HUMAN MEDICINES

WHAT WAS THE PROBLEM UNDER THE OLD PROTOCOL?

All medicines in Northern Ireland were subject to EU rules and authorisation under the old Protocol. This meant for novel medicines, including innovative cancer drugs, it was the European Medicines Agency (EMA), not the UK's Medicines and Healthcare Regulatory Agency (MHRA), which approved medicines for the Northern Ireland market.

Although the EU made some changes last year, some elements of the 2022 fixes were only a temporary sticking plaster - risking the ongoing supply of life-saving medicines, such as cancer drugs.

This has created uncertainty for industry and the Northern Ireland healthcare system, which, with the need to meet various EU labelling requirements, risked significant discontinuations. This was not a sustainable way forward.

WHAT HAVE WE ACHIEVED IN THIS AGREEMENT?

Patients in Northern Ireland will be able to access the same medicines in the same packs, with the same labels, as the rest of the UK - permanently protecting the supply of UK medicines for Northern Ireland.

The UK regulator, the MHRA, will always be able to approve all medicines on the market in Northern Ireland, whatever the drug, whatever the setting.

This agreement removes any EU Falsified Medicines Directive packaging, labelling and barcode requirements for medicines.

Medicines sent from Great Britain to Northern Ireland will travel via the new Green Lane which means that goods staying in the UK will be freed of unnecessary paperwork, checks and duties, with only ordinary commercial information required.

We have also ensured that drugs and products produced in Northern Ireland will continue to enjoy frictionless access to the EU market - preserving access for Northern Ireland's world-leading pharmaceutical and medical technology firms.

WHAT IT MEANS FOR YOU

Businesses will only need to secure approval for a UK-wide licence from the UK's MHRA to supply medicines to Northern Ireland, not the European Medicines Agency.

Businesses will be able to produce a single medicines pack for the whole of the UK, including Northern Ireland.

There will be no cliff-edge relating to the Falsified Medicines Directive in 2024. Northern Ireland-based pharmaceutical and medical technology firms can conti nue to enjoy frictionless access to the EU Single Market, as long as they meet EU licensing rules.

WHAT DO I NEED TO DO, AND WHEN?

Businesses won't need to do anything yet. We will engage with industry in due course on the operationalisation of these changes.

We will consult and work with business over the coming months ahead of implementing any changes required by these arrangements.

Meanwhile, current guidance on the supply of medicines in Northern Ireland can be found on the GOV.UK page.