Industry Stakeholder meeting on Brexit and operation of the centralised procedure for human medicinal products

Welcome and opening remarks

Presented by Olga Solomon,

Head of Unit, DG SANTE B5, Medicines: policy, authorisation and monitoring on 20 April 2018

UK's withdrawal from the EU

Main ongoing work strands:

- Withdrawal agreement ("Article 50 agreement")

- "Transition period" (part of the "Article 50 agreement")

- "Future relationship"

Bottom-line: UK will be a "third country" on 30/3/19

Withdrawal agreement

- "Winding down" of EU membership

- Draft text has been published, the EU and the UK have agreed, at negotiators' level, on the colour-coded text, indicating areas of agreement, disagreement or where further clarifications are needed.

The withdrawal agreement needs to be ratified by both sides.

-The Heads of State or Government of the EU27 to evaluate on 23 March at the European Council (Article 50) the state of play of the negotiations

- The EP will also evaluate the progress.

"Transition period" (i)

- Full acquis applies to the UK

- Dynamic reference, i.e. including acquis that starts applying in the transition period

- No UK participation in EU institutions or EU bodies

- No UK participation in Member State meetings (subject to exceptions)

- No UK role as "leading authority"

- Full role of Court of Justice, Commission, Court of Auditors, etc.

"Transition period" (ii)

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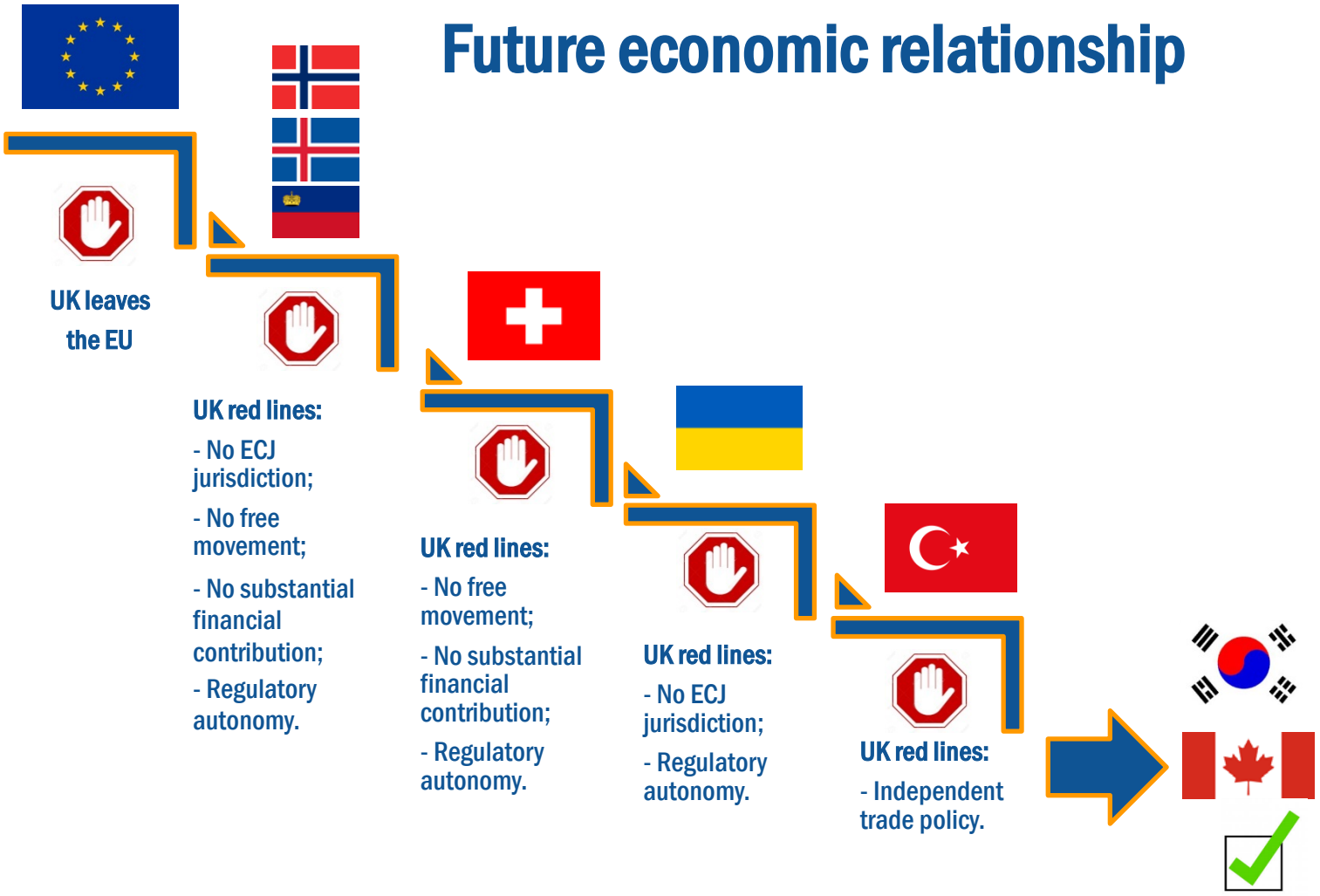
Duration: until 31 December 2020 (incl.)

