

HMA Secretariat

Danish Medicines Agency

Icelandic Medicines Control Agency

Medical Products Agency, Sweden

National Agency for Medicines, Finland

Norwegian Medicines Agency

State Agency of Medicines, Estonia

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AVAILABILITY OF MEDICINES IN A SMALL MARKET AND COMMON NORDIC PACKAGES

The Heads of Medicines Agencies (HMA) published earlier this year a report on the availability of medicines, particularly in small markets. The pharmaceutical industry supports some of the measures proposed in the HMA report, particularly in relation to solving language issues in package leaflets and labelling. Alternative ways of providing patients with package leaflets could improve availability.

We are pleased that also the Nordic Council of Ministers has paid attention to the need to improve medicine availability on the small Nordic market.

The Nordic pharmaceutical trade associations met recently with the Nordic medicines agencies to discuss common Nordic packages. Common packs are an important solution to bringing medicines to small markets such as the Nordic countries. It is the opinion of the pharmaceutical industry that common packs should be encouraged throughout Europe to ensure the patient has access to medicines. It is important that common Nordic packages are supported by the authorities by implementing harmonised and practical solutions. Our meeting on Nordic packs in August showed that achieving common packs is challenging because of national requirements and interpretation of legislation and guidelines. Dialogue between the agencies and also with the industry is vital in achieving common Nordic packs. In further developing and improving the cooperation on Nordic packs, the Nordic region can serve as a role model for common packs in other parts of Europe.

While supporting the above, the HMA report also proposes measures that the pharmaceutical industry cannot support. The report suggests making it easier for member states to grant marketing authorisation to products for which no application has been submitted by the pharmaceutical company. This process would create a lot of confusion with regard to responsibilities and duties related to all obligations implied by a marketing authorisation. Pharmaceutical companies cannot be forced to carry out unprofitable business by having to sell unprofitable products. If business is made unprofitable, this is most likely to reduce and not increase the overall availability of medicines. The possibility of imposing fines for availability problems would also further increase the business risks of pharmaceutical companies, decreasing their willingness to bring new products to the market. The industry is also opposed to the proposal that the launching of a medicine in all EU countries be set as a condition for granting marketing authorisations.

As we are aware that this topic will be discussed within the HMA in the near future, we would encourage the authorities to focus on practical ways of increasing availability within the existing framework rather than forcing the marketing authorisation holders in doing unprofitable business. Our meeting on Nordic packs showed that there is a lot that can be done in making common packs more achievable, especially when it comes to harmonising national requirements and implementation of legislation and guidelines. Minutes from the meeting reflecting the current challenges and future opportunities will of course be distributed to the authorities.

It is our goal that common packs will become an easy way to ensure availability without reducing information to patients. We hope HMAs focus on Availability of Medicines will contribute to this.

Yours sincerely,



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cc. EFPIA