IMPLEMENTING ACT ON THE REQUIREMENTS FOR THE ASSESSMENT OF THE REGULATORY FRAMEWORK APPLICABLE TO THE MANUFACTURING OF ACTIVE SUBSTANCES OF MEDICINAL PRODUCTS FOR HUMAN USE

COMMENTS FROM THE EUROPEAN INDUSTRIAL PHARMACISTS' GROUP (EIPG)

EQUIVALENCE ASSESSMENT OF THE REGULARITY OF INSPECTIONS TO VERIFY COMPLIANCE WITH GMP AND THE EFFECTIVENESS OF ENFORCEMENT OF GMP.

Given the complexity in the API manufacturing processes and the number of different countries that may be involved, it is necessary that compliance to the registered specification of the Drug Substance is achieved. Unfortunately, this is frequently not the case.

The regulatory GMP compliance inspection is thus essential but is often not undertaken due to limited resources. Organisations such as EDQM can achieve much, since they will not only inspect the API manufacturing site, but will also monitor all variations in the manufacturing process and will provide a 3 year certificate of suitability for the specific Drug Substance. However, this service is limited to those Drug Substances included in the European Pharmacopoeia. Other Authorities such as the FDA provide a similar service, but there are a considerable number of API suppliers that are not monitored.

The problem occurs with those drugs NOT included in any pharmacopeia and cheap drugs supplied from certain third countries , since the Regulatory Authorities in many third countries do not have the resources to adequately monitor GMP compliance. Also, many generic companies, who have to buy drugs cheaply, do not have the time or money to carry out GMP compliance checks.

For this reason we believe that Regulatory Agencies should ensure that at the time of submission of the Marketing Authorisation, all the detail required in CTD Module 3S Drug Substance is supplied and also the means by which GMP will be monitored throughout the life cycle of the product. It is only then that the cheap and adulterated drugs from China and India will be excluded from use in the manufacture of Medicinal Products.

REGULARITY AND RAPIDITY OF INFORMATION PROVIDED BY THE THIRD COUNTRY RELATING TO NON COMPLIANT PRODUCERS OF ACTIVE SUBSTANCES.

The rapid alert system is essential within the European Regulatory framework and does now seem to be better than in the past. However, for such a system to be effective it is essential that it should link

with organisations such as WHO and FDA to obtain early warning of possible problems. It is in this area that there needs to be improved communications.

OTHER ISSUES

All the points raised will benefit the systems of CONTROL of GMP, but are heavily limited by the lack of resources available within the EMA and many National Regulatory Agencies.

The issue of Drug Substance adulteration increased with the entry of China and India into supplying cheap API's for the Pharmaceutical Industry. This was only made possible by the demand for cheap generic medicines which is not always in the best interest of the patient.

Governments from around the world need to consider the risk /benefit and the cost of monitoring for possible adulterated medicinal products. So often we hear of the economic assessment of drug treatments considered by organisations such as NICE but rarely do they take into account the quality of these medicines.

EUROPEAN INDUSTRIAL PHARMACISTS' GROUP (EIPG 3.2012)