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# Europe tries to lower drug prices with small doses of transparency

*By* Jessica Davis Plüss April 13, 2021

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For countries in Europe, negotiating a deal with a pharma company over drug prices is the equivalent of a David and Goliath matchup. Payers have little leverage to push back against prices and terms set by pharma companies, causing many to accept demands for confidentiality in exchange for a discount.

Increasingly, though, some European governments are calling for an end to the secrecy in a bid to rein in drug prices.

At the heart of the issue are so-called managed entry agreements that emerged more than a decade ago and that have now become the norm across much of Europe. In short, countries agree to cover new medicines, sometimes with limited clinical evidence, in the interest of expanding access. In exchange, pharma companies grant individual countries confidential discounts.

Critics, however, say these deals haven't necessarily improved access to medicines, and in some cases, even undermined it. In the process, they say, countries are losing bargaining

power they would have if they acted collectively.

“A company is negotiating with 27 EU member states individually, and they know what kind of discount they gave each country, but the other countries have no idea,” said Sabine Vogler, a health economist at the Austrian National Public Health Institute.

The pharmaceutical industry argues that confidentiality allows it to tailor pricing strategies to the different needs of different countries. Such tiered pricing is based on the value a medicine delivers, which is country-specific in some respects.

“To have the flexibility to be able to differentiate between countries is important in order to facilitate access in countries with very different economic profiles. To have confidentiality around that is an important tool, not for the industry solely, but also for the health system,” said Andy Powrie-Smith of the European Federation of Pharmaceutical Industries and Associations.

The cost of hospitalizations if you’re in Sweden, he noted, is radically different than the cost of hospitalizations in Romania. This means, from a cost perspective, the savings are much greater in monetary value if you’re in Sweden than in Romania.

Those arguments are now under scrutiny by payers. And as health systems strain under high prices, the European Union is trying to figure out how it can use transparency to rebalance power dynamics with pharma companies.

Managed entry agreements began to take shape in the mid-2000s, as more expensive treatments, especially for rare diseases and cancer, came on the market. The trend spread across Europe, and by 2018 some countries had hundreds of such agreements in place.

In October 2019, the Italian Medicines Agency, one of the first to introduce such agreements, reported 71 agreements for 48 active ingredients in 45 distinct therapeutic areas. In Belgium, 7% of the drug budget[4] went to medicines with a managed entry agreement in 2012. By 2017, it was 24% of the drug budget. In Bulgaria and Slovenia, managed entry agreements are required for all new medicines.

Most of these agreements include a financial deal. In 2012, some 25 European countries out of 31 surveyed[5] by Vogler and colleagues received some form of discount on medicines. These were most commonly price reductions and refunds linked to sales volume, but could also be in-kind support and risk-sharing agreements.

An OECD study[6] published in 2019 found the majority of managed entry agreements didn't include any expectations on the performance of medicines. The majority were also shrouded in secrecy. In addition to final pricing, information about the discounts and drug performance data were also being held under lock and key. In some cases, the fact that an agreement existed at all was kept out of public view.

Even countries including Norway and Switzerland, which had long-standing commitments to transparency, have introduced confidential discounts on certain drugs in the past couple of years.

Switzerland is currently considering revising its federal health insurance act to officially anchor confidential discounts in law, following similar moves in other countries.

With so much hidden from public view and no objective comparison, it has been difficult to evaluate these deals.

But there's no disputing that prices for new medicines have risen in Europe in the last 10-15 years, and health systems are under more stress. In 2019, for instance, Norway rejected[7] 22% of new medicines and treatments because they were too expensive.

"Managed entry agreements make the final prices of medicines lower than list prices but that does not mean that it makes final prices affordable," wrote a spokesperson from AIM, the International Association of Mutual Benefit Societies, an umbrella organization for health insurers that has been advocating for fair and transparent prices.

A 2016 study[8] in 15 countries found the difference in list price and actual price could be more than 30% for some cancer medicines. It also found no clear correlation between GDP and pricing levels. Romania and Lithuania paid more than Spain, the Netherlands, and France for many drugs.

A study[11] led by Kerstin Vokinger at the University of Zurich also found that, when drug companies offer rebates, it typically takes twice as long for prices to be negotiated and for a medicine to go from approval to being put on the list for reimbursement in Switzerland. Vokinger believes one reason could be that price negotiations are more complicated and therefore take longer.

