

The Acceding Countries Declaration

We, the Ministers of Health of the Acceding Countries,

Conscious of our social responsibility to provide the recent medicines as early as possible to our people, we wish to reiterate our concerns relating to data exclusivity provisions within the Review of European Pharmaceutical Legislation.

The ongoing review aims to increase the availability of innovative medicines while favouring competition with generics as well as to pave the way for enlargement. While sharing the overall goals of these processes, we are convinced that these issues cannot be achieved without the active participation of the acceding countries in drafting the current amendments to the legislation taking place before accession.

We wish to refer to the agreement reached during the accession negotiations to bring national legislation in line with the *acquis communautaire*. In some areas of outstanding importance, the 2001 Review comprises amendments to legislation, where agreement to bring our legislation in line with community legislation in force was reached as a result of lengthy and difficult negotiations.

It concerns in particular the extension of the **data exclusivity period up to 10 (8+2) years**, while Community legislation in force allows the application of a 6-year data exclusivity period.

The proposed amendments will influence significantly the fragile national health systems and the public health situation in our countries. It will also significantly weaken the availability and affordability of medicines to the public, place greater burden on the National health insurance fund¹, and have a negative impact on the fragile national pharmaceutical industry, which is already bearing the full cost of alignment in our countries.

Generics, constituting the majority of medicines available on the acceding countries' markets at least by volume and accordingly on the national reimbursement lists, contribute to considerably reducing patient co-financing payments as well as public health insurance contributions. As such, a strong generic sector is a powerful stimulus to innovation, creates budget headroom for the purchase of new innovative medicines and, at the same time, is an essential component of cost-containment.

According to these stated reasons maintaining a 6-year protection period is recognised by the undersigned Ministers of Health as high priority and should be maintained in EU pharmaceutical legislation for all the interested acceding countries.

Signed in Milan on 5 September 2003

¹ The real spending per capita in the Accessing Countries on healthcare is less than €400 p.a. compared over €1600 in EU - 15.

Ministers of Health of the

Republic of Cyprus

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Czech Republic

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Republic of Estonia

Marko Jaurenty

Republic of Hungary

d. Balogh 5/9/03

Republic of Latvia

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Republic of Lithuania

[Handwritten signature]

Republic of Malta

[Handwritten signature]

Republic of Poland

[Handwritten signature]

Slovak Republic

R. B. [Handwritten signature]

Republic of Slovenia

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Signed in Milan on 5 September 2003