The Joint EU Member States Procurement of Rare Disease Medicines Initiative:

BY KARL PETROVSKY

Everything started with the EU Commission setting up a “Joint Procurement Agreement on medical countermeasures for combating serious cross border health threats” in June 2014. This was a reaction to the uncoordinated response of EU Member States to the Ebola crisis and the earlier H1N1 pandemic of 2010 when EU Member States were competing with one another to get hold of scarce supplies of medicines. This resulted in panic buying and Member States felt that they were obliged to pay high prices for medicines. Communicable diseases and many other health threats do not respect borders and thus it was felt that better EU coordination is needed.

The EU Joint Procurement agreement was signed by 22 EU Member States, with France being the most recent one in September 2015. So far, the agreement is limited to vaccines and other medicines and equipment that address “serious cross-border health threats.”

However, in the current European climate of concern over the cost of medicines, the agreement is considered to be a model for much wider common action in buying pharmaceuticals, especially high cost and high volume medicines. For many European governments, high drug prices have an increasing influence on their policies with
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The EU Health Commissioner openly encouraged Member States to jointly procure costly medicines, which goes beyond the remit of the 2014 EU agreement.

**THE BELGIUM/DUTCH INITIATIVE**

The Belgian and Dutch Ministries of Health were first to start an initiative under this agreement, which set up first a Memorandum of Understanding and then an agreement in April 2015 to work together on negotiating prices for medicines for rare diseases, especially orphan drugs. Luxembourg recently joined the initiative. The Dutch-Belgium-Luxembourg effort is considered innovative because most EU member countries closely protect their sovereignty over pricing matters. Other countries (e.g., Austria and Italy) announced their intention to join later if the initiative proves to show positive results.

The Belgian, Dutch, Luxembourg plan is, at present, to run a pilot program with a few selected companies for the purchase of high cost, orphan medicines for rare conditions. However, the initiative is not targeting so called “Me-too” products. Both the Belgian and Dutch Ministers of Health have made it clear that they intend the agreement to go much further in aligning drug authorization and pricing processes across a broader range of products. The initiative goes well beyond jointly negotiating with industry. The three countries also want to exchange data, share registries, and coordinate assessment methodologies. They will also examine together which innovative drugs will be commercialized in the coming years and how they can best prepare. Currently, three companies participate in this pilot phase, where the governmental agencies are already concretely negotiating with industry.

**THE ROMANIA/BULGARIA INITIATIVE**

Bulgaria and Romania announced in June 2015 that they will set up a common initiative to jointly procure costly medicines. The framework for this initiative will be elaborated by a working group which will be published soon. The initiative is open to incorporating other countries in the emerging markets part of the EU.

**IMPACT AND CONCLUSION**

These developments show that EU Member States’ governments are now concentrating on ensuring equal accessibility of effective, high-cost drugs to patients and they are shifting away from considering industry interests, which generates innovation. When Luxembourg assumed the EU presidency in July of 2015, innovation was high on the agenda but it is oriented to serve patients first, and not in the sense that industry deserves to be rewarded for innovation.

The Netherlands, which will hold the EU presidency in the first half of 2016, has already indicated that it is keen to pursue the exploration of joint negotiation or joint purchasing of medicines, to get better value out of deals with the pharmaceutical industry.

Larger countries like Germany, the UK, and France are not currently a part of these efforts. One reason is that they want to keep “pricing sovereignty”. Germany, especially, sees the wider Joint procurement initiative as a strictly voluntary effort amongst the EU Member States. They do not see legal grounds in the EU Treaty to make mandatory that EU Member States organize joint drug pricing negotiations. And they insist that the EU Commission has no coordination role in this, not even in the voluntary version of it. The French Minister of Health recently explained such resistance, but she also gave an outlook: “Every country must remain sovereign in pricing... at least at this very stage in time. We may move onto further integration (at EU level, sic) in the long run, that may seem logical, but for some countries “there are a number of concerns”. (Kim Dixon, “Benelux joint medicine talks moving forward,” PoliticoPro, October 30, 2015)

Joint EU Member States procurement (or joint Member State price negotiation) of rare disease medicines will, for the time being, mostly attract small to middle market size Member States. It remains to be seen whether this initiative will be applied by other countries and, more importantly, whether it would be applied to plasma protein therapeutics.

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