Industry faces tough task to meet EU API deadline

By Warwick Smith, Director General of the BGMA

Changes to the EU's rules governing the importation of active pharmaceutical ingredients (APIs) will come into effect in July 2013. The new regulations are part of the implementation of the EU falsified medicines directive and have been prompted in part by high profile safety scares in recent years.

However, while the ethos of the API regulation changes are aimed at improving and harmonising quality standards, the new legislation has not been universally welcomed. Much of the opposition has focused around the requirement for third country competent authorities to certify that the APIs being exported by companies in their jurisdictions comply with EU or WHO standards.

The template includes a statement by the third country authority that the standards of good manufacturing practice (GMP) applicable to an API supplier's manufacturing plant "are at least equivalent to those laid down in the EU".

As an association, our view is that we would always support in principle regulations which ensure the quality of medicines and clearly API is at the basis of this.

However, the timeline for compliance of less than a year is very tight and may prove problematical. Regulators and industry now face a tough challenge to prepare for the new requirements and a lack of certainty from the European Commission about what exactly is needed may add further delays.

The key point is that each exporting country has to give written confirmation of compliance to EU standards. What is needed from the Commission is clarification of what is acceptable and what is not. While in some countries, certification to EU standards will be relatively straight-forward, in other markets these changes will be more of a step-change. Without clear direction from the Commission, the July, 2013, deadline will be harder to meet which has potential consequences for supply. Overall, as an association we can’t help feeling this has been badly managed by the Commission and blame for any consequences of not meeting the deadline lie with their handling of the entire process.

It has been unacceptable not to have had early and effective communication with the main API exporting countries before passing domestic EU legislation.

To do so would have avoided the situation where some countries misinterpreted the move as an attack on their sovereignty.

Manufacturers and their associations have done all they could to spread the word and encourage API suppliers to approach their competent authorities. However, it should be the Commission’s responsibility to ensure this was carried out.

The Commission's core job in all this is to ensure the supply of medicines and they seem to have fundamentally misunderstood their role and consequently passed the buck to others.

Even at this late stage, it is the lack of clear intent from the Commission in terms of acceptable practice under the written confirmation requirements from the directive which still threatens to undermine the process further. Some accountability is required.

Allied to this, there is also a direct unintended consequence for the generic manufacturing industry in Europe which needs highlighting. There will be specific requirements for the quality approval of API but the same provisions will not apply to the import of finished dosage form products.

This means that it may actually be easier to manufacture outside of the EU and then import rather than import the API and then manufacture. Surely this wasn't intended when the legislation was first thought through?