

Friday, 3 July 2009 09:38 GMT

Keywords: BIOTECH LEGISLATION PRICING REGULATION REIMBURSEMENT GSK RAPPAGLIOSI EUROPABIO PEOPLE GLAXO

EuropaBio president will boost biotech's healthcare profile in Europe - interview

by Peter O'Donnell

BRUSSELS, July 3 (APM) - The new European Parliament and the new European Commission are going to hear a whole lot more about the healthcare potential of biotechnology, promises Andrea Rappagliosi, the new president of EuropaBio.

Rappagliosi, whose day-job is European government affairs vice-president of GlaxoSmithKline, was voted in last week as the new figurehead of the European biotechnology association best-known for its battles over genetically modified crops and biofuels.

In an interview with APM on Wednesday, he made clear that he sees his two-year term as giving the healthcare sector a chance to lead the association. "We're going to send a strong message that healthcare is a priority for EuropaBio," he said.

He points out that some three-quarters of all the smaller firms in the biotech industry are working in the healthcare field. "We want to boost the fertility of this galaxy of smaller firms," he says. EuropaBio has recently changed its statutes to give a bigger voice to the 1,800 smaller firms in its membership (see APM June 29).

With his background in GSK - and previously in Merck Serono - Rappagliosi is also keenly aware of the importance of biotech for big pharma too, but he sees promoting the interests of both as complementary rather than conflicting priorities.

"More than in other sectors, we've developed the collaboration between smaller firms and big pharma in the last seven years, in product development and in basic research. There is no strict separation between big and small. Look at all the annual reports of big pharma and see the number of R&D tie-ups with smaller firms."

He plans to present EuropaBio's potential as "an opportunity -a valuable partner" to the EU, and will focus his campaign on achieving what he describes as "three main policy drivers": better science, better regulation, and better access to medicines.

Improving science in Europe means, for Rappagliosi, developing better quality thinking about the scope for new developments in areas such as predictive biomarkers or personalised medicine. "There's plenty of interest, but there is not yet a strategic vision," he says, pledging to support a more coherent and informed view "with EuropaBio members' knowhow".

He sees better regulation as making adjustments in the rules so as to allow fuller realisation of the promise of biotechnology.

Now that it is possible to tailor medicines more closely to more-tightly defined diseases ("no-

one talks about just lung cancer anymore - now it is specific types of cancers"), and to identify eligible populations using predictive testing based on individuals' genetic make up, it is time to look again at many of the assumptions in current regulations, he argues.

"We should look at the clinical trials directive and its implementation, and how clinical development can better match these technological opportunities", he says.

He envisages modifications to make clinical trials rules more responsive to the limited patient populations that are increasingly targeted by new medicines. "You could reduce the scale of Phase II and Phase III trials, or simplify them, or avoid the need for some major trials, or re-assess the usefulness of placebo or adaptive trials," he speculates.

What is important, he believes, is to increase the understanding of opportunities, to make expectations realistic, and to work towards making improvements happen. "But at present legislation is very rigid," he says.

Other regulatory changes he will be seeking include "a more centralised and responsive pharmacovigilance system", and the adoption of effective rules to combat counterfeiting. "We want to see the proposal in the pharma package emerge in an appropriate form," he says.

The discussions of counterfeiting so far have been "too driven by the commercial interests of the actors in the distribution chain", he says. "When we are talking about complex products, the interests of patients must come first," he insists.

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Rappagliosi sees hopeful signs of positive movement on some of the longstanding questions about ensuring that patients have better access to medicines. As he points out, this European debate has for years revolved essentially around questions of pricing and reimbursement, which remain national prerogatives. But now the EU member state authorities are starting to recognise that it is a debate in which industry and patients must also be involved.

In his view, the EU's high-level pharmaceutical forum that concluded last year marked a watershed in this process. "This was the first time that the authorities in all 27 member states sat down with the stakeholders to really discuss pricing and relative effectiveness." It was, he said, "more systematic" than previous EU attempts to seek consensus, and led to member states themselves calling for more transparency. "It was," he says, "a point of no return".

He is optimistic that the current economic crisis may also have some constructive consequences for healthcare. "It is obliging policymakers to think more long term in taking decisions", he believes. Already, he sees signals of a deeper understanding of the need to invest in innovative approaches to health in the UK and in France. "The healthcare sector is a great legacy", he says. "The question now is whether Europe will be willing to invest in it."

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peter.odonnell@apmnews.com

[15696] 03/07/2009 09:38 GMT - INDUSTRY