European Medicines Agency
Celebrating ten years – 1995 – 2005

"A Scientific Perspective on the Future of Medicines"

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Making Medicines Affordable

EMEA 10th Anniversary Conference - London 11th March 2005: Statement by Greg Perry, Director General, EGA

The EGA has a very special interest in the 10th Anniversary of the EMEA, as this is also the year which sees generic companies in Europe preparing to use for the first time the EU's Centralised Procedure for generic and bio-similar products.

To date the EGA has focused on its relationship with national medicines agencies, as the generic industry has become the principal user of the current Mutual Recognition Procedure. Whilst our industry will continue to develop its relations with national medicines agencies through the new Decentralised Procedure, the industry will also become a new user of the Centralised Procedure (CP). Undertaking registrations with the EMEA will be a new experience for our sector of the industry.

In order to prepare the ground for an abridged Centralised Procedure a team of EGA companies have been working together with EMEA staff over the past year. Similarly we have worked for some time with the EMEA staff in relation to the development of a regulatory pathway for Bio-similars. At this point, I would like to thank the EMEA for the constructive, open and highly professional manner in which the dialogue has operated in both these areas.

There is still work to be done in preparing the way for the generic partnership with the EMEA.

As regards to the use of the CP for generic equivalents of CP approved originator products it should be recalled that this is an option and companies can still use the MRP-DCP route. It is therefore important that a competitive fee structure and a clearly defined time structure are developed for the abridged CP.

In the case of bio-similars the creation of the regulatory pathway ahead of the USA has now created an enormous competitive advantage for Europe. We believe that the combination of this pathway and the introduction of a EU Bolar provision will give us the opportunity to make Europe the global leader in bio-similar medicinal products. However, we must move quickly in relation to the development of guidelines in this area and to hold the long awaited workshop on bio-similars earlier rather than later in the year.

In conclusion, for us in the generic sector this 10th anniversary is not only an important celebration of the success of the EMEA and of the major contribution that the Agency has made to public health. It is also a turning point year for our industry as we enter a new and important relationship with the Agency. I hope in 10 years time the EGA will be able to report back on a decade of success in generic and bio-similar medicines applications with the EMEA.

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