FEDERCHIMICA
ASCHIMFARMA
Associazione nazionale produttori principi attivi e intermedi per l'industria farmaceutica

For the attention of: European Commission – Enterprise and Industry Directorate General – Consumer Goods - Pharmaceuticals

Response of Aschimfarma to the "*Public Consultation in preparation of a legal proposal to combat counterfeit medicines for human use*".

ASCHIMFARMA, a branch of the Italian Chemical Industry Federation (FEDERCHIMICA), is the Association of producers of pharmaceutical fine chemicals. These companies produce organic chemical substances obtained through high technological industrial processes, both in the development and production phases. Italy holds a primary position in the world market in this sector and exports more than 85% of its production to more than 90 countries. The companies associated to ASCHIMFARMA are characterized by their strict application of Good Manufacturing Practices which allows them to reach the highest levels of quality and reliability.
During the last years, in a strongly growing market like that of generic drugs, the aggressiveness of new competitors from China and India is becoming more and more apparent, with their highly competitive prices and a quality, for the most part, still not comparable to that of European Manufacturers. About 80% of all APIs and intermediates consumed in Europe are imported from India and China. Production facilities of such lower price APIs suppliers are, until now, rarely inspected by EU Authorities. According to some calculations, a plant that does not comply with GMP rules gives a cost reduction of 25%. This behaviour, reducing the safety of drugs, objectively increases the risk for human health, as the recent facts demonstrate.

On these preliminary remarks Aschimfarma explains here below the main topics to allow the Authorities to take the best decisions to defend the Public Health:

1. ***"Written Declaration of the European Parliament on active pharmaceutical ingredients no. 61" dated November 30, 2006.***

   On November 30, 2006 the European Parliament, in plenary session, approved with 378 favourable votes the "*Written Declaration of the European Parliament on active pharmaceutical ingredients*" submitted by MP Amalia Sartori and supported by all political groups, as well as by the Parliamentary Committee of Environment and Public Health.
   With the approval of this written declaration, the European Parliament addresses to the Council of the European Union, the European Commission and the parliaments of the member States, pressing for 1) *the submission, both by producers and importers of active ingredients, of a "Certificate of good manufacturing practice" delivered by the European Authorities following mandatory inspections at sites of*

production and proposing 2) *to introduce the traceability of the active ingredient, with indication of its origin (ex., Country, Company, site of production), to discourage the relabelling or the repackaging of non-EU product, for better defence of public health.*

2. ***Necessity of mandatory inspections on the observance of GMP rules in API production.***

   The aim of mandatory inspections requested for by the European Parliament for the assessment of the actual compliance with GMP by companies producing API, EU or non-EU, is to ensure consumers of all member States that each single active ingredient used in the composition of medicines produced and/or marketed within the EU is safe for human health and makes therefore safe medicines bought in the States of the European Union.

3. ***Proposal for the modification of the community legislation concerning pharmaceutical products – Mandatory inspections at EU and non-EU API sites of production.***

   It is necessary to provide for an urgent modification of the currently in force Community legislation concerning pharmaceutical products that 1) provides for mandatory inspections for the assessment of the GMP observance, both at the sites of production within EU and at those of non-EU Countries, and 2) expressly appoints EMEA and/or public law bodies of the single member States qualified in medical-pharmaceutical matters to conduct the said inspections (being subjects of well-established knowledge and experience in the matter and also as "*super partes*" control bodies).

4. ***Respect of GMP for API quality and safety of medicine.***

   To clearly understand the importance of the non-respect of GMP rules, it must be taken into consideration that all scientific studies carried out during the last years on the problems concerning safety of medicines for human use have come to the conclusion that the problems related to the quality of medicines, namely the active ingredients contained in them, are a source of risk for human health.

5. ***Damages to health originating from non-observance of GMP.***

   Unfortunately a great number of cases has already occurred in which failure to quality of active ingredient has had harmful effects on human beings. Risks to health due to the failure of therapeutic action of the active ingredient due to lack of proper quality are, however, even more serious. Suffer damages to health due to a toxic medicine and not being able to be cured due to a medicine lacking in therapeutic effectiveness, are similarly serious and dreadful situations.

