The European APIs industry: Alive and kicking

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Dr Gian Mario Baccalini, CEO of Euticals and chairman of the EFCG's Pharma Business Committee, was on good form at the annual press conference at CPhI Worldwide 2015 in Madrid earlier in October. And with good reason, because the last few years have seen plenty of positive developments for an industry that once looked beleaguered and even feared for its long-term continued existence.

The EFCG estimates the global API market at $84 billion, divided roughly beween $41 billion captive and $43 billion merchant production. Over the last few years, Baccalini said, the market has grown in both volume and price terms for advanced products. European API producers are increasingly integrated into the supply chain. More and more, they are emphasising dosage form capabilities as well as APIs (hence, perhaps, the sudden increase in companies calling themsleves 'CDMOs', a term that was barely used last

time CPhI was in Madrid), increasing their size through merger, acquisition and investment and generally getting closer to the pharma industry, while exploiting opportunities in emerging markets that have started to want the kind of quality Europeans can offer.

"Big Pharma companies are returning to Europe for their APIs," he continued. "That is my view based on Euticals enjoying 12% growth last year, for example, but many others agree and they are engaging in medium- and long-term agreements with European pharma players. Six or seven years ago, the belief was that the European fine chemcials industry was close to decline but the new philosophy of the customers "gives us a big opportunity to reconsider our relationships with the Big Pharma companies who fell in ove with the Asians five to seven years ago."

There have been 11 FDA Warning Letters to Indian producers of late, Baccalini noted. Meanwhile, China has adopted much more stringent laws and many sites have had to shut down because they cannot produce to the levels of containment needed. By some estimates, this amounts to 800 factories - based on 10% of an estimated 8,000, though he admitted that it is difficult even to guess how many facilities there were or still are in China.

In regulatory terms, much has been achieved, though much still remains to be done. The Falsified Medicines Directive (FMD, 2011/62/EU) has been in force for over two years and has been transposed into law in all EU member states. The key remaining issue is still the lack of enforcement, given that 70% of all APIs sold into the EU are made outside the EU and there are no mandatory inspections of these sites. This, Baccalini said, "is a crazy situation" and he called for such inspections to be made law, paid for, if need by by industry in the way that the Generic Drug Users Fee Act (GDUFA) does in the US.

GDUFA itself is due to expire in September 2017 and the EFCG is taking part in discussions with the US FDA about 'GDUFA II'. The US, according to Baccalini, is not necessarily aware of the EU'e level of regulation, which is sometimes stricter than the FDA's. A positive development has been a big reduction in the number of Drug Master Files registered and a concurrent doubling in fees since 2013; this has broadly weeded out the less committed and been to the benefit of European producers.

The Transatlantic Trade & Investment Partnership will also affect the industry in the coming years. The EFCG has joined SOCMA in pushing for Mutual Recognition Agreements for GMP inspections on both sides of the ocean to reduce the burden of repeated inspection and free up regulators to identify and target high-risk sites, including in countries outside the EU and the US. "I'm not confident of it happening soon because bureaucracies are hard to change," said Baccalini, "but it is necessary. Too often accidents happen for lack of quality at certain sites. You cannot control impurities without absolute respect for cGMP."

Looking ahead, however, Baccalini said that investments in more quality compliance by European API producers are paying off. Business is positive and the outlook for the pharma supply chain for the next few

years is good, not least because Big Pharma is now looking at two- to five-year agreements more than spot deals. As well as simply quality, European companies can now offer wider capabilities, having invested beyond organic chemistry in areas like chromatography, and the trend towards outsourcing can be expected to grow. "Sustainability and compliance have to remain the key drivers for our business, with no comprpmise on quality," he concluded.