

**From the Chief Medical Officer
Prof Sir Michael McBride**



Department of
Health

An Roinn Sláinte

Máinnystrie O Poustie

www.health-ni.gov.uk

HSS(MD) 43/2022

FOR ACTION

Chief Executives HSC Trusts for onward cascade to Medical Directors

Chief Executives, Public Health Agency/SPPG

GP Medical Advisers, SPPG

All General Practitioners and GP Locums (for onward distribution to practice staff)

Director of Pharmacy at SPPG (for cascade to prescribing advisers and community pharmacies)

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Our Ref: HSS(MD) 43/2022

Date: 8 September 2022

Dear Colleague

EUROPEAN MEDICINES AGENCY (EMA) APPROVAL OF COMIRNATY AND SPIKEVAX BIVALENT ORIGINAL / OMICRON BA.1 COVID-19 VACCINES

1. Further to my letter of 31 August HSS(MD) 39/2022, <https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-hss-ms-39-2022.pdf>, the purpose of this letter is to inform you that the European Medicines Authority (EMA) and Medicines and Healthcare products Regulatory Agency (MHRA) have both now approved the adapted Original / Omicron BA.1 bivalent vaccines manufactured by Pfizer BioNTech (Comirnaty) and Moderna (Spikevax).
2. The Comirnaty (Pfizer) bivalent vaccine has been approved for use as a booster dose in individuals aged 12 years and over. This is the second bivalent vaccine approved for use in the UK, following the earlier approval of Spikevax (Moderna) bivalent Original/Omicron BA.1 vaccine by MHRA on 15 August.
3. Under the terms of the Ireland / Northern Ireland Protocol, the EMA marketing authorisation applies in Northern Ireland for both bivalent vaccines, and supplies of Comirnaty (Pfizer) bivalent vaccine to Northern Ireland will be made under the EMA authorisation from the start of the programme. Please see **Annex A** for pack and vial label images for the approved Comirnaty (Pfizer) bivalent vaccine.
4. Initial supplies of the Spikevax (Moderna) bivalent vaccine to Northern Ireland are being made from batches released prior to EMA authorisation under the

previous Regulation 174 temporary authorisation issued by the MHRA on 15 August, with EMA licensed commercial stock expected to become available in Q4 2022.

5. The initial supply of Spikevax (Moderna) Bivalent vaccine will have different carton and vial labels to the later EMA licensed commercial product, and will carry the description “0 (Zero) / O (Omicron)” on the carton artwork and “0/O” on the vial label. In particular, the word ‘Bivalent’ is not included. The product, although packaged differently initially, is the approved Spikevax bivalent product. Please see **Annex B** for pack and vial label images for the initial supply, and expected subsequent commercial supplies later this year.
6. The Summary of Product Characteristics (SmPC) for the [Comirnaty bivalent vaccine](#) has now been uploaded to the EMA website (see page 65 onwards). Further information on the Regulation 174 approval for the Spikevax (Moderna) bivalent vaccine, including Regulation 174 Information for Healthcare Professionals and Patient Information Leaflet, is available on the [MHRA website](#).
7. JCVI have advised “*simplicity is central to an efficient vaccination programme. Deployment of a single type of vaccine throughout the autumn booster programme promotes simplicity and is therefore desirable. If sufficient doses of mRNA bivalent Original ‘wild-type’/Omicron BA.1 vaccine become available to complete the autumn booster programme, JCVI considers that it is expedient to aim to offer authorised bivalent vaccines throughout the autumn programme, subject to operational considerations. Where substantial delays might be incurred in deploying a bivalent vaccine, the principle of timeliness should take priority and an alternative UK-approved booster vaccine offered, such as a monovalent Original ‘wild-type’ mRNA vaccine. Individuals offered vaccination should be advised that timely boosting is desirable to increase protection over the winter, and therefore to accept whichever booster vaccine is offered.*”

The updated JCVI statement can be viewed here at –

<https://www.gov.uk/government/publications/covid-19-vaccines-for-autumn-2022-jcvi-advice-15-august-2022/jcvi-statement-on-the-covid-19-booster-vaccination-programme-for-autumn-2022-update-15-august-2022>

8. In line with JCVI advice and as stated in HSS (MD) 39/2022, sufficient doses of either of the approved mRNA bivalent Original ‘wild-type’/Omicron BA.1 vaccines should be available to complete the autumn booster programme although this will involve deliveries of the bivalent vaccine(s) into NI throughout the course of the programme.
9. Therefore GPs, Community Pharmacies and Trusts should plan on the basis of using either mRNA bivalent Original ‘wild-type’/Omicron BA.1 vaccine for the vast majority of patients and only use the original ‘wild type’ vaccine for those aged 12 years and over if there is a significant delay in bivalent vaccine supplies or in exceptional circumstances. Vaccine providers may wish to refer to [NHS Specialist Pharmacy Services \(SPS\)](#) guidance with good practice

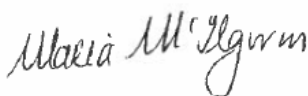
points to ensure good governance when planning or designing vaccination services where multiple vaccines are used.