According to industry-backed research[12], time to market launch has not gone down in recent years. While flexible contracts should reduce delays, the research notes that the ability to agree on new payment mechanisms varies considerably across countries.

"What we see in practice is that at the end of a contract, the uncertainties are still there," explained Ward Rommel from the Flemish Cancer Society and head of the access to medicines task force at the European Cancer Leagues. "Companies often don't really bother to do the additional clinical trials or to to collect real-world evidence that could reduce the uncertainties."

Experts note that, once a medicine is available, it becomes very difficult to pull it from the market when it is the last hope for patients with rare diseases.

Vogler, who leads the Pharmacoeconomics Department at the Austrian National Public Health Institute, conducts independent price reviews to inform external reference pricing, which is widely used across Europe. Her team can only do price surveys on the basis of the list price, because the actual price paid isn't known. This not only makes it impossible to compare prices effectively, she said, but also "incentivizes industry to first launch in high-income countries to set a very high list price. Other countries see this and realize they can't afford it and then want to negotiate a lower price."

The result is a vicious cycle throughout Europe. "Countries feel like they are in a prisoner's dilemma. They can't be the ones to start off saying that they don't want any confidential deals anymore because they are afraid that they won't get supplied medicines anymore," she added.

Some governments are starting to voice concerns. The Italian government[13] was behind a drug transparency resolution adopted at the World Health Assembly in 2019. Although Germany, the U.K., and Hungary disassociated themselves from the resolution, several European countries including Spain, Switzerland, and Norway eventually backed it.

The fact that the United States is considering using European prices as a reference to help bring down drug prices there is also creating some urgency.

"If the U.S. introduces external reference pricing linked to the prices in Europe, then Europe is in trouble. Prices are going to go up in Europe," said Yannis Natsis of the European Public Health Alliance. There is a sense, he said, that Europe needs to get this under control before the U.S. takes action.

Vogler doesn't think Europe will do away with managed entry agreements entirely. External price referencing has its drawbacks as well, but it is a cost-effective way to set prices, as it doesn't require lengthy negotiations around every drug.

She argued that the shift away from a pill a day to one-off gene therapies calls for new pricing approaches, but there still needs to be more transparency to "rebalance the power."

That's an approach Natsis and other public health advocates endorse. On their own, countries have little negotiating power. "The information asymmetry serves to keep the power imbalance," he said.

One way for payers to become "empowered buyers," Natsis said, is by facilitating and enabling an exchange of information and through collaboration.

There are signs this is already starting to happen. Two of the countries that make up the bloc known as Beneluxa[15], which includes Belgium, the Netherlands, Ireland, Austria and Luxembourg, concluded the first joint negotiation with a company in the case of negotiations over Biogen's drug Spinraza, used to treat spinal muscular atrophy. Although the final price paid was not made public, the countries exchanged pricing information and carried out joint negotiations for reimbursement and procurement.

A couple of Beneluxa countries are now conducting a joint assessment for Novartis' gene therapy Zolgensma and have been outspoken about concerns regarding the company's managed access program.

Another collaboration, the Valletta Declaration, which includes a larger and more heterogeneous group of countries, hasn't made as much headway.

There's also a push for standards to calculate clinical effectiveness or value through health technology assessments and fair price[16] calculators.

Natsis doesn't expect the EU to start buying medicines together as a bloc anytime soon, but he does think collaborations will pick up speed.

The European Federation of Pharmaceutical Industries and Associations supports efforts to advance access but has reservations about joint negotiations. "We agree with the need for more transparency around how prices are determined, how reimbursement decisions are made from the company side, but also from a health technology assessment body," explained Powrie-Smith.

When asked about Beneluxa, Powrie-Smith responded that it is important that collaborations like this "don't just create an extra layer of approvals and negotiations."

The European Commission adopted a new pharmaceutical strategy[17] last November, in which it committed to foster transparency of price information to help member states make better pricing and reimbursement decisions. Although it doesn't reveal any sweeping changes at the E.U. level, "at least the word transparency is in there," said Vogler. "That wouldn't have been there some years ago."

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