

Annex 1: Brexit affected products licensed via Exceptional Marketing Authorisation (art 126a) which are considered critical

No	Active Ingredients/ Pharmaceutical Form
1	EPINEPHRINE BITARTRATE 0.01 % (W/V) SOLUTION FOR INJECTION
2	EPINEPHRINE BITARTRATE 1mg/ml SOLUTION FOR INJECTION
3	EPINEPHRINE 1 mg/ml SOLUTION FOR INJECTION
4	SUXAMETHONIUM CHLORIDE 50 mg/ml SOLUTION FOR INJECTION
5	GLYCERYL TRINITRATE 500 µg TABLETS
6	CHARCOAL, ACTIVATED 81.3 % (W/W) GRANULES FOR ORAL SUSPENSION
7	ACETYLCYSTEINE 20 % (W/V) SOLUTION FOR INFUSION
8	HEPARIN SODIUM 10 IU FLUSHING SOLUTION FOR MAINTENANCE OF PATENCY OR IV DEVICES
9	HUMAN PLASMAPROTEIN 160 mg SOLUTION FOR INJECTION
10	MORPHINE SULFATE 30mg SOLUTION FOR INJECTION
11	MORPHINE SULFATE 2mg ORAL SOLUTION
12	PHENOBARBITAL SODIUM 200 mg/ml SOLUTION FOR INJECTION
13	REMIFENTANIL HYDROCHLORIDE 1 mg/vial POWDER FOR SOLUTION FOR INJECTION
14	REMIFENTANIL HYDROCHLORIDE 2 mg/vial POWDER FOR SOLUTION FOR INJECTION

15	REMIFENTANIL HYDROCHLORIDE 5mg/vial POWDER FOR SOLUTION FOR INJECTION
16	HYDRALAZINE HYDROCHLORIDE 20mg POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION OR INFUSION
17	ETHYLENE DIAMINE ANHYDROUS 0.523 % (W/V) THEOPHYLLINE 2.11 % (W/V) SOLUTION FOR INJECTION
18	HYDROCORTISONE ACETATE 25 mg/ml SUSPENSION FOR INJECTION
19	ADENOSINE 3 mg/ml SOLUTION FOR INJECTION
20	GLYCERYL TRINITRATE 1mg/ml SOLUTION FOR INFUSION
21	ATROPINE SULFATE 600 mcg/ml SOLUTION FOR INJECTION
22	MAGNESIUM SULFATE 20 % (W/V) SOLUTION FOR INJECTION
23	MAGNESIUM SULFATE HEPTAHYDRATE 50 % (W/V) SOLUTION FOR INJECTION
24	CALCIUM CHLORIDE DIHYDRATE 10 % (W/V) SOLUTION FOR INFUSION
25	SODIUM BICARBONATE 84 mg SOLUTION FOR INJECTION
26	MITOMYCIN 20 mg /vial POWDER FOR SOLUTION FOR INJECTION
27	MITOMYCIN 2mg/vial POWDER FOR SOLUTION FOR INJECTION
28	MITOMYCIN 10mg/vial POWDER FOR SOLUTION FOR INJECTION
29	TAMOXIFEN CITRATE 10mg/5ml ORAL SOLUTION

30	CALCIUM FOLINATE 10mg/ml SOLUTION FOR INJECTION
31	CHLORPROMAZINE HYDROCHLORIDE 0.5 % (W/V) SOLUTION
32	CARBOPLATIN 10mg/ml SOLUTION FOR INFUSION, CONCENTRATE
33	EPHEDRINE HYDROCHLORIDE 3. % (W/V) SOLUTION FOR INJECTION
34	PROTAMINE SULFATE 10mg/ml SOLUTION FOR INJECTION
35	COLCHICINE 500 mcg TABLETS
36	DIGOXIN 0.25 mg TABLETS
37	DIAZEPAM 5mg (2mg/ml) RECTAL SOLUTION
38	DIAZEPAM 10mg (4mg/ml) RECTAL SOLUTION
39	PHENYLEPHRINE HYDROCHLORIDE 10mg/ml SOLUTION FOR INJECTION OR INFUSION
40	GELATIN SUCCINYLATED 4g/100ml SOLUTION FOR INFUSION
41	CLOMETHIAZOLE 192mg SOFT CAPSULES
42	LITHIUM CARBONATE 400mg PROLONGED-RELEASE TABLETS
43	WARFARIN SODIUM 1mg TABLETS
44	WARFARIN SODIUM 3mg TABLETS

45	WARFARIN SODIUM 5mg TABLETS
46	HYDROCORTISONE 10mg TABLETS
47	HYDROCORTISONE 20mg TABLETS
48	SODIUM POLYSTYRENE SULFONATE 99.934 % (W/W) POWDER FOR ORAL ADMINISTRATION
49	CODEINE PHOSPHATE 30mg TABLETS
50	PAMIDRONATE DISODIUM 3mg/ml CONCENTRATE FOR SOLUTION FOR INFUSION
51	LABETALOL HYDROCHLORIDE 100mg TABLETS
52	LABETALOL HYDROCHLORIDE 200mg TABLETS
53	LABETALOL HYDROCHLORIDE 5mg/ml SOLUTION FOR INJECTION
54	DANTROLENE SODIUM 25mg HARD CAPSULE
55	DANTROLENE SODIUM 100mg HARD CAPSULE
56	DANTROLENE SODIUM 20mg/vial POWDER FOR SOLUTION FOR INJECTION
57	TRIMETHOPRIM 50mg/5ml ORAL SUSPENSION
58	TOBRAMYCIN 40mg/ml SOLUTION FOR INJECTION
59	DISODIUM PAMIDRONATE 15mg/ml CONCENTRATE FOR SOLUTION FOR INFUSION

