ASPIRIN AND REYE’S SYNDROME IN THE UNDER 16s

From 1 October 2003 all products containing aspirin will be required to include a statutory label warning – “Do not give to children under 16 years, unless on the advice of a doctor”.

Following a full 8-week public consultation exercise (MLX290) the Medicines Commission endorsed the earlier advice of the Committee on Safety of Medicines that the new warning was required. The Government has accepted the advice of the Commission and a coming into force date of 1 October 2003 – in time for the next cold and flu season will be adopted.

The chairman of the Medicines and Healthcare products Regulatory Agency (MHRA) – Professor Alasdair Breckenridge said

“The best way to make sure this message gets across to the people who need to know – parents and young people, is for every pack of aspirin to carry the warning. Many manufacturers have already adopted the new wording but we need to make sure they all do – and before the next cold and flu season. We also want people to be aware that the pack in the bathroom cabinet may not have the new warning and there will be further publicity to raise awareness as winter approaches”.

“There are plenty of analgesic products containing paracetamol and ibuprofen for this age group not associated with Reye’s Syndrome. There is simply no need to expose those under 16 to the risk – however small”.

OUTCOME OF THE CONSULTATION EXERCISE (MLX290)

Consultation letter MLX 290 was issued on 23 October 2002 with a deadline for comments of 31 December 2002. It was circulated within the health services, to interested organisations and officials in the Scottish Executive, Welsh Assembly and Northern Ireland (devolved administrations). A copy of a draft Regulatory Impact Assessment (RIA) was part of the MLX, all of which appeared on the MCA website. The MCA received 27 responses in total, which can be broadly categorised as follows:

- Pharmacy Colleges etc. 2
- Pharmacy interests 6
- Replies from the Industry 5
- Other professional bodies 1
- Other bodies 7
- Devolved administrations 1
- Medical Colleges 5
- TOTAL 27

As part of the consultation process, MA holders for products already on the market who were affected by the proposals were given the opportunity to make oral representations to the Medicines Commission. No MA holders opted to do so.

A further 12 replies were received which made no comment on the proposals.

25 replies supported the proposal overall although some raised other issues. Only 2 organisations objected to the proposal.

MHRA
4 April 2003