Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 27827

2. Name of Authorisation Holder GALEN LIMITED

3. Legally registered address of GALEN LIMITED, SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, NORTHERN IRELAND,

Authorisation Holder BT63 5UA, UNITED KINGDOM

4. Address(es) of Site(s)

GALEN LIMITED, SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, BT63 5UA, NORTHERN

IRELAND, UNITED KINGDOM

5. Scope of authorisation (complete for

each site under 4)

9. Annexes attached

ANNEX 1

6. Legal basis of authorisation Regulation 18 of the Human Medicines Regulations 2012

7. Name of responsible officer of the

competent authority of the member state Confidential

granting the wholesaling authorisation

8. Date 20/11/2023

Annex 1 Scope of wholesale distribution authorisation Annex 2 (Optional) Address(es) of

contract wholesale distribution sites and their authorisation number Annex 3 (Optional)

Name(s) of responsible person(s) Annex 4 (Optional) Date of Inspection on which

authorisation was granted Annex 5 Additional provisions

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site:

GALEN LIMITED, SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, BT63 5UA, NORTHERN IRELAND, UNITED KINGDOM

1. MEDICINAL PRODUCTS

- 1.1 With "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)
- 1.3 Without "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in the UK and not intended for the UK market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.1 Procurement
- 2.3 Supply
- 2.4 Export

Issue Date: 20 Nov 2023

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.1 Narcotic or psychotropic products

Any restrictions or clarifying remarks (for all users)

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines, 4.4 Pharmacy



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