Belgium, France, Luxembourg and the Netherlands support the recast of Directive 78/25/EEC on colouring matters which may be added to medicinal products.

Belgium, France, Luxembourg and the Netherlands however have concerns about colour E128 Red 2G. In paragraph 5) of the proposed Directive on colouring matters which may be added to medicinal products there is a reference to Annex I of Directive 94/36 on foodstuffs which lists the colour E128 Red 2G as a permitted colour.

After being alerted to the possible serious risks to health of E128 Red 2G, on 26 July 2007 the Commission took emergency measures and implemented a suspension on the use of E128 Red 2G in foodstuffs in Regulation 884/2007 (Article 1 paragraph 1).
However, the way the suspension is introduced by the Regulation it only applies to foodstuffs and not to human medicinal products, since the colouring matter is not removed from Annex I of Directive 94/36 but only from Annex IV which lists the permitted uses in foodstuffs. Because of this, there is no suspension for the use of E128 Red 2G in medicinal products for human use.

Due to the fact that E128 Red 2G causes serious health risks, Belgium, France, Luxembourg and the Netherlands would like to express their concerns about the situation where this colouring matter will still be allowed to be used in human medicinal products.

Belgium, France, Luxembourg and the Netherlands realise that this legal deficiency might not be solved before 20 January 2011, which is the latest date for the revision of the allowed food additives provided for in article 30 of Regulation 1333/2008 on food additives. Therefore Belgium, France, Luxembourg and the Netherlands requests that the Commission treats this revision as a matter of urgency.