Government Decree

amending the Government Decree on the decree on the mandatory stockpiling of medicinal products

By decision of the Government,

Sections 1, 2(2), 3 and 4 and the Annex to the Government Decree on the mandatory stockpiling of medicinal products (1114/2008), as well as their presence in Section 1 of Decree 308/2012 and Section 2(2) and 3 in Decree 1106/2015, are *amended* as follows:

Section 1

Scope of the obligation

Under the act on the mandatory stockpiling of medicinal products (979/2008), hereinafter referred to as the *Mandatory Stockpiling Act*, the following active substances and their pharmaceutical forms included in the categories of medicines referred to in Section 4(1) are subject to the stockpiling obligation:

1) *antimicrobials*: amoxicillin, amoxicillin+clavulanic acid, aciclovir, azithromycin, benzylpenicillin, doxycycline, etambutol, phenoxymethylpenicillin, fluconazole, genmastain, isoniazid, caspofungin, cefalexin, ceftriaxone, ceftriaxone+lidocaine, cefuroxime, clindamycin, cloxacillin, levofloxacin, meropenem, metronidazole, nitrofurantoin, oseltamivir, piperacillin+tazobactam, pivmecillinam, pyrazinamide, rifampicin, ciprofloxacin, sulfa+trimethoprim, tobramycin, trimethoprim, vancomycin, voriconazole and the HIV medicines abacavir+dolutegravir+lamivudine, biktegravir+emtricitabine+tenofovir alafenamide, dolutegravir, doravirine+lamivudine+tenofovir disoproxil, emtricitabine+tenofovir alafenamide and emtricitabine+tenofovir disoproxil;

2) *medicinal products used in electrolyte and fluid imbalances and parenteral nutrition:* albumin, amino acid solution, glucose, potassium chloride, calcium gluconate, calcium chloride, magnesium sulphate, sodium bicarbonate, sodium glycerophosphate pentahydrate, sodium chloride and combinations containing the above-mentioned active substance;

3) *medicines for cardiovascular diseases and diuretics:* intravenous adrenaline, as well as amiodarone, amlodipine, atorvastatin, bisoprolol, dobutamine, intravenous etilefrine and furosemide, glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate, candesartan, losartan, metoprolol, noradrenaline, ramipril, rosuvastatin and spironolactone;

4) *medicinal products for metabolic and endocrine disorders:* dapagliflozin, hydrocortisone, insulins and insulin derivatives, levothyroxine, metformin, methylprednisolone and prednisolone;

5) *painkillers and anti-rheumatic medicines*: etoricoxib, hydroxychloroquine, ibuprofen, methotrexate, morphine, naproxen, oxycodone, oxycodone+naloxone, paracetamol, parecoxib, pregabalin and tramadol;

6) *medicines used in local anaesthesia and general anaesthesia*: alfentanil, atropine, bupivacaine, dexmedetomidine, esketamine, fentanyl, lidocaine, intravenous midazolam, neostigmine+glycopyrronium bromide, propofol, remifentanil, rocuronium, ropivacaine, sevoflurane and suxamethonium;

7) *antidotes, vaccines, immunoserums and immunoglobulins:* charcoal, naloxone, hepatitis A, B and rabies vaccines, gamma-globulins for intravenous and intramuscular use, and immunoglobulins for the treatment of hepatitis B, as well as vaccines and other medicinal

products included in the national vaccination programme imported or procured by the National Institute for Health and Welfare, with the exception of influenza vaccines and similar seasonally administered vaccines;

8) *medicinal products for respiratory diseases:* budesonide, fluticasone, fluticasone+salmeterol, formoterol+budesonide, montelukast, salbutamol and tiotropium;

9) *medicines for digestive disorders*: esomeprazole, mesalazine, metoclopramide, pantoprazole, sulphasalazine and ursodeoxycholic acid;

10) *psychotropic substances*: amitriptyline, aripiprazole, diazepam, escitalopram, haloperidol, clozapine, lithium, lorazepam, mirtazapine, oxazepam, olanzapine, sertraline and venlafaxine;

11) *neurological medicines*: lacosamide, lamotrigine, levetiracetam, levodopa combination products, midazolam oral solution, oxcarbazepine and valproic acid;

