# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

3: Address(es) of manufacturing site(s)

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

8: Authorisation Date

9: Annexes attached

UK MIA 42551

COPEA PHARMA LIMITED

COPEA PHARMA LIMITED, 25 COMPASS WEST, SPINDUS ROAD, LIVERPOOL, L24 1YA, UNITED KINGDOM

COPEA PHARMA LIMITED, 25 COMPASS WEST, SPINDUS

ROAD, LIVERPOOL, L24 1YA, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

Confidential

25/09/2024

Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

COPEA PHARMA LIMITED, 25 COMPASS WEST, SPINDUS ROAD, LIVERPOOL, L24 1YA, UNITED KINGDOM

**Human Medicinal Products** 

**Authorised Operations** 

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

# Part 1 - MANUFACTURING OPERATIONS

[ 1.1 ] Sterile Products

[1.1.3] Batch certification

[ 1.2 ] Non-sterile products

[ 1.2.2 ] Batch certification

[ 1.3 ] Biological medicinal products

[ 1.3.2 ] Batch certification

[1.3.2.2] Immunological products

[1.3.2.5] Biotechnology products

[ 1.5 ] Packaging

Issue Date: 25 Sep 2024

[1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

# [ 2.2 ] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[ 2.2.1.1 ] Aseptically prepared

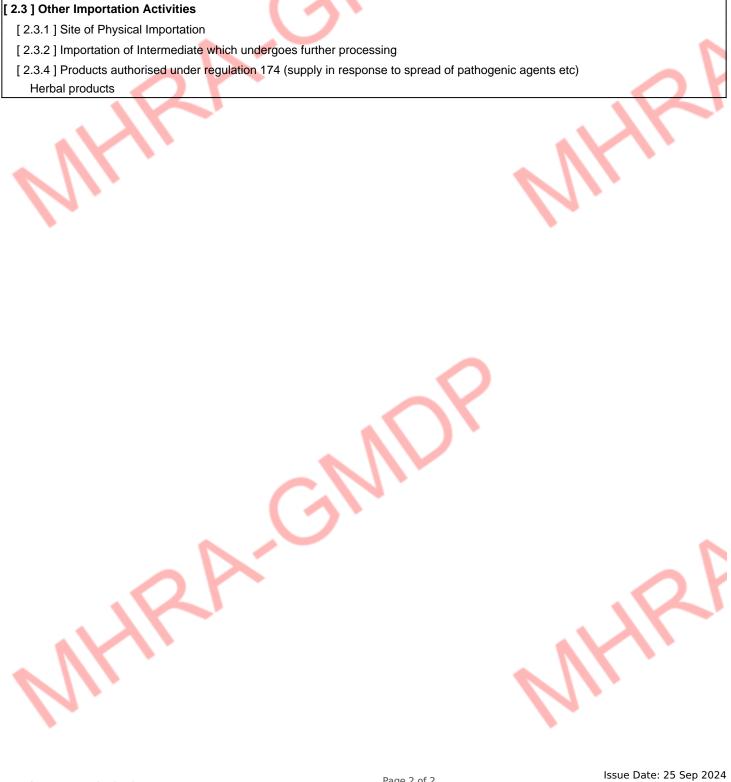
[ 2.2.1.2 ] Terminally sterilised

[2.2.2] Non-sterile products

[ 2.2.3 ] Biological medicinal products

[2.2.3.2] Immunological products

[ 2.2.3.5 ] Biotechnology products



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