Agreement still needs to be negotiated, agreed, and ratified

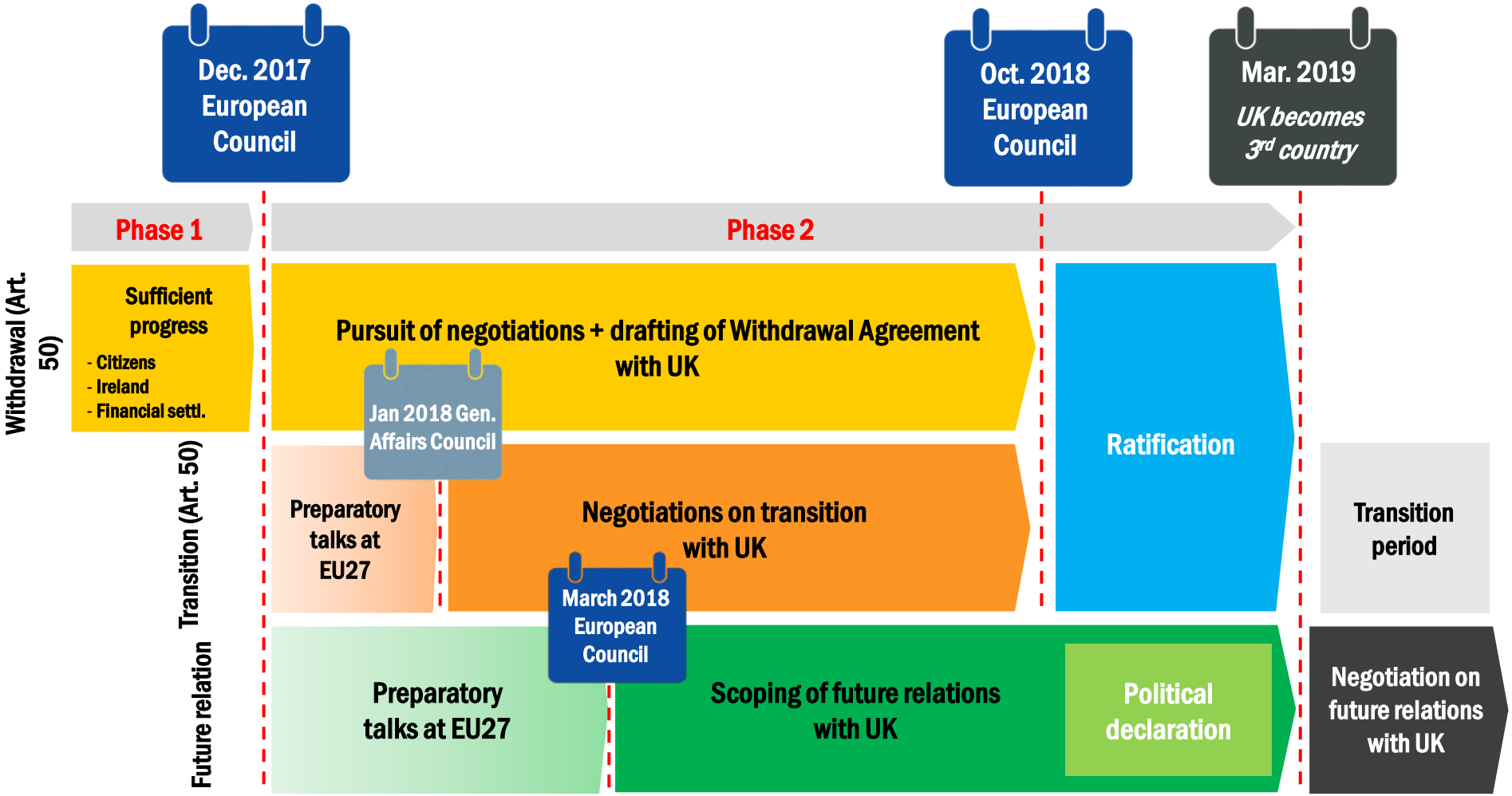
!! Do not rely on the "transition period" !!

Future economic relationship



WORLD TRADE ORGANIZATION

Brexit – Next steps



"Brexit preparedness"-medicinal products

Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/05/WC500226603.pdf

Q&As related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure

https://ec.europa.eu/health/sites/health/files/files/documents/qa_on_brexit.pdf

Other areas for "Brexit preparedness"

- **Intellectual property**: Protection granted by EU trademarks and designs will no longer apply to the UK

- **Value-added tax (VAT):** Rules change from "intra Community supply" to those for EU import/export

- **Medical devices** placed on the market after Brexit require a certificate of a EU-27 notified body

- The shipment of certain chemicals to the UK (a "third country") may become subject to additional permits under sectorial legislation

Commission departments have published "notices to stakeholders" on these and other aspects: https://ec.europa.eu/info/brexit/brexit-preparedness_en

"Brexit preparedness"-medicinal products

MAHs need to consider timely to adapt processes and changes to the terms of the marketing authorisation e.g.:

- **MAHs, MAAs and sponsors of orphan designations need to be established in the EU (EEA)**
- **QPPV reside and carry out tasks in EU (EEA). PSMF located in EU.**
- **Batch control, batch release site need to be located in the EU (EEA)**

Thank you !