60	TERAZOSIN HYDROCHLORIDE 5mg TABLETS
61	SODIUM IODIDE (131 I) 222. GBq (37MBq to 5.55GBq) HARD CAPSULES
62	SODIUM IODIDE (131 I) SOLUTION 0.333 MBq (0.333- 3.7 MBq) DIAGNOSTIC HARD CAPSULE
63	IOBENGUANE (131 I) 9.25 MBq (9.25-18.5MBQ/ml) SOLUTION FOR INJECTION FOR DIAGNOSTIC USE
64	IOBENGUANE (131 I) 185 MBq SOLUTION FOR INJECTION FOR THERAPEUTIC USE
65	HUMAN ALBUMIN COLLOIDAL PARTICLES 0.5 mg/vial KIT FOR RADIOPHARMACEUTICAL PREPARATION POWDER FOR SOLUTION FOR INJECTION
66	EXAMETAZIME 500mcg/vial KIT FOR RADIOPHARMACEUTICAL PREPARATION
67	DINOPROSTONE 0.666 mg/g VAGINAL GEL
68	FOSCARNET SODIUM HEXAHYDRATE 24 mg/ml SOLUTION FOR INFUSION
69	GLYCOPYRRONIUM BROMIDE 0.2 mg/ml SOLUTION FOR INJECTION
70	SULFASALAZINE 500mg GASTRO-RESISTANT TABLET
71	CHLORAMPHENICOL 0.5 % (W/V) EYE DROPS
72	PILOCARPINE HYDROCHLORIDE 2. % (W/V) EYE DROPS
73	PILOCARPINE HYDROCHLORIDE 4. % (W/V) EYE DROPS
74	ATROPINE SULFATE 1. % (W/V) EYE DROPS

75	METRONIDAZOLE 7.5 mg/g VAGINAL GEL
76	ONDANSETRON HYDROCHLORIDE DIHYDRATE 4mg/5ml SYRUP
77	HYALURONIDASE 1500IU/AMP POWDER FOR SOLUTION FOR INJECTION/INFUSION
78	METRONIDAZOLE BENZOATE 320mg (200mg/5ml) ORAL SUSPENSION
79	FUROSEMIDE 20mg/5ml ORAL SOLUTION
80	SODIUM BICARBONATE 500mg HARD CAPSULE
81	ISOSORBIDE DINITRATE 40mg PROLONGED-RELEASE TABLET
82	CYANOCOBALAMIN 1000 mCG SOLUTION FOR INJECTION
83	PREDNISOLONE 20mg/100ml RECTAL SOLUTION
84	PARACETAMOL 325. mg ISOMETHEPTENE MUCATE 65. mg HARD CAPSULE
85	CYCLIZINE HYDROCHLORIDE 50. mg CAFFEINE MONOHYDRATE 100. mg ERGOTAMINE TARTRATE 2. mg TABLET
86	PHOLCODINE 5mg (1mg/ml) ORAL SOLUTION
87	FLUMETASONE PIVALATE 0.02 % (W/V) CLIOQUINOL 1. % (W/V) EAR DROPS

88	PROPAMIDINE ISETIONATE 0.1 % (W/V) EYE DROPS
89	DIBROMPROPAMIDINE ISETIONATE 0.15 % (W/V) EYE OINTMENT
90	DISODIUM HYDROGEN PHOSPHATE DODECAHYDRATE 9.4 g SODIUM DIHYDROGEN PHOSPHATE DIHYDRATE 21.4 g ENEMA
91	METRONIDAZOLE 0.75 % (W/W) GEL
92	FLUOCINOLONE ACETONIDE 0.25 mg GEL
93	FLUOCINOLONE ACETONIDE 0.25 mg/g OINTMENT
94	FLUOCINOLONE ACETONIDE 0.25 mg CLIOQUINOL 30mg CREAM
95	CLIOQUINOL 3.02 mg FLUOCINOLONE ACETONIDE 26.5 mg OINTMENT
96	FLUOCINOLONE ACETONIDE 27.69 mg NEOMYCIN SULFATE 0.599 mg CREAM
97	FLUOCINOLONE ACETONIDE 26.5 mg NEOMYCIN SULFATE 0.55 mg OINTMENT
98	HYDROCORTISONE MICRONISED 1. % (W/W) CREAM
99	CINNAMIC ACID 0.045 g ZINC OXIDE 0.1 g LIDOCAINE HYDROCHLORIDE 0.065 g BENZOIC ACID 0.04 g BISMUTH OXIDE 0.02 g CREAM
100	METFORMIN 500 mg PROLONGED-RELEASE TABLETS
101	METFORMIN HYDROCHLORIDE 750 mg PROLONGED-RELEASE TABLETS

102	METFORMIN HYDROCHLORIDE 1000 mg PROLONGED-RELEASE TABLETS
103	LIDOCAINE HYDROCHLORIDE 0.33 % (W/W) CETYLPIRIDINIUM CHLORIDE 0.1 % (W/W) ORAL GEL
104	ACTIVATED DIMETHICONE 30% (42mg/5ml) ORAL SUSPENSION, DROPS
105	LIDOCAINE HYDROCHLORIDE 0.66 % (W/W) AMINOACRIDINE HYDROCHLORIDE 0.05 % (W/W) ORAL GEL