PINK SHEET
CITELINE REGULATORY

27 Mar 2024 | **Interviews**

'Don't Compromise The Pharma Innovation System,' Says Outgoing IFPMA Head Thomas Cueni

by Ian Schofield

Thomas Cueni is stepping down after seven years at the helm of the International Federation of Pharmaceutical Manufacturers and Associations. In an interview with the *Pink Sheet* ahead of his retirement, he reflects on the proposed pandemic treaty, what still needs to be done to ensure equitable access to medicines, the importance of tackling AMR, moves towards regulatory reliance – and what his post-IFPMA life might look like.

Thomas Cueni may be retiring in April after seven years at the helm of the International Federation of Pharmaceutical Manufacturers and Associations, but he will still be keeping a close eye on one of the most talked-about topics of the day: the World Health Organization's proposed pandemic treaty.

This week sees the close of the ninth meeting of the WHO's Intergovernmental Negotiating Body, which is tasked with steering the talks on the treaty towards final agreement in time for the World Health Assembly at the end of May.

Many view the deadline as unrealistically tight given the ongoing disagreements over key proposals such as the pathogen access and benefit sharing (PABS) system, which would link industry's future access to pandemic pathogens with obligations to share the resulting benefits, such as vaccines, therapeutics and diagnostics.

In an interview with the *Pink Sheet* shortly before he was due to step down, Cueni warned that the treaty must not compromise the pharmaceutical innovation system, which, he said "works so

PINK SHEET
CITELINE REGULATORY

well." He believes it is "essential that companies, whether they are from the global north or south, have free access to genetic sequence information on pathogens," as they did during the COVID-19 pandemic.

"Our concern is that when I look at the draft text of the INB Bureau, all of this will be jeopardized, which is exactly what you shouldn't do with a treaty."

The pandemic treaty was among several topics that the outgoing IFPMA director general spoke about in the interview. Others related to how to ensure equitable access to medicines, moves towards regulatory reliance, and the importance of tackling antimicrobial resistance (AMR), an area in which he has been "very personally engaged."

THOMAS CUENI

Monitoring The Treaty

Regarding the WHO pandemic treaty, Cueni, who is also Secretary of the Biopharmaceutical CEO Roundtable (BCR), believes the negotiators have to get this right, otherwise the world will not be ready for the next pandemic. He also says that industry will have a vital role in preparing for such an event.

"The world in 2020 was really ill prepared for SARS-CoV-2," Cueni said. For many the outbreak of the pandemic was "the day of reckoning" – and one that had the effect of showing the "critical" role of the private sector in "bringing innovation to patients to get us out of the pandemic."

Within less than a year, "you had not one vaccine but several vaccines against COVID. Within a little more than a year, you had several effective treatments, some antivirals, a menu of treatment options. Industry and science really delivered in a big way."

However, the world "did not do well on equitable rollout" of medical countermeasures, Cueni concedes, adding that it was "too easy" just to blame the politicians.

The pandemic treaty is intended in large part to address the equity issue. The idea of the PABS is to make industry's access to pathogens directly dependent on benefit sharing, including "timely, effective and predictable access to relevant diagnostics, therapeutics or vaccines."

But in an 18 March statement, the IFPMA said the latest negotiating text of the treaty was "a

step backward" that included "a large number of disincentives for the industry to enter into a PABS system" and made industry's broad engagement in pandemic preparedness and response "even more risky and uncertain."

With the May deadline for agreement on the pandemic accord fast approaching, the federation has come up with a new set of proposals, including the establishment of a multistakeholder "Partnership for Equitable Access" to which companies could voluntarily sign up by adopting a range of legally binding "equitable access commitments".

It also supports a "feasible and workable" PABS scheme that offers "rapid access to pathogens and data without conditions" and is "open and unmonopolized." It should integrate rather than replace existing systems and networks and be a "broader partnership of member states and stakeholders" that includes industry.

"We want an agreement, and we clearly state that companies are willing to commit to binding mandatory obligations to share, whether it's with the WHO, GAVI UNICEF or UNITAID, for rollout to those with the highest medical needs, provided the system is workable," Cueni declared.

Whether the federation's proposals are taken on board by the negotiators – and included in some form in the final text of the pandemic treaty, whenever that emerges – remains to be seen.

Wider Access Challenges

Ensuring the fair distribution of pandemic-related products is just a part of the wider challenges of access to medicines, particularly in less well-resourced countries, where it is estimated that two billion people have no access to essential drugs. What role does industry have to play here?

