



Response to MLX 309

Response of the National Pharmaceutical Association to Consultation [MLX 309](#)

Thank you for giving the National Pharmaceutical Association (NPA) the opportunity to comment on MLX 309. The NPA represents the interests of Britain's community pharmacies. We have, in voluntary membership, around 11,000 community pharmacies, which comprises the majority of the 12,000 pharmacies in the UK, with the exception of the Boots chain. The NPA provides a representative voice for its members as well as a range of services to help them with both commercial and professional aspects of running their businesses.

1. Data exclusivity for legal status switches – Article 74a
The NPA believes that there would be benefit to the competitiveness of the UK's pharmaceutical industry and to the wider availability of non-prescription medicines in the UK if this Article was implemented in January 2005. In our response to MLX 279, we stated that many pharmaceutical manufacturers were reluctant to invest in an application for a change in legal status of a product as the period of exclusivity was not long enough. We believe that implementing this article early will mean that more pharmaceutical companies will be encouraged to apply for reclassification of medicines which will help fulfil the Government's intention to increase the availability of non-prescription medicines.
2. "User testing" of patient information – Article 59.3
We welcome the early introduction of user testing of Patient Information Leaflets (PILs) and believe this will help in improving the information available to patients. PILs are often unclear and pharmacists are frequently asked to help patients interpret the information in them. One of the most commonly misunderstood sections is that on adverse effects and we believe that user-testing may also help with this and hence, with patient safety.
3. Pharmacovigilance – Article 23
We believe that the early adoption of this article will lead to earlier improvement in patient safety.