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Increasing the sustainability of state-funded health care systems requires changing the way we calculate and account for expenditures overall, says Luca Pani, director general of AIFA | Universal Images Group via Getty Images

Q&A with Luca Pani, DG of Italy's AIFA

EMA board member talks pricing, how to define innovation and data.

ROME — Luca Pani, director general of AIFA, the Italian agency in charge of drug pricing and reimbursement, sat down with POLITICO to talk about Mediterranean countries exploring collaborating on pharmaceutical pricing, affordability of innovative drugs and the sustainability of state-funded health care systems.

He also addressed a clinical trial comparing hepatitis C drugs and a definition of innovation for pharmaceuticals.

Mediterranean countries met in Athens two weeks ago to discuss possible joint drug pricing. Where do things stand?

If you don't have a unique platform you can't do much. Ideally, we would like to reach joint drug pricing at some point, but at the current stage, all we can aim for is several pricing brackets. What is needed is an 'informatics revolution,' and we have to do it as fast as possible. If we are not able to do this in a maximum of one and a half years, we will lose. The data we need is on innovative pricey drugs, not overall patient data. The alternative is that these countries will not have access to innovative drugs. We can give them our software but they have to start if they want to control expenditures.

What about Germany and France? Are they also interested in joint negotiations?

France seemed interested but I'm not sure how it ended. Germany was not at all interested from the beginning. Germans act when it comes to drug pricing the same way they do in the rest of their EU affairs, the same on banks, migration and so on. I think they might lose from acting like this, they might even lose in reputational terms.

With multimillion-euro treatments becoming more common, how can Italy afford it?

First of all we have to define innovation, or better said we have to define what does not constitute innovation. As regulators and payers we have to define what we do not consider as innovative. With what is left we have to agree in the early stage that it constitutes innovation.

We have to change the way we pay for drugs. We cannot keep paying per blister package or per pill. We have to introduce progressive payments. The overall therapy costs, let's say €100,000, and lasts X years or the whole life, and I will pay you by result. If you keep delivering what you have promised, I'll keep paying you or I will suspend the payment.

In Italy we are currently faced with a sustainability problem of innovative drugs and we need a constant flow of funds allocated to them. Data we receive from [Italian] regions show that some regions are actually saving money while others are wasting. We need to harmonize the way regions spend their health care budget.

For sure what needs to be re-discussed is the threshold in hospital expenditure; that is too low and nearly each region has breached it.

Would you consider renegotiating the price of innovative drugs after two years?

We already do that based on real world data. For hep C drugs for example we already have data on 53,000 patients with positive results in more than 95 percent of the cases. We therefore re-negotiate based on evidence. This procedure should be considered an advantage for the industry as well, since they could end up with better results than the ones they obtained during clinical trials.

Two members of the Italian Parliament have proposed a law that would enable patients to use the generic version of pricey drugs such as Gilead's Harvoni and Sovaldi. The proposal wants to authorize access to the Italian market for the generics. Is this going to happen?

We have to respect the patent cooperation treaty; a generic version of a drug cannot enter the market as long as the branded drug has the exclusive right. We were contacted by those MPs and we told them what was feasible: since there is the wrong understanding that the generic version of these innovative molecules are not really equivalent to branded ones, what we can do to dismantle this belief is to start randomized trials on let's say 2,000 patients. Half will get the generic version and the other half the branded one. This is an easy clinical trial, which lasts between eight and 12 weeks. I have also suggested to do that on patients who are in the early stages of the disease. The government has already agreed … It will not be reimbursed from the national health care system but it will give us very important data, and might reduce costs in the future.

What else can be done to increase the sustainability of state funded health care systems?

The main thing is to change the silo mentality and the way we calculate and account for expenditures overall. With these new hep C drugs we avoid transplants for example, and therefore save money. We also avoid lost working days, which also saves money. We should take all this saved money and be able to turn it, for example, over to innovative drugs. I think that we are currently in a phase where the government has understood that we need to redefine the pharmaceutical governance of our country, which has one of the largest public health care systems in Europe.

-- By Giulia Paravicini