Friday 06 November 2020

Joint EU-UK pharmaceutical industry response to Specialised Committee outcome

Following the fourth meeting of the Ireland/Northern Ireland Specialised Committee, the UK and the EU have agreed a phased process for implementing medicines regulation in Northern Ireland up to 31 December 2021.

This will provide additional time for businesses to prepare in relation to batch testing, importation, and Falsified Medicines Directive requirements.

In a joint statement, six bodies* representing the EU and UK pharmaceutical industry said:

"This is good news for patients in Northern Ireland. We are pleased the UK Government and EU Commission have responded to the concerns raised by industry and removed the immediate threat of a cliff-edge in the way medicines are distributed to Northern Ireland from the end of this year.

"We await the detail of how this will work in practice and there is much work to do. But this is a pragmatic step in the right direction. Both sides must now use the next 8 weeks to clarify the rules which will apply in Northern Ireland from 2022, so that companies can make full use of this extra time to prepare for the long-term."

Under the Northern Ireland Protocol, medicines in Northern Ireland will be governed by EU rules and regulations. However, these rules are to be enforced by the UK's medicines regulator, the MHRA.

Both sides need to agree how the regulations will be interpreted and implemented come December 2021.

While this joint decision addresses one of the immediate priorities of the UK and EU pharmaceutical industry, we continue to call on the UK Government and EU Commission to negotiate a Mutual Recognition Agreement for medicines manufacturing.

Read more about why this is important for patients and the economic case.

*Signatories

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Nathalie Moll, Director-General, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Jurate Svarcaite, Director General, Association of the European Self-Medication Industry (AESGP)

Adrian van den Hoven, Director General, Medicines for Europe

Warwick Smith, Director General, British Generic Manufacturers Association (BGMA)

Michelle Riddalls, Chief Executive Officer, PAGB, the consumer healthcare association