

“The price for innovative medication should focus on the value for the patient”

NATHALIE MOLL, DIRECTOR GENERAL OF THE EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS (EFPIA)



What is high-tech medicine worth? And what’s a proper orientation mark for its price? A debate between the Brussels-based biotech lobbyist Nathalie Moll and Dr. Carlos Correa, head of a think tank in Geneva that represents the interests of developing countries

MODERATION **MATTHIAS RUCH, JÜRGEN KRAUTER**

Ms. Moll, Dr. Correa, what is your most important lesson of the Covid-19 pandemic?

MOLL The biggest learning from this pandemic is that we couldn’t contain it. It also taught us the value of collaboration and innovation as well. Imagine if we hadn’t had anything to start from.

CORREA The pandemic has shown to us that the global community was not ready to handle it. Health systems were not well prepared.

What were the biggest challenges for your industry when Covid-19 hit our planet?

MOLL At the beginning we focused on three key areas. The first was support on the ground to countries to keep their systems running, for example giving personal protective equipment that



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DR. CARLOS MARÍA CORREA, EXECUTIVE DIRECTOR OF THE SOUTH CENTRE

tion model. The current model is based on intellectual property rights and legal monopolies that are granted by patents. They are used in order to charge prices that are often completely unaffordable both to governments and individual patients—even in developed countries. But innovation without access doesn’t make sense.

MOLL Innovation is pointless without access, that’s true. If we only have access to vaccines in one part of the world this pandemic will never end. That’s why at the beginning of April our industry published twelve commitments spanning all stages—from research collaboration to access. The current discussion about vaccines on a European level shows this commitment in action on the part of the industry that is focused on ensuring available and accessible products.

Why are patents and intellectual property (IP) so important for innovation?

MOLL If we hadn’t had incentives like IP rights in Europe we would have had nothing to start from to research the treatments, diagnostics, and vaccines we are working on for Covid-19. Patents, apart from IP, ensure the publication of science. Thanks to patents, we share science quickly and can thus advance overall research faster. Thanks to patents, we have a base of innovation on the European level and we have the investment needed to move forward. →

we have in our companies. Secondly, we had to ensure supply. And then we had, of course, to do research for treatments, vaccines, and diagnostics that serve to fight Covid-19. Our companies are working non-stop to make sure they can supply whatever happens. In some cases that means increasing production by 400 percent.

Dr. Correa, with regard to Covid-19, do we take the problems of developing countries sufficiently into account?

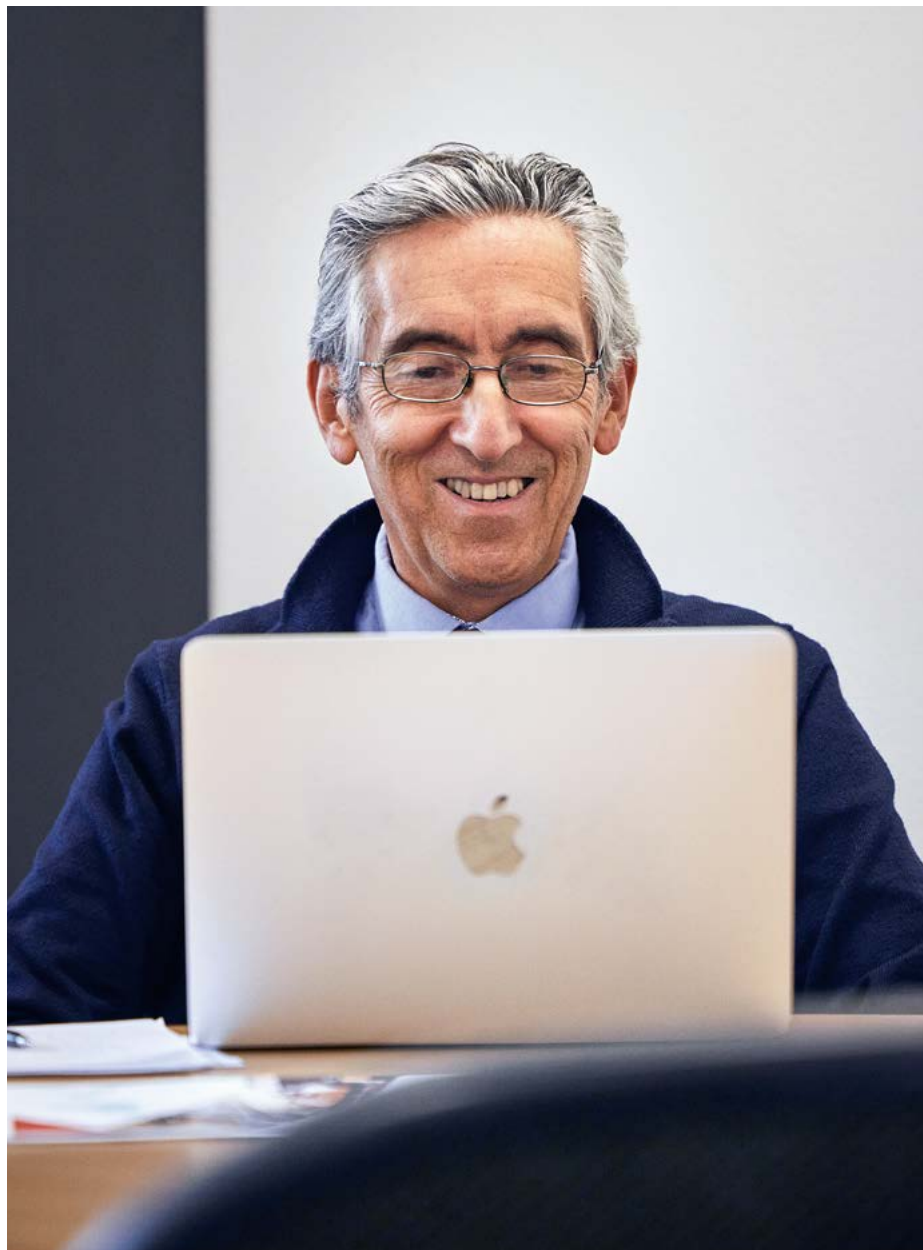
CORREA The European Commission has provided some funding for an international facility to ensure distribution of vaccines also to developing countries that don’t have access to either treatment or prevention. Many of these countries are facing a major crisis because of foreign debt and lockdowns. This pandemic requires a global response. But there is another conclusion that you can draw from this crisis. And this is about the innova-

