Response from Ireland

Agenda Point: AOB 2 Update on External study on Availability

Ireland welcomes the Study. The study, together with the analysis and discussion of the situation is appropriate and the findings are applicable to the situation in Ireland. It identifies the key issues which our experience to date has shown to have contributed to the availability of medicines/medicines shortages in Ireland.

Medicines shortages have become increasingly prevalent over the last decade. Ireland is particularly vulnerable to medicines shortages because of the small size of the Irish market. The Department of Health and the national competent Authority the Irish Medicines Board work closely with the key stakeholders to effectively manage potential shortages.

Some specific points we would like to highlight relating to the survey are as follows.

The Article 126a procedure as a means for authorisation of medicinal products and facilitation of supply to the market place is not used in Ireland. To date we have been able to address the issue of unavailability through other means.

Ireland fully supports the recommendations relating to revision or withdrawal of the sunset clause. Ireland is a small market and in line with the analysis set out within the survey, vulnerable to shortages. We consider that in the interest of public health it is desirable to maintain as many marketing authorisations in our market as possible. If a proposal to revise the clause rather than withdraw it were to be progressed, it is important that the application of the clause by member states can be made optional. Currently exemptions from the application of the clause can be applied by member states in exceptional circumstances, based on public health need. It is important that further flexibility is given so that member states can take into account the need to apply the clause based upon the circumstances of their own market.

We also welcome the recommendations concerning more effective transposition and implementation of Article 81. It is also important that further clarity is provided in relation to the meaning of this article and how it is intended to be used. Article 81 specifically refers to the obligation of the marketing authorisation holder "within the limits of their responsibility" to ensure continuity of supply. It would be very helpful to have further clarity on what the limits of this responsibility should be interpreted to include. We note the points highlighted in relation to the lack of harmonisation on the transposition of public service obligations. Consideration should be given to including within the Directive further definition on what can be considered to be covered by a public service obligation, and the various actors within the supply chain to which this should be supplied.

We welcome the recommendations concerning improvement of the implementation of simplified procedures for traditional herbal medicinal products (THMPs) and homeopathics. The analysis provided highlights that only 7 countries have registered more than 20 THMPs. In Ireland the number of applications received had been disappointingly low and has not increased since 2011. However, we note that some member states have been relatively more successful than others in achieving registration of products. Of the total 572 THMPs authorised,

90% of these have been authorised by just 4 member states. It would be useful to have further information or analysis of approaches that may have been taken by these member states to attract applications.

We note the points highlighted with respect to the authorisation of OTC medicines and particularly the difficulties with using centralised and MR/DC procedures. This reflects our experience whereby the national route offers greater flexibility with respect to the authorisation of OTC products. We would agree that this has the potential to result in fewer incentives for developing innovative self-care products and should be reviewed from this perspective.

One issue that has not been addressed by the survey is how the introduction of generic substitution may have impacted on the availability of medicines in member states that have an established system of this nature in operation at pharmacy level. Ireland has recently introduced a system of generic substitution and referencing pricing and would be interested in the experience of other member states in relation to this impacting on medicines availability.

Finally the IMB has a specific procedure in place to try to ensure that nationally-authorised medicines continue to be available and which facilitates continuity of supply on a short term basis – a batch specific procedure. The procedure can be used as a means of dealing with shortages and temporary unavailability of an authorised medicinal product. Typically it involves the authorisation of a batch of medicinal product procured from another market onto the Irish market with appropriate revisions to product information as necessary. This has proven to be an effective means in dealing with short term interruptions in supply and availability.

Department of Health/Irish Medicines Board
28th April 2014.