

Draft: Impact of Corona Virus on medicines manufacturing and supplies in Europe

Dear (10)(2e)

In response to your request, Medicines for Europe has consulted its members on the potential impact of the Corona Virus on medicines manufacturing and supplies and in Europe.

China is a major producer of pharmaceutical inputs – notably of active pharmaceutical ingredients and intermediate products. The global pharmaceutical industry (including European and Indian manufacturers that supply the European market) imports from China and there are several hundred factories located in the regions most affected by the viral outbreak (Hubei & Zhejiang provinces host over 100 production sites). A extended shut down of Chinese production or block on Chinese exports would certainly affect global pharmaceutical production and likely materially affect global production costs.

Based on media reports and data collected by the Indian pharmaceutical ministry, we know that China is by far the leading supplier of API or key intermediates (i.e. in a near global monopoly situation) for certain essential medicines including but not limited to: metronidazole, paracetamol, ibuprofen, metformin, amoxicillin, ofloxacin, salicylic acid, ciprofloxacin, cefixime and ampicillin.

Based on the information from our members, there is limited immediate risk to production or supplies in Europe resulting from this situation. This is because companies typically maintain 2 months of ingredient stock for their manufacturing networks. In addition, it is likely that some additional stock would be available with chemical traders or due to stockpiling for the recent Chinese New Year holiday period (where production shuts down temporarily). Our members are continuously monitoring the situation to evaluate their stock levels and potential impacts on manufacturing and supplies in Europe.

It is not currently possible to evaluate the risks for future supplies from the affected areas in China. This will depend on the resumption of production in factories including how many workers will return to those sites (as there are many restrictions of person movement in China to control the outbreak). This will also depend on the impact this could have on exports from China to key pharmaceutical production centres in Europe and India. Travel restrictions (official or corporate) for personnel to the affected regions could also have an impact on supplies. We will communicate this information to you as and when we receive updates from our membership. Without wanting to raise unnecessary alarm bells at this point in time, we would nevertheless recommend that the Commission and regulatory agencies consider Medicines for Europe's recommendations to address potential shortages related to active pharmaceutical ingredient production problems – notably the possibility for emergency variation procedures and accelerated regulatory reviews for both active ingredients and for finished



products. Should production or export problems arise from this situation in China, manufacturers will need to act quickly to maintain supplies. In addition, it would be important to ensure pan-European coordination as national measures could have spill over effects on the rest of the EU.

We would like to underline that in case the situation becomes more serious, we could not exclude an important impact on supplies due to the potential market effects of the crisis. A temporary delay of Chinese ingredient production or exports could hypothetically impact the price of those ingredients with a knock-on effect on the cost of goods of pharmaceutical production globally. As most European countries apply some form of regulated pricing policies, often combined with price control policies such as maximum ceiling prices for tenders, there could potentially be an unsustainable market situation in the months ahead. Past experience has shown that this affects not only manufacturers but also the distribution chain for medicines. Without wanting to raise unnecessary alarm bells, it would be important to consider the potential market problems that could arise from a worsening of the situation and a sudden increase in production costs such as:

- Under certain circumstances, manufacturers cannot legally sell products at a loss (i.e. EU procurement forbids “abnormally low bids”).
- Distributors could start to hoard supplies in order to comply with public service obligations or due to different incentives in the market leading to a suboptimal distribution to patients.
- Hospitals and pharmacists are often reimbursed according to a reference price. They could struggle to supply patients if the reference price would become negative, below their costs or substantially lower than their past returns.

Medicines for Europe will continue to monitor this situation with manufacturers. We are also prepared to reflect with regulators and with the Commission on the above-mentioned policy matters that could also impact manufacturing and supply in Europe in a worst-case scenario.

Yours respectfully,

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