"The tension between the industry's business model on the one hand and equitable access on the other hasn't gone away," Cueni said. Thirty years ago, for example, "we saw big clashes on access to HIV/AIDS drugs," but we have seen "big progress in successfully treating HIV/AIDS, and we have seen industry making big strides to make these drugs more available and affordable. Voluntary licensing, technology transfer, the Global Fund of course have helped a lot."

However, "we are far from equitable access on a global level," Cueni said. "We all have challenges, some companies more so than others, but I think we are really seeing a willingness to move."

Among the more recent access initiatives that Cueni has engaged with are the COVID-19 Technology Access Pool (C-TAP) and its successor, the Health Technology Access Pool (HTAP).

The C-TAP was launched at the beginning of the COVID-19 pandemic as a platform for

developers of COVID-19 therapeutics, diagnostics, vaccines and other health products to voluntarily share their intellectual property and know-how to manufacturers in low- and middle-income countries. However, it was widely regarded as a failure. What does Cueni think of its successor, the HTAP, which was launched this year as a "more attractive" scheme than C-TAP?

"I have to admit, four years ago I had quite a number of discussions with the WHO and also with the then ambassador of Costa Rica, because C-TAP was a Costa Rican idea, and it has always escaped me: what is the gap they're trying to fill? They haven't found it yet."

He has similar doubts about the HTAP. "I never quite understood what the HTAP is intended to deliver that the Medicines Patent Pool or bilateral agreements can't deliver. I haven't heard any of our members say, 'Oh yes, we want to jump at this HTAP', which means I would not expect miracles from it."

Cueni sees approaches such as voluntary licensing and tiered pricing as more viable options. "Ten years ago, if you had meetings with industry leaders, many of them were concerned, saying 'aren't we shooting ourselves in the foot if we sell our drugs at a much lower price in developing countries?' Now you have seen tiered pricing with differentiation between high, middle and low income countries. And I hear some of the largest industry CEOs saying it worked in COVID-19, and we really see this as a way in the future."

The Longstanding AMR Problem

Another urgent matter that has long been on the international industry's agenda is antimicrobial resistance. Despite the launching of countless initiatives to encourage the development of new antimicrobials, the Access to Medicines Foundation, an independent non-profit organization, said in a recent report that while there were a "handful of promising projects," overall there was still a lack of R&D programs targeting priority pathogens and AMR threats.

Asked what more industry should be doing on this front, Cueni said that the "handful" description was correct, but that the problem was the "broken" market. "There is no sustainable business model," he said. "We need pull incentives, not just a few token subsidies for research."

As for potential ways to address the problem, he cited the promise of the UK's "subscription-type" model, as well as the European Commission's proposal for a transferable exclusivity voucher. "Whatever is done, you need a model which helps you to make the argument that it's worth investing in antibiotics, and that it's in all our interests."

He added that he was "very personally engaged" on AMR and antibiotics. "Without overstating it, I'm sort of the father of the AMR Action Fund, where 23 companies put up close to a billion dollars for antibiotics research, even though there is no business case for it."

PINK SHEET
CITELINE REGULATORY

Regulatory Reliance

Regulatory reliance is another global development that Cueni views favorably as a way to streamline regulatory procedures, cut down on duplication of effort and accelerate drugs' speed to market. This, he said, follows the "extraordinary coordination and collaboration" among regulatory agencies during the pandemic.

The contacts between the US FDA, the UK MHRA, the EMA and also the PMDA in Japan during the pandemic were "amazing," Cueni declared. "I think it would have been very challenging if this had not happened."

He said the IFPMA was "engaged with the WHO in their efforts to increase regulatory reliance," noting that the organization was moving away from its classic SRA (stringent regulatory agency) concept to the new "WHO listed authority" framework, "which we welcome a lot... This is making strong progress."

Life After IFPMA

So what next for someone who has headed the IFPMA for the past seven years and has been involved with the pharmaceutical industry since 1988?

"I do have ideas," Cueni said, noting that he was interested in sharing some of his experience in working on pharmaceutical innovation and global public health challenges.

Does that mean a book is in the works?

"Actually it's potentially some lectures, and it may lead to a book," he said. Given his time at the IFPMA and a total of 36 years working in the pharmaceutical industry, "I think there will be some interesting perspectives. I will never give up my belief in our business model. Because I think the business model has served the world well."

Cueni's successor as IFPMA director general will be David Reddy, who is currently CEO of the Medicines for Malaria Venture.