We're now facing a crisis arising from an infectious disease. But we also have bacterial infections which cannot be treated with conventional antibiotics. Is the pharmaceutical industry doing research on the most relevant diseases?

CORREA Incentive systems based on patents don't necessarily lead to an ideal outcome from a public health perspective. With regard to antibiotics we clearly have a case of underinvestment. The same applies for neglected diseases in developing countries like tuberculosis. The current model of innovation leads to doing innovation for markets with a certain profitability and not for markets with huge demand but people who are unable to pay high prices.

You are referring to expensive drugs for example against rare diseases?

CORREA Yes, and I would also like to highlight that high prices pose a problem to the public health system not only in developing countries. These drugs are useful only for a very limited number of people. But they are very profitable because of the monopoly that can be obtained. The main point is that patents grant legal monopolies. They allow the owners to set a price which is far beyond the marginal cost. Patents should be used in a manner that the society's objectives are reached. For Ritonavir, an AIDS-related medicine, the World Intellectual Property Organization found 800 patents. Some companies want to prevent generic competition and delay it as long as possible through so-called evergreening strategies.



Dr. Carlos María Correa, 71, is Executive Director of the South Centre, an intergovernmental organization of 54 developing nations with its headquarters in Geneva. It serves as an independent policy think tank and holds Observer Status at the United Nations. Correa is a renowned international authority on intellectual property and technology issues. He was member of several commissions and has advised several governments on intellectual property, innovation policy, and public health. He is both a lawyer and an economist and holds a Ph.D. in law from the University of Buenos Aires.



“Thanks to patents we have the investment needed to move forward”

NATHALIE MOLL



Nathalie Moll, 47, is Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA). This trade association, based in Brussels, represents the research-based pharmaceutical industry operating in Europe with 33 national associations and 40 leading pharmaceutical companies as members. Moll has spent over 20 years working for the biotech industry at the EU and national levels in associations and corporations. In 2017, she was named one of the 15 leading women in biotech in Europe. Moll holds an Honours Degree in Biochemistry and Biotechnology from St Andrews University, Scotland.

MOLL Dr. Correa, the reason why antibiotics are not being researched is because there are no incentives to do so. Antibiotics do not follow the normal market logic since they should be sold and used sparingly to avoid resistance. It's the perfect example of unmet medical need where the incentive system is missing—worldwide. We have to look at new systems to ensure that the industry can invest in research and survive at the end of the day. At the moment we are witnessing the downfall of biotech companies involved in antibiotic research and development (R&D). In July our industry launched a €1 billion fund to support clinical research of innovative new antibiotics that would address the most resistant bacteria. It's an artificial incentive while we wait for governments to implement the right structures to support the development of antibiotics.

CORREA I think you're wrong. The market for antibiotics is there. It is just not as profitable as other markets. And this is the point: A company's research agenda is led by profitability. This is why there is no investment in antibiotics. It's not about the patent system. The patent system is there. Patents will be granted on antibiotics if they are new, inventive, and industrially applicable. However, if a vaccine against Covid-19 were developed one additional problem is that there is not enough production capacity. Without licensing and transfer of technology sufficient supply will not be possible.