6. ***Safeguard of public health and comparison with Community legislation in the food sector.***

   In the food sector a rigorous and scrupulous regulation is in force, which has imposed substantially systematic medical controls on the goods imported from non-EU Countries.

Logically thinking, safety of the food we ingest and that of the medicine we take should have both the same importance.

7. Counterfeiting in the pharmaceutical sector.

Damages deriving from the counterfeiting phenomenon in the pharmaceutical field are very high, since they affect the most important value for human beings: health.
The University of Würzburg in Germany published, on assignment by the German Ministry for Health, a study which collects interesting and, at the same time, alarming data on the phenomenon of the marketing in the Common Market of counterfeited active ingredients in the years 2002-2003. In fact, in this study it results that most of the active ingredients circulating in the EU market comes from India and China, countries where between 10,000 and 15,000 API manufacturers are concentrated, and that approx. 33% of the active ingredients imported in the Common Market from non-member Countries are counterfeited API.

Recently some dangerous situations for the health of the EU citizen were published:

- on October 2nd-4th, 2007 during CPhI, the most important worldwide exhibition for APIs, many Chinese companies were accused by American Authorities for: patent violations, shipping counterfeit drugs. This situation was reported in an Article of the New York Times (dated October 31st, 2007) entitled "*Chemicals flow unchecked from China to drug market". I extract these words: "Pharmaceutical ingredients exported from China are often made by chemical companies that neither certified nor inspected by regulatory Authorities*";

- the Warning Letter (dated October 31st, 2007) issued by the US FDA to the Chinese company "Northeast General Pharmaceutical " for some products for which the mentioned company had two approved CEPs issued by EDQM;

- the article of New York Times issued on December 17th 2007 entitled "*Counterfeit Drugs' Path eased by Free Trade Zones*". The article highlights the routes of the counterfeited drugs that from China through the Persian Gulf entered into the Europe;

- the article of New York Times issued on February 29th 2008 *"Blood thinner might be tied to more death*", which refers about the many deaths caused by the use of contaminated heparin.

8. Traceability of the active ingredient.

It is also evident the importance of point b) of the "*Written Declaration of the European Parliament on active pharmaceutical ingredients"* with which the European Parliament proposes to the Council of the European Union, the European Commission and parliaments of the Member States the introduction of traceability of active ingredients in the Community legislation, namely the obligation to indicate the origin of every active ingredient (i.e., Country, company, site of production), in order to avoid relabelling or repackaging of non-EU products, for a greater defence of public health.

9. Mandatory inspections and appointed subjects.

It is necessary to have the mandatory inspections conducted by selected and highly qualified personnel, better if in a team, without private and personal interests in the good outcome of the inspection. In this connection, it is evident that only the personnel of a public law body could guarantee the above mentioned requirements and, in particular, the lack of private interests potentially bent on profit-making.
These inspectors can be managed by EMEA, EDQM or by the more engaged Agencies in EU with a common database that can be used by all the European countries. We would like also to remember that a possible tight-up with FDA can speed up the target for being effective in a short time.

10. Conclusions.

In the light of the above, hopefully the Council of the European Union, the European Commission and the parliaments of all member States accept the proposals indicated in the "*Written Declaration of the European Parliament on active pharmaceutical ingredients no. 61*", dated November 30, 2006, implementing urgently the necessary modifications to Community regulation and national implementation regulations.

All we wrote above concern the safety of medicine and consumer. The mentioned proposals, on our opinion, are the unique solutions that can assure the safety of drugs. We wish underline that these measures must be applied as soon as possible by the competent Regulatory Authorities. We have positive examples in the food and agriculture sector where the applications of harmonized legislation have had positive influence for the health of the citizen. For that we ask that the same rules are implemented in the active pharmaceutical sector.