PAGB, the consumer healthcare association – written evidence, dated 17 January 2022

European Affairs Sub-Committee on the Protocol on Ireland/Northern Ireland

Response to EU proposals on provision of medicines from Great Britain to Northern Ireland

Submission from PAGB, the consumer healthcare association

17 January 2022

PAGB, the consumer healthcare association, welcomes the opportunity to provide this evidence to the European Affairs Sub-Committee on the Protocol on Ireland/Northern Ireland, with our response to the EU proposals pertaining to the supply of medicines to Northern Ireland.

PAGB is the UK trade association representing the manufacturers of branded over-the-counter (OTC) medicines, self care medical devices and food supplements. These products can be bought from a pharmacy or other retail outlets without a prescription and help people to stay healthy and self care for self-treatable conditions which do not require consultation with a medical professional.

Summary of key points

i. PAGB has welcomed the legislative proposals published by the EU Commission and the UK's acceptance of the proposals.

ii. PAGB is confident that the implementation of these proposals would allow for the continued supply, distribution, and sale of OTC medicines in Northern Ireland.

iii. The extension of the grace period to the end of December 2022 (or sooner if the legislation is in place) will ensure continuity of supply of OTC medicines to Northern Ireland from 1 January 2022.

1. The EU legislative proposals

1.1 PAGB has welcomed the legislative proposals put forward by the EU Commission to resolve issues of medicines supply to Northern Ireland. It is clear that the Commission has heard and taken steps to address concerns raised by industry and European Trade Associations.

1.2 The inclusion of an extension to the grace period, which was due to end of 31 December 2021, to the 31 December 2022 (or earlier if legislation is available) will ensure the continuity of supply of OTC medicines to Northern Ireland from 1 January 2022 and is very much welcomed.

1.3 The EU proposal and accompanying legislative details do provide the clarity industry was seeking to ensure that the proposed solutions will prevent barriers to supply.

1.4 The proposals appear to provide the solutions that industry has been seeking and, when implemented, will allow medicines to viably be sold and distributed into Northern Ireland. Specific concerns addressed by the EU proposals are:

- OTC/generic medicines (such as paracetamol) will be able to choose to authorise under national UK procedures, in compliance with EU rules on medicines. People in Northern Ireland will have access to these medicines at the same time as people in the rest of the UK
- All regulatory functions can remain in the UK for national licences
- For medicines brought into Northern Ireland from the rest of the UK, batch testing does not need to be repeated if it has already been carried out in Great Britain or the EU
- No manufacturing authorisation or import licenses are needed for medicines supplied from Great Britain to Northern Ireland, subject to certain conditions
- National authorisation by the UK regulator allows companies located in Great Britain to use a single pack and leaflet when supplying markets in Great Britain and Northern Ireland. There will be no need for separate packaging
- The proposal provides for packaging requirements to ensure that UK-authorised medicines do not enter the Single EU Market
- The UK assumes sole responsibility for authorising medicines for Northern Ireland. This is contingent on the UK complying substantively with EU law on quality, safety and efficacy of human medicines when issuing market authorisations for Northern Ireland. This reduces risks for the EU Single Market.

1.5 PAGB is optimistic that these proposals will ensure smoother regulatory procedures and resolve the issued we identified that would impact the supply of OTC medicines to Northern Ireland.

2. Outstanding issues or clarifications needed

2.1 Clarification is sought with regard to the clause to be added in both Article 20 and Article 48, paragraph c, that "the manufacturing authorisation holder declares that it does not have at its disposal a qualified person established in the union". There are scenarios where a UK-based qualified person (QP) may need to be used and clarification is needed that these scenarios are acceptable:

- The manufacturing authorisation is based on the address of the site, and there is a scenario that the holder, may also own a site in the EU with EU QPs, but still can not send product to the EU site and get it tested there, and therefore needs to utilise the site in the UK
- There is also a scenario that a UK manufacturing authorisation has an EU based QP named on the licence.

2.2 Furthermore, there appears to be no explicit reference in the proposal to the acceptance of a UK based QP who has been approved to UK standards equivalent to those in EU (as opposed to EU standards), and to

Manufacturing Authorisations used are issued by UK regulator. Whilst it appears that this implicit, it does not specifically state this within the proposal. Annex TBT -2: Medicinal Products of Trade and Cooperation Agreement may provide the legal basis for this but confirmation is required.

2.3 Confirmation is required that a Wholesaler Dealers Authorisation (WDA) which is registered for a site in Great Britain or Northern Ireland and issued by a UK competent authority is acceptable to import from Great Britain to Northern Ireland.

2.4 Following the welcome confirmation that a UK-wide national licence can be issued in the UK, even if there is, or has been, a MR/DC procedure taking place for the same product elsewhere in the UK; a process is needed to enable companies to unite a NI licence issued under a MR/DCP with a GB licence. MHRA should put a process in place which is as simple and straightforward as possible with minimal administrative burden.

3. Additional issues addressed by the EU proposals

3.1 The EU Commission proposals include a positive reference that the QP for pharmacovigilance (PV) may be located in a part of the UK other than Northern Ireland, However, further information is needed on the implications of this.

- Does this mean that PV safety reporting within the EU (which currently does not include GB) should be for the whole of the UK if the QP PV is located in UK?
- If there is a UK-wide licence, do PV safety reports for whole of UK need to be submitted to the EU as well as the UK authorities?
- Does MHRA access to EU databases change as result of this proposal?
- How will the Periodic Safety Update Report (PSUR) process change in relation to ability for UK wide licence?
- Will the PSUR process change if there is a QP PV based in UK?

4. Next steps

4.1 To ensure the continued access and smooth transit into NI, it is important that UK regulator does not impose additional testing and release burdens on product entering the UK from Europe. This would directly impact this proposed solution and in all likelihood add further complexity and supply disruption to Northern Ireland.

4.2 As outlined above, the EU proposals do offer a way forward for the supply of OTC medicines to Northern Ireland. However, this is predicated on the UK remaining aligned to the EU, with equivalent standards in all areas, but also making sure that additional regulatory burdens are not imposed on medicines imported into UK, to ensure continuity of supply to Northern Ireland.

- For example, the UK will need to ensure the reliance route remains available as a means of companies distributing medicines to Northern Ireland

- Equally, the MHRA will need to ensure it publishes and meets timelines for licensing procedures related to UK national licences, which are consistent with those within the EU framework.

4.3 The joint Medicines Working Group, that the Trade and Cooperation Agreement commits to establishing, will need to oversee and monitor the implementation of these proposals to ensure their ongoing effectiveness in delivering continuity of supply of medicines for the people in Northern Ireland.

Michelle Riddalls
Chief Executive Officer

17 January 2022