MOLL Very recently the World Intellectual Property Organization came out with a statement noting that there is no evidence that IP is a barrier to access to Covid-19 preventive measures, treatments, and cure. In our commitment from April 1, our industry declared we would be expanding our manufacturing capabilities once a successful vaccine is developed. The current productivity of the world is 5 to 7 billion doses a year of all vaccines together. In the case of Covid-19 we need about 14 billion doses if we have to vaccinate everybody twice. From the very beginning we've been

working on changing and adapting our lines and sharing and seeing the legal implications of producing one another's products. I think we're turning the world upside down and with it our ways of working to respond to the crisis.

What is a fair price for medications that make such a difference to both patients and healthcare systems?

CORREA In some cases the pricing is exorbitant. Recently, there was the approval of the US Food and Drug Administration for Zolgensma, a life-saving medication to treat young children with spinal muscular atrophy. The price for one dose is \$2.1 million. In the United States, the cost for a treatment with Sofosbuvir that provides a cure for hepatitis C is \$84,000 which means that each pill costs \$1,000. →

Business as usual

Eight months after the breakout of the coronavirus pandemic, videoconferencing has long been part of everyday life. The discussion between Nathalie Moll (in Brussels) and Carlos Correa (in Geneva) at the beginning of October also took place via Internet. The moderators were Matthias Ruch (Essen), the head of external communication at Evonik and Editor in Chief of *Elements*, and Jürgen Krauter (Frankfurt), the head of market communication. And even in these days of our participants—and millions of other professional people—mostly working from home, all four participants went in to their offices for the discussion—because of the better Internet connections.



This pill can be produced for about one dollar. In the past the pharmaceutical industry said these prices were needed to recover the costs of research and development. The problem is: Nobody knows these costs. The new theory seems to be that it is not relevant any more what the company has invested in R&D. Now they value the medicine in terms of solving a health problem. If we follow that way we have to ask: What is the cost of a life? What is a person willing to pay to save his or her life or the life of a family member? I think this is not an acceptable approach.

How can you measure these outcomes?

MOLL It's hard to measure today because we don't have complete data sets for all diseases. For example, take patients who suffer from a chronic disease—how do you put a price on restoring their health to the extent that they can re-enter the labor market and get a job? We are in need of a paradigm change. There are new technologies that are revolutionizing our health-care system so we have to change the way we pay for healthcare. And as with all change, that is hard.

CORREA Nathalie, what you are saying is really a matter of concern. Because you are not talking about reasonable logical profits for the companies. You are just saying you will put a price that will depend on the value for the patient, so this may have no relation, no proportionality with the cost of R&D and production. You say the companies should make any extraordinary profit they can. I think the only outcome you will get following this doctrine is that the governments will come and regulate.

MOLL Focusing on the cost for R&D doesn't help us. Think of Alzheimer's disease: 400 research projects have failed. What are you going to charge for the one that doesn't fail? A price that offsets the cost for all the ones that failed? I would argue that the price should focus on the value for the patient, for the healthcare system, and for society as a whole.

CORREA This paradigm doesn't take into account that most medicines are based on inputs from the scientific field. But in the end the companies appropriate the whole benefit of that.

MOLL As you likely know, we don't define our own prices, we negotiate these with governments. We are not like company X, who can charge a chosen price for their product Y. We have always said that the price of a product in a country should depend on the prevalence of the disease, on what the healthcare system needs, the value for patients, and other country-specific

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MOLL Unfortunately, Dr Correa, we are an industry and we need to make money that we can reinvest in innovation. The question is: What do you want to incentivize? Whatever you base the price on will define what you are incentivizing. If you based the price on R&D you would incentivize spending on R&D. I don't think we want companies simply to spend a lot of money on R&D. We want them to give the best outcomes to patients.

factors. I'm surprised when you say that's not going to work, because that's exactly what we've always been doing.

CORREA You are negotiating prices with governments in Europe, but this is not the case elsewhere. If this trend continues and prices are rising further without any proportionality there will be no other option for governments than to go into the regulatory framework. When a government negotiates with a company that holds a legal monopoly as a patent it hasn't got too many options. One is to issue compulsory licenses in order to lower prices.

Will the Covid-19 pandemic change our view on the global health system?

MOLL It already has. It is really impressive to see the European Union taking global leadership when the Commission's President Ursula von der Leyen launched a global pledging conference at the begin-

ning of May. She raised €7.4 billion within two hours and at the end of June this was supplemented so the amount came up to €15.9 billion. It really gave me a shiver when I watched that. It was the opportunity to do things in a completely different way and together. I don't think we have ever had a pledging event like this—except, maybe, for the Live Aid concert back in the eighties. That's encouraging.

CORREA We need to move forward to reach universal health care also in countries that have not reached this level right now. This is not an easy thing, because it requires enormous investment by the governments. And we need to make sure medicines are priced in a sensible manner. This has all to be taken into account to build a system that is resilient and is able to face this and other pandemics. —

