With reference to the EUROPEAN COMMISSION's Public Consultation paper "Key ideas for better protection of patients against the risk of counterfeit medicines", Indena is willing to offer a brief contribution.
Indena S.p.A. is an Italian manufacturer world leader in the production of API of botanical origin. Indena group consists of five production sites, four in Europe and one overseas, with more than 700 employees globally. European facilities are routinely inspected and authorised by the competent national pharmaceutical agencies (AIFA and AFSSAPS).

Indena deems that a strict control on APIs should be considered pivotal and absolutely necessary for assuring quality of medicines in order to maintain a proper guardianship of European citizens health, considering overall that an astonishing three quarters of the API consumed in Europe do come from outside Europe (mainly from India and China).

On the other hand Italian API manufacturers are accustomed to consider regular periodic inspections of their facilities and strict enforcement of GMP rules, according to ICHQ7A, as a basic component of the work, and it seems surprising that such a situation is not considered as a necessary stringent prerequisite for API introduction on the European Market.

Indena strongly believes that there should be a regular and efficient GMP enforcement by the EC competent authorities, regardless to where APIs are produced, as they are to be consumed by Europeans.

The principle of the "Written declaration on pharmaceutical active principles (0061/2006)" that both producers and importers of active principles should submit a certificate of good manufacturing practice delivered by the European authorities is certainly actual.
Such fundamental principle should imply mandatory inspections by competent authorities at the site of production, on a general routine basis and not only in case of suspected non-compliance with GMP. Rules should be set and resources allocated to enforce such control in third countries. Moreover traceability of the API, meaning transparency in identifying the original supplier of the API, should be put in place.

Indena considers not deferrable the principle that the competent authority should carry out inspections of active substance manufacturers also in third countries in order to verify compliance with the principles of good manufacturing practice.

To better enforce controls, such inspections should be carried out directly by Competent Authorities and not delegated to directly involved parties, such as applicants or other private institutions.

Modern tools, such as fingerprint technologies (e.g. NMR, NIR or chemometric technologies) could help to identify counterfeiting and adulterations not only on finished products but also on API, and should be implemented as part of GMP system to also identify unauthorised deviations from the manufacturing process.