Paris, 14 May 2018

Prescrire's contribution to EMA's public consultation concerning the EU template for GMP non-compliance statement

Prescrire will not comment on the proposed updated template because we strongly disagree with any initiative accepting the risk to expose patients to substandard critical medicines.
Because, as reminded in the public consultation announcement, "*Compliance with Good Manufacturing Practice ("GMP") is an essential part of the pharmaceutical quality system*" (1).

Indeed, today in Europe there are too many problems of **compliance with GMP** (see for instance Bayer's case in Germany) (2). And clearly **shortage of critical medicines** is a growing concern. According to the French Health Products Agency (ANSM – Agence nationale de sécurité du medicament et des produits de santé) in 2017 France had to deal with supply problems for more than 500 medicines of major therapeutic interest (3). The increasing problem of shortages across the European Union threatens patient care and require urgent action (4). But these two issues should not be dealt with by lowering the quality bar. Why should patients accept risks that directly derive from lack of responsibility from companies and authorities?

For dozens of years GMP compliance has been mandatory and monitored by medicines agencies inspections, and there are sanctions in cases of non-respect or failure. In our view, under no circumstances should EMA send the message to companies that they can relax their general obligation re GMP.

Shortage of medicine is a global issue and accepting substandard medicines

will not solve the problem. Pharmaceutical companies have reorganised their production with a view to limit cost and maximise profit, most of the time in outsourcing production in low cost countries. The fact that a pharmaceutical company producing a critical drug is not able to deliver the product is too often the consequence of relying on one single production source. This is not a fatality: it's the companies' choice. Because it threatens patient's quality of care and safety, this policy should be confronted with a very strong position by health and public authorities. A drug marketing approval includes rights but also obligations: to produce drugs in due quantity and due quality.

In conclusion, we consider that EMA and health authorities should not cave in to industry pressure and accept the marketing of substandard drugs. Instead, they should call on the companies to fulfill their responsibilities and duties, including the timely delivery of supply orders of critical medicines while fully respecting GMP.

References:
1- "Public consultation concerning the EU template for GMP non-compliance" statement
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2018/04/WC500246646.pdf
2- "Bayer in FDA's bad books over facilities failures" *Scrip* 23 February 2008 : 15.
3- "Médicament: les signalements de rupture et de risque de rupture en hausse de 30 % en 2017 (ANSM)" APM news 13 February 2018: 2 pages.
4- "Medicines shortages" European Association of Hospital Pharmacists" http://www.eahp.eu/practice-and-policy/medicines-shortages: 3 pages.

For more information