10. Individuals offered vaccination should be advised that timely boosting is desirable to increase protection over the winter, and therefore to accept whichever booster vaccine is offered.
11. The Pfizer (Comirnaty) Original/Omicron BA.1 bivalent vaccine will be available to be ordered from Movianto in the same way as other COVID-19 vaccines. Vaccine packs will be thawed to order and will be distributed to vaccine providers in packs of 10 vials, with each vial containing 6 doses of 0.3 mL per vial. The Public Health Agency (PHA) and Strategic Planning and Performance Group (SPPG) will work together with vaccine providers to agree quantities that will be available to order, and further details will be provided in the coming days.
12. Both bivalent vaccines are currently only licenced as booster vaccines and cannot be used in the administration of primary doses to eligible patients. The original 'wild type' Spikevax (Moderna) vaccine remains available for primary doses through the Community Pharmacy network, while the original 'wild type' Comirnaty (Pfizer) vaccine remains available via Trust led vaccination clinics.

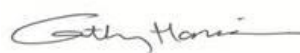
Yours sincerely



Prof Sir Michael McBride
Chief Medical Officer



Maria McIlgorm
Chief Nursing Officer



Mrs Cathy Harrison
Chief Pharmaceutical Officer

Circulation List

Director of Public Health/Medical Director, Public Health Agency (*for onward distribution to all relevant health protection staff*)

Assistant Director Public Health (Health Protection), Public Health Agency

Director of Nursing, Public Health Agency

Assistant Director of Pharmacy and Medicines Management, SPPG (*for onward distribution to Community Pharmacies*)

Directors of Pharmacy HSC Trusts

Director of Social Care and Children, SPPG

Family Practitioner Service Leads, SPPG (*for cascade to GP Out of Hours services*)

Medical Directors, HSC Trusts (*for onward distribution to all Consultants, Occupational Health Physicians and School Medical Leads*)

Nursing Directors, HSC Trusts (*for onward distribution to all Community Nurses, and Midwives*)

Directors of Children's Services, HSC Trusts

RQIA (*for onward transmission to all independent providers including independent hospitals*)

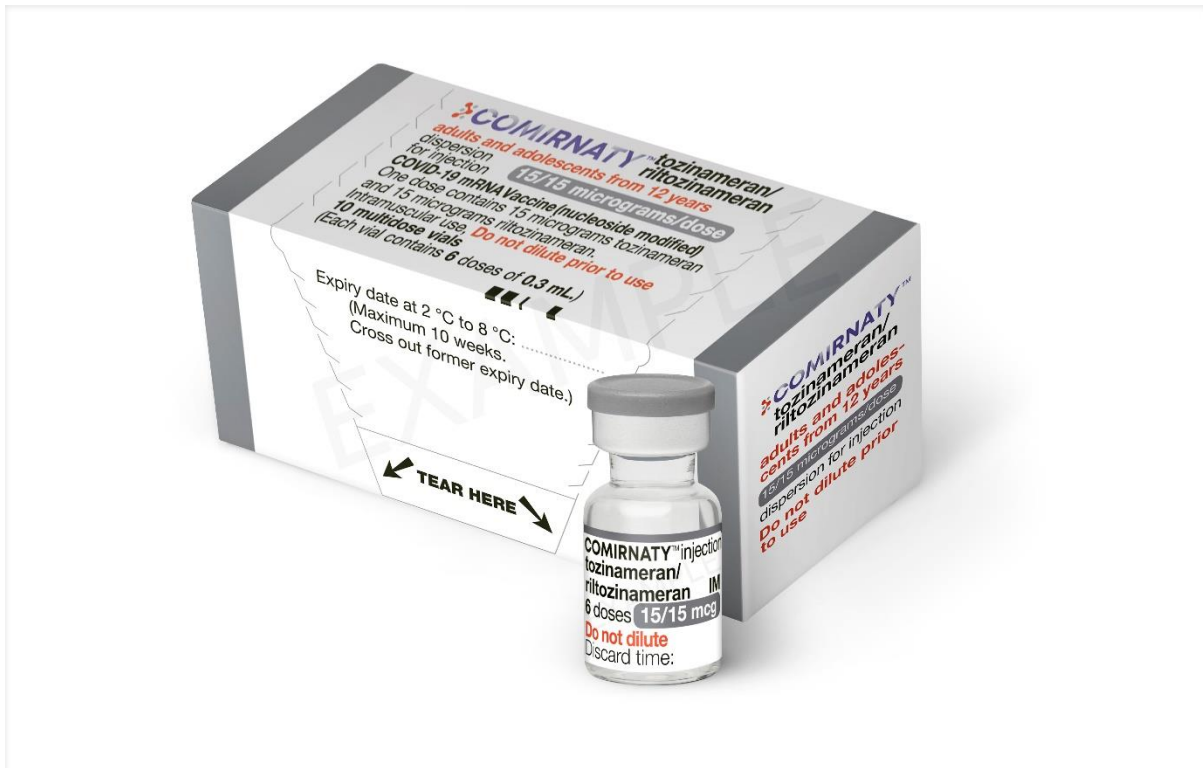
Joe Brogan, Assistant Director, Head of Pharmacy and Medicines Management,

Strategic Planning and Performance Group (SPPG) *(for onward distribution to SPPG Pharmacy and Medicines Management Team and community pharmacists)*
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Regional Pharmaceutical Procurement Service, Northern HSC Trust
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Michael Donaldson, Head of Dental Services, SPPG *(for distribution to all General Dental Practitioners)*
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Trade Union Side
Clinical Advisory Team
Louise McMahon, Director of Integrated Care, SPPG

This letter is available on the Department of Health website at
<https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications>

ANNEX A

Comirnaty bivalent vaccine – pack and vial image



ANNEX B

Spikevax bivalent vaccine initial (Sept 2022) supply - 2.5mL pack and vial labels





Spikevax bivalent vaccine subsequent supply - 2.5mL pack and vial labels (Q4 2022)

