He argues that two conditions must be met, however. First, it needs to become politically acceptable for groups of countries to participate in the joint procurement, and both countries and the Commission should develop the necessary technical skills to keep it running smoothly.

Malta's health ministry has gone one step further. As a spokesperson laid out in an email, Malta wants a Commission-hosted buying team represented by each member state, whereby countries opt in if they want to use this mechanism to purchase a certain medicine.

EU countries "should participate on a voluntary basis," the spokesperson said, noting that "almost all" are currently in a

regional buying group, such as Valletta or Beneluxa, “so there’s clearly an interest.”

If countries opt in to jointly purchase a treatment with a drugmaker, they shouldn’t conduct parallel negotiations with the same pharmaceutical company bilaterally — a stipulation also applying to existing vaccine agreements.

The steering group could then identify which drugs to buy and “negotiate on behalf of all member states, or on behalf of a more restricted number of member states” depending on which countries want to participate.

While it might be “easier” to agree to purchase expensive drugs for rare diseases at first, “other products for which there are common challenges should not be excluded,” the spokesperson noted.

For EURORDIS’ Boselli, trialing an EU joint procurement system with rare diseases first “makes sense” since there’s already an established infrastructure across the bloc to facilitate the treatment of rare-disease patients. That includes the clinical infrastructure provided by the European reference networks, which allow rare-disease patients to access expertise and treatment anywhere in the EU.

These centers will be able to set up disease registries, collate data and examine whether new therapies change the natural course of the disease. This information could form part of the annual regulatory review for medicines that have a conditional license, as is already the case for coronavirus vaccines.

According to McKee, a natural home for further EU joint procurement would be within the proposed European Health Emergency Preparedness and Response Authority (HERA) — the EU’s version of BARDA in the U.S., which buys up stocks of vaccines and therapies for health crises. Such a move, however, would limit its scope to therapies for crisis situations such as the pandemic, he noted.

For its part, the pharmaceutical industry is cautious about a bigger EU role in buying medicines. The sector supports this push only when it “facilitates faster access for patients across member states,” said Nathalie Moll, director general of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

“Vaccines have proven to be a good case for joint purchasing as the needs and epidemiological situation of member states have been very similar,” Moll said. “[But] it would be much more complicated for many innovative therapies ... where the current standard of care, patient populations and health care organization differs between member states.”

EU countries have “different ways of assessing the value of innovative medicines, and have different health policy priorities,” she added. “In these cases, joint procurement/purchasing would slow down access to innovative therapies to the detriment of patients all over Europe.”

### **How keen is the EU?**

Joint procurement naturally benefits smaller, under-resourced countries, but it’s not so black and white. Even countries like Belgium don’t have the suite of top-shelf medicines expected of a wealthy EU state.

For example, cystic fibrosis (CF) campaigners have long been calling on the Belgian government to sort out a deal with Vertex for Orkambi, a life-changing therapy for some patients. Because it’s a rare disease, the EU could naturally expand into this field, according to Boselli. And the fact that the Commission contracted research into health care procurement says something about its interest, he added.

But to date, there remains no agreement — and therefore no access — for Belgian CF patients.

**5.1.2e** **5.1.2e**, policy manager for universal access and affordable medicines at the European Public Health Alliance, has a more optimistic take, pointing to the successes with vaccines and remdesivir as playing perfectly into the Commission’s hands.

“Remdesivir ... was the first time that we had procurement of medicines in a very speedy manner ... using public funds and with Brussels taking the lead 100 percent,” he said.

“Brussels wants to have a role in medicines procurement,” he said. “[But] I doubt members will go with it. Countries like Malta can be ecstatic about having access to the vaccines. But vaccines are vaccines — it’s not medicines, which is a

different deal.”

Natsis expects regional drugs-buying groups like Valletta, whose work has been on pause throughout the pandemic, to take off again when the next highly targeted and expensive therapy like Zolgensma is approved. The [gene therapy](#) for the ultra-rare muscle-wasting disease has a retail price of around €2 million — making it the most expensive drug in the world.

As for the political backlash over the EU vaccine purchasing, it’s only a temporary bump for the EU’s potential longer-term evolution into a drug buyer, says Natsis.

“The atmosphere will be very different by May, June, if everything goes well,” he said. “There’s going to be a lot of euphoria again.”

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