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Europe's planned rules on drug distribution provoke industry accusations of red tape

BRUSSELS, Feb 7 (APM) - The European Union's plans to tighten up its rules on drug distribution have unleashed a stream of hostile comment from medicine manufacturers, wholesalers, pharmacists, and even regulatory agencies, who accuse the EU of a heavy-handed approach.

The European Commission published a draft of its update to its Good Distribution Practice for medicines last year, and it has just published the comments made by industry and other players in the medicines supply chain.

The Commission wants to bring the rules - now nearly 20 years old - into line with modern conditions, and to adapt them to the new requirements for wholesale distributors and brokers in the directive adopted last year to combat counterfeiting and to prevent falsified medicines getting into the legal supply chain.

GIRP, the European full-line wholesalers association, says many of the proposed new requirements "raise significant concern for us and go far beyond the spirit of the changes contained in the falsified medicines directive".

It sees the text as "overly burdensome to achieve a relatively limited step forward to overhaul a currently well-functioning quality system".

Several of the proposed measures "are, from a cost perspective, seriously disproportionate to the expected additional benefits", and cannot be justified, particularly given the difficult current economic and financial circumstances.

"We would call on your services to fully reflect on the cost/benefit balance in the exercise of revising the GDP," says GIRP.

It says good distribution practices as outlined in the proposed text are "overly influenced by standards of good manufacturing practice", and cover issues which are "only applicable to pharmaceutical manufacturers".

Among the specific criticisms that GIRP levels are the suggestion that a responsible person should be physically present 24 hours a day at each wholesale distribution site. "As our members operate over 1,600 warehouses in Europe, the new requirement would result in an annual cost increase of approximately 20 million euros," it calculates.

Similarly, proposed changes concerning humidity controls are "a disproportionate measure", since in Europe humidity "is not a problem for medicinal products in their secondary packaging". And since pharmaceutical wholesale distributors "are only involved in the handling, storage and distribution of medicinal products in their secondary packaging, no product contamination can occur and therefore a requirement to store medicinal products separately from other products needed by pharmacies and health care professionals is in no way justified".

The criticisms are echoed by the Association of Pharmaceutical Full-line Wholesalers in Germany, which says that "the proposal in its current state goes far beyond what is necessary to ensure the safe handling, storage and transportation of medicines."

The Pharmaceutical Group of the European Union underlines that "the current distribution system of medicines in Europe is highly efficient, and consistent with the rights and needs of European patients", and insists: "it is essential that any changes to the guidelines are proportionate, and do not place excessive burdens on wholesale distributors which may necessitate the lowering of current high service standards".

The pharmacists' grouping also calls the proposed measures "burdensome".

EFPIA's less vigorously expressed comments nonetheless reveal the same concerns about over-regulation. The manufacturers' federation calls for "sufficient flexibility", based on "the key principles of science- and risk-based decision-making". That approach should inform the revision of the rules, "in lieu of specific expectations put forward", it concludes.

The Association of the European Self-Medication Industry (AESGP) notes the increasing complexity and level of detail in the proposed guideline - which, it points out, has shot up in length from the four pages it required in 1994 to 32 pages in the current draft.

This "does not seem to be in line with the principle of better regulation", says AESGP, questioning the necessity of the stringent new provisions.

The European generic medicines association (EGA) has urged greater precision in the draft rules, including in what it sees as erroneous references in the text to 'distribution' and 'wholesale distribution' "as if the two terms were interchangeable".

Companies raise specific practical issues with the draft. Bristol-Myers Squibb queries the proposed blanket requirement to ship all pharmaceutical products in controlled temperature conditions. "The controlled temperature trucks fleet is not enough in several EU countries," it points out.

It urges a more nuanced provision that "where non-dedicated vehicles and equipment are used, procedures should be in place to ensure that the quality of the medicinal product will not be compromised."

Merck Sharp & Dohme says it is "concerned that several of the requirements are unrealistic from a practical perspective and unnecessarily stringent as the same level of safety could in our view be obtained through other means."

Regulatory agencies too see excessive rigour in the draft new rules. The Danish Medicines Agency questions the need for a proposed requirement to segregate medicines destined for the EU from those destined for other markets. The treatment of products should be the same regardless of the destination, it argues, adding: "At the time of delivery, the final destination of the product it is not always known".

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