Industry stakeholders' perspective

Impact of Brexit on medicines availability

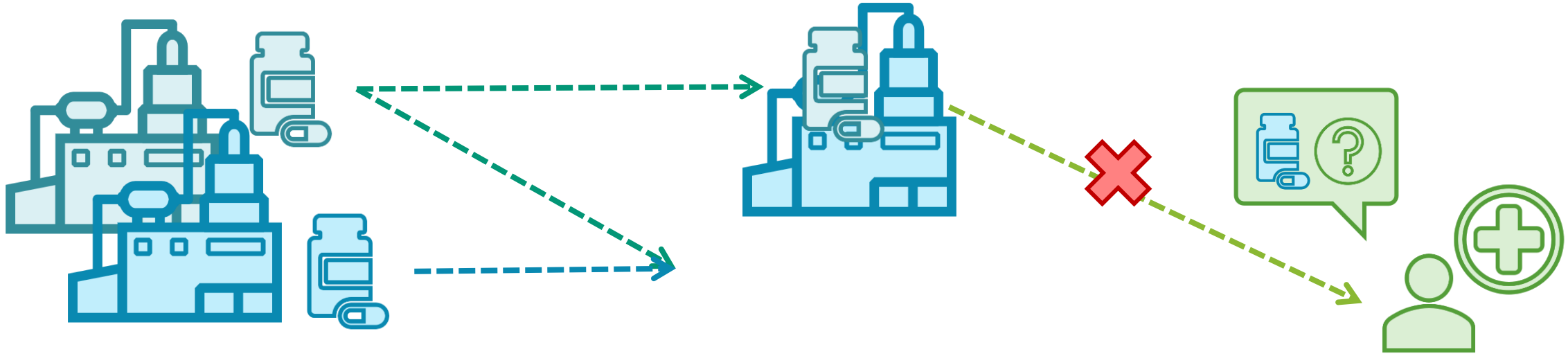
Yvonne Stewart

9 November 2018

Multi-stakeholder workshop

HMA/EMA task force on availability of authorised medicines for human and veterinary use

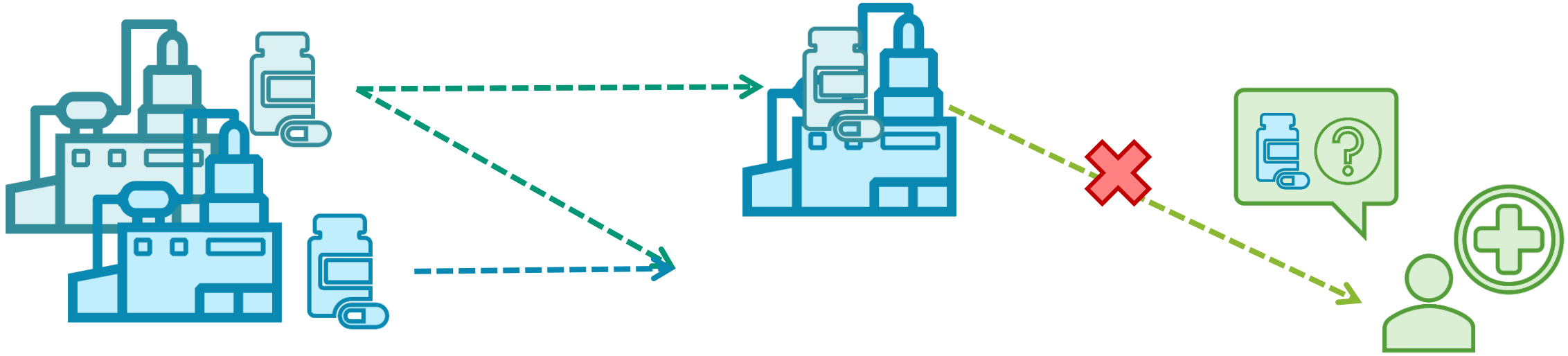
Brexit-specific scenarios Leading to “shortages”
Completion of required changes to Quality arrangements



The medicine is available in the supply chain

RISK: additional / alternative EU site of product testing & batch release site is not complete by 29 March

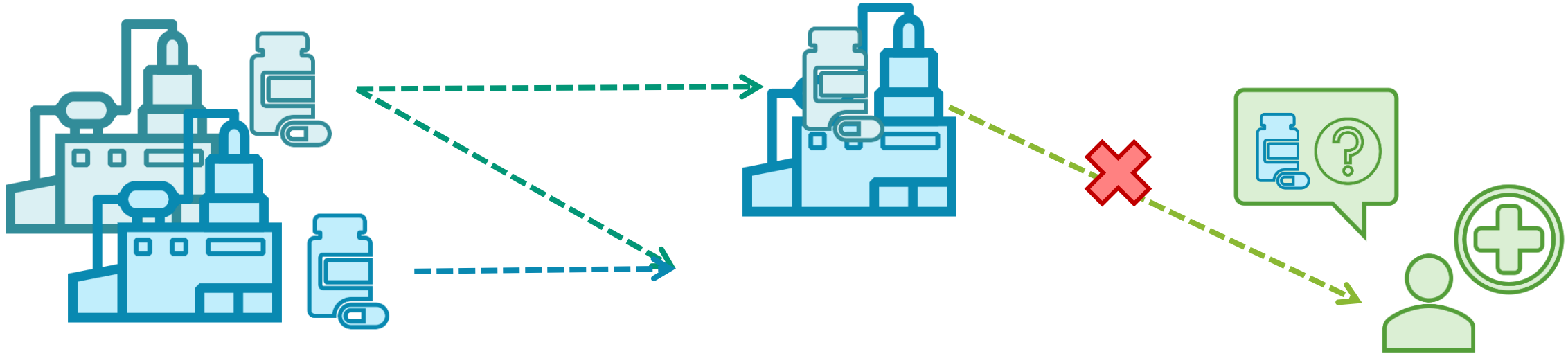
Brexit-specific scenarios Leading to “shortages”
Validity of bulk stock tested in UK before Brexit



The medicine is available in the supply chain

RISK: an EU site cannot repeat testing or change existing manufacturing operations to accommodate re-test of bulk stock imported to EU

Brexit-specific scenarios Leading to “shortages”
Placement of goods on the EU market



The medicine is available in the supply chain

RISK: product tested and QP certified in UK before Brexit but not owned by an EU27 entity until after Brexit will require retesting & QP certification in EU