

CEPIC/APIC POSITION PAPER

CEPIC/APIC Position on Counterfeiting of APIs

A product is as safe as its ingredients are. This simple and straightforward principle underlines the importance of the quality and safety of active pharmaceutical ingredients (APIs) for the safety of the medicinal products that contain them.

It is well known that unsafe, low quality pharmaceutical ingredients can lead to catastrophes. One horrible example has been the fatal poisoning in 1996 of about 90 children in Haiti as the result of a paracetamol syrup containing glycerine that was contaminated with diethylene glycol.

More and more pharmaceutical authorities worldwide are recognising the need for an increase in regulatory oversight over APIs. This is resulting in the revision of existing laws and the proliferation of large numbers of new laws, regulations, directives and guidelines regarding APIs.

While the application of these stricter rules for API manufacture will undoubtedly result in a higher safety of medicinal products, it is important to remember that compliance with these rules by the API industry also involves very high costs. The bottom line here is that society is willing to invest significant amounts of money in safer medicinal products for the patient. As long as these new regulations will be enforceable and workable for all parties involved and will thus indeed result in increased patient safety, CEPIC/APIC fully supports the view that these investments are justified.

However, since compliance is such a costly matter, there is an obvious risk that these new rules may result in the exact opposite of what they intend to achieve: This risk is that APIs that are not manufactured in compliance with these regulations - and are therefore being produced at much lower cost! - will still somehow continue to reach the market place. Such non-complying APIs can be offered at extremely competitive price levels. They are therefore well positioned to continuously increase their illegitimate market share. It is obvious that such a situation constitutes a large danger to human health that may be described as a ticking time bomb.

It is obvious that, linked to the new extensive system of API regulations, a forceful system has to be simultaneously put into place that will ensure that only complying APIs will reach the market. In other words, the implementation by authorities of a strict framework of API rules automatically self-imposes the need for a waterproof system of inspections and enforcement upon these same authorities!

In conclusion, CEPIC/APIC finds it of utmost importance that compliance with regulations and with submitted information will be enforced through worldwide, mandatory inspection of API manufacturing facilities. Only thus can both the health of patients and the continuity of the complying API industry be protected in an effective manner.

CEPIC/APIC is extremely concerned that today the EU, contrary to the USA, has neither a legal basis for GMP compliance of API production, nor an API inspection- and enforcement system in place at all. It is CEPIC/APIC's view that the EU should accelerate the revision of the pharmaceutical legislation and implement such a worldwide inspection system without delay. The imminent, potential, growing danger that the current situation implies to the patients in the EU should be an ample basis for a large sense of urgency at the EU authorities. Illustrative for the required urgency to improve the situation in the EU is the following example:

Recent research performed by BfArM in Germany has resulted in the astonishing conclusion that 17 out of the in total 21 samples of the antibiotic API gentamicin they have collected from the German market appeared to have not been manufactured by the registered, approved API producers. The Marketing Application holders for the involved gentamicin dosage forms in Germany appeared to be unaware, though, that they were including these unapproved APIs in their medicinal products.

Should this example be a representative picture for all medicinal products on the EU market today - which is something that APIC would like to see investigated with the highest priority - then the current situation already would be extremely critical. But also if the inroad of illegitimate APIs in the EU is still more limited, this constitutes a very dangerous situation that should meet zero tolerance

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