It’s Make Your Mind Up Time

EU Commissioners looking for a way to to inspire innovation in European healthcare could learn a lot from the successes of the EMEA, writes Reflecto, EPE’s new columnist.

When a star-studded cast from across Europe turns up for an anniversary party in the pharmaceutical sector, something big is going on. The bash that recently brought together AIDS pioneer Luc Montagnier, Mars di Bartolomeo (President of the European Health Council), and a galaxy of invited luminaries from the pharmaceutical sector was indeed celebrating something big: the tenth birthday of the European Medicines Agency (EMEA).

It wasn’t an easy birth, and it wasn’t a universally popular child. By definition, it trampled on a lot of toes — and not just those of member state regulators; plenty of company bosses who had become comfortable with their own national arrangements also resented EMEA’s intrusions.

But EMEA’s emphasis on scientific impartiality has gradually wrested control of medicines authorization away from parochialism and into the realm of the rational. Throughout the last 10 years, as its powers and reputation have evolved, EMEA has established itself as a credible player, not only for the European drug industry, but also among regulatory authorities around the world. And that’s worth a glass of champagne and a Canary Wharf canapé any day.

So much for the past. But what of the future?

Talking shops

By coincidence, one of the invited stars missing from the EMEA anniversary party was European Commission Vice-President Günther Verheugen, the German on whom much of the future of Europe’s industry and enterprise. As a gesture of goodwill, he sent along one of his top officials to read out his congratulations for the future.

“Without a doubt, the future of Europe’s industry depends. He has been given one of the top jobs in the newly appointed European Commission: developing Europe’s industry and enterprise. As a gesture of goodwill, he sent along one of his top officials to read out his congratulations for the future.

“The historical dominance of the European pharmaceutical industry has been eroded, particularly by the growth of the industry in the United States,” his message ran. And because Europe needs a strong and competitive pharmaceutical industry to deliver innovative medicines for the health of Europeans and to
create high-quality jobs. "We need to be active," Verheugen insisted, envisaging "thorough regulation" of medicines "while, at the same time, increasing competitiveness and innovation."

This is a difficult balance at the best of times, and has proved an insuperable challenge for Europe in its approach to pharmaceuticals. Because even if the 10-year-old agency has done a commendable job in raising the quality of drug assessment, Europe's confused attitude to pharmaceuticals has repeatedly led to disappointment among its entrepreneurs over economic policy towards the sector. Despite repeated European Union acknowledgements of the importance of the pharmaceutical sector to the European economy, for 25 years Europe has consistently failed to put its money where its mouth is when it comes to pharmaceutical industry policy.

A long list of European Commissioners responsible for industry affairs has, since the 1970s, said much the same as Verheugen is saying today. Etienne Davignon, Karl-Heinz Narjes, Martin Bangemann, Erkki Liikanen stepped forward, one after another, with recognition of the industry's economic imperatives — and one after another they failed to deliver any real improvements in economic circumstances. But the blame does not lie uniquely with them. The EU's confusion about pharmaceutical policy has been the real villain: industry Commissioners have tried to build pro-industry policies, but they have achieved little.

Other Commissioners, responsible for social security or consumer affairs, have watered those policies down, and the EU's member states, who in any case retain full sovereignty over the key questions of drug pricing policy, have carried on doing whatever they want. The resulting "thorough regulation" — including as it does the systems that have led to Europe's flourishing parallel import trade, and the countless selective reimbursement lists — has tended to stifle both competitiveness and innovation.

For EMEA's anniversary party, the only example Verheugen provided of thorough regulation actually increasing competitiveness and innovation was the EU's orphan drugs regulation. He claimed that its incentives have so far led to 21 medicines being developed and innovation was the EU's orphan drugs regulation. He claimed provided of thorough regulation actually increasing competitiveness has tended to stifle both competitiveness and innovation.

Evidence-based changes?
So the current evidence does not suggest much significant change in the all-important economic circumstances for the industry. Concrete examples of where regulation is improving competitiveness are thin on the ground, for all the rhetoric. And alongside his vision of a new future for enterprise-oriented pharmaceutical policy, Verheugen made clear his agenda also included "the need to reinforce our community system for ensuring the safety of medicines," and the challenge of assuring patients' rights "to more and better information about their medicines" — worthy and important goals, but only tenuously related to boosting enterprise.

Worse, although Verheugen admits that there are key issues still unresolved at EU level, and these include notably the crucial areas of product pricing, he nevertheless appears at present to be content with only the blandest recipe for dealing with them: more talking, based on the last round of failed talks. It is only last year that the EU's most recent attempt to come up with real answers on pharmaceutical economic policy petered out, with the demise of the notorious G10 High Level group. The G10 exercise in effect drowned in its own contradiction-ridden verbosity: its broad membership eventually produced conclusions of such careful compromise that by trying to offer something to everybody they in fact offered nothing to anybody.

The new Commissioner is undaunted, however: "With the end of the G10 High Level group, the Commission is now reflecting on how to build further on this positive experience," his message to the EMEA birthday party concluded. He conceded that "While the G10-group has delivered valuable outcomes, I am fully aware that some of its recommendations still have to be implemented and require further discussions between member states and industry under active participation of the Commission." But, chillingly, his final word was that "There can be no doubt that the G10-process has demonstrated that dialogue and collaboration are the best way forward."

For decades, dialogue and collaboration failed to generate a working EU system for drug assessment. The EMEA's success, currently being so widely — and rightly — celebrated, has been possible only because the EU finally realized 10 years ago it had to make the tough choice to replace dialogue and collaboration with an effective decision-making process. The same is now true for the economic aspects of medicines provision. Without a courageous, even radical, political approach that can break through the current stalemate on pharmaceutical enterprise policy, the European pharmaceutical industry risks slow suffocation, as dialogue and collaboration continue to fail to deliver real change.