Commentary: Jean-Claude Muller

A way forward for pricing new pharmaceuticals

Two trends have become strikingly clear in the years since patents began expiring on the biopharmaceutical industry's most lucrative products. First, companies have successfully taken steps to rebuild their pipelines with new products, many of which deliver real innovation to patients. Second, this innovation in science hasn't been matched by an equal amount of inventiveness in the pricing of new products. To the contrary, the prices that are being demanded for some new medicines are well beyond society's ability to pay. If left unaddressed, this problem will turn society against the industry with negative consequences for all concerned.

In this commentary, we propose four measures that might be taken by industry and the healthcare community to overcome the disequilibrium that currently exists between the prices being asked for new drugs and their value to the community at large. This involves rethinking the correlation between the cost of innovation, a company's return on investment and the value the products deliver to society.

The first issue is about transparency. It is mandatory that the industry comes forward with a transparent market access evaluation and communicates the real cost of developing new medicines in the context of their value to society. For years there has been a lively debate over what it costs to develop a new drug. In 2003 Joseph DiMasi and colleagues from the Tufts Center for the Study of Drug Development put this figure at $802 million. Since that time, they have raised their estimate to $2.6 billion. Other organisations, notably the Office of Health Economics in the UK, have weighed in with separate analyses which review the cost of drug development, taking into account out-of-pocket expenses, success and failure rates, development time and the cost of capital. Companies also do their own analyses and this information should be shared with the public. In this way, a realistic discussion about the cost of innovation could take place.

Second, companies need to start thinking about new pricing models for their medicines based on their likely success in preventing, slowing, or even curing disease. In July, Novartis announced plans to offer Entresto, its new heart failure treatment, to insurers in the US on a 'pay-for-performance' basis where the price would start low and then rise if the drug proved to be effective. The effectiveness would be tracked by digital technology. More recently, the US insurer Harvard Pilgrim Health Care has agreed to a pay-for-performance deal with Amgen to cover its anti-cholesterol drug Repatha. According to the *Boston Globe* newspaper, the insurer has agreed to include Repatha as the only drug of its kind in its formulary. In return, Amgen will supply the drug at a discount to the $14,100 list price per annum, and give rebates if it doesn't reduce cholesterol to specific levels.

It is too early to tell whether any of these deals can be administered effectively. But they do have the distinct advantage of explicitly linking a drug's price to performance, a concept also known as 'value-based pricing.'

As innovation accelerates, the drug regulators have become more active in making sure that the most promising products reach the market faster. In 2012, the US Food and Drug Administration introduced a 'breakthrough therapy designation' for promising drugs that treat life-threatening diseases which complements other speedy review policies. In Europe, the European Medicines Agency also operates an accelerated review policy. While the exclusivity clock starts ticking once a medicine with an accelerated review gets to the market, companies still get a substantial benefit by being able to launch their products early. In our view, they should return some of this value to payers and patients by committing early on to substantially and progressively lowering their prices over time. The same principle should apply to currently marketed drugs which get new indications and expanded market access. The principle of a pricing revision every three years has been in existence in Japan for several decades.

A fourth measure that should be considered is 'bundling pricing' for drugs that treat large chronic diseases, particularly for ageing populations. Bundling means offering a discount for marketed medicines that are gradually being replaced by new premium-priced products for the same indication. The industry fears that such a policy would 'cannibalise' their existing policies. For example, Sanofi recently launched its new anti-diabetic Toujeo in the US at the same price as Lantus, which has kept its premium price. But shouldn't the Lantus price be lowered? This type of pricing policy wouldn't be tolerated in the mobile telephone market where manufacturers routinely discount existing products when new models are brought onto the market.

Finally, whether industry initiates new pricing policies or not, there is bound to be more price monitoring by public bodies in the US and Europe. These groups are likely to be increasingly vocal about whether a proposed drug price is sustainable. Unfortunately, these issues are not high on the agenda of most biopharma executives. They should be. Managements should be thinking about pricing policies for some of the new combination products, particularly in oncology, and to the huge sums currently being paid for in-licensing new products and technology. If current profit margins are applied to some of the products covered by these deals, the cost of these products will be completely out of the range of payers.

To be clear: there should be a reward for innovation. But 'value-based pricing' will progressively become the norm. Transparent and independent assessments will be performed by novel or already established independent institutions. Excessive price increases and huge profit margins will come under more and more scrutiny.

This commentary was written by Jean-Claude Muller, a pharma industry consultant, and former senior vice president at Sanofi SA.