12) *ophthalmic medicines*: ophthalmic dexamethasone, chloramphenicol, latanoprost, levofloxacin, oxybuprocaine hydrochloride eye drops, pilocarpine, prednisolone eye drops, cyclopentolate eye drops, timolol and tropicamide eye drops;

13) *oncological medicines and medicinal products to treat their side effects, immunostimulants, immunosuppressants and antithrombotic drugs and haemostats:* abiraterone, alteplase, apixaban, acetylsalicylic acid, azathioprine, bicalutamide, dalteparin, dasatinib, enoxaparin, filgrastim, goserelin, heparin, hydroxycarbamide, factor IX, coagulating factor VIII, imatinib, capecitabine, clopidogrel, chlorambucil, lenalidomide, letrozole, mercaptopurine, mycophenolate mofetil, pegfilgrastim, rivaroxaban, ciclosporin, tacrolimus, tamoxifen, temozolomide, Tenecteplase, ticagrelor, tinzaparin tranexamic acid, warfarin, venetoclax and the active substances specified in the Annex; and

14) *veterinary medicinal products*: benzyl penicillin, dexamethasone, detomidine, ivermectin, ketamine, ketoprofen, chlortetracycline, cloprostenol sodium, oxytetracycline, oxytocin, pentobarbital, procaine-benzylpenicillin, rabies vaccine, sulfadiazine+trimethoprim, T 61 vet solution for injection, parenteral administration of enrofloxacin and iron preparations, and parenteral administration of glucose, sodium chloride, calcium salts, magnesium salts and combinations of the above active substances.

The obligation to stockpile the medicinal products listed in the Annex referred to in paragraph 1(13) above applies only to the operators of healthcare units.

Section 2

Arranging for the stockpiling obligation in special cases

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A party subject to the stockpiling obligation referred to in Sections 6 and 7 of the Mandatory Stockpiling Act may fulfil their obligation to stockpile a medicinal product, in whole or in part, by stockpiling a corresponding quantity of the active substance or intermediate product, or another medicinal product containing the same active substance that is suitable for the treatment of the same patient group.

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Section 3

Exemption from the stockpiling obligation

The Finnish Medicines Agency may exempt a party from the mandatory stockpiling obligation of medicinal products, either in full or in part, if:

3) the stockpiling obligation of a party subject to the obligation laid out in Sections 5, 6, 7 and 8 of the Mandatory Stockpiling Act is minimal, or the stockpile is otherwise manifestly unnecessary, and exemption from the stockpiling obligation would not jeopardise an adequate security of supply;

4) the stockpiling obligation of a private service provider that sells medical services to a wellbeing services county, the City of Helsinki, HUS Group or the Province of Åland is limited.

Section 4

Applying for stockpiling compensation, payment thereof, and other compensation procedures

Applications for mandatory stockpiling compensation must be submitted in writing to the National Emergency Supply Agency by the end of February following the stockpiling year.

The application must indicate the minimum capital committed to the mandatory stockpile, separated for each quarter of the stockpiling year. The capital must be indicated according to the categories of medicinal products laid down in Section 4(1) of the Mandatory Stockpiling Act. This must also indicate the permits to fall behind the stockpiling obligation, granted under Section 15(3) of the Mandatory Stockpiling Act, and the exemptions from the stockpiling obligation pursuant to Section 9(3), as well as the effects of said permits and exemptions on the stockpiling compensation.

The application must be accompanied by a declaration from the responsible director or similar of the organisation applying for compensation, confirming that the amounts that form the basis of the application, taken from the capital committed to the mandatory stockpile, have been correctly derived from the organisation's accounts.

The National Emergency Supply Agency must pay the compensation into the account declared by the beneficiary of the stockpiling compensation by the end of April each year.

This Decree enters into force on 1 January 2027. However, Section 4 does not enter into force until 1 January 2028.

A party subject to the stockpiling obligation must stockpile 15 per cent of the total quantity of medicinal substances subject to the obligation introduced by this Decree by 1 January 2028. A party subject to the stockpiling obligation must stockpile 40 per cent of the total quantity of medicinal substances subject to the obligation introduced by this Decree by 1 January 2029. A party subject to the stockpiling obligation must stockpile 75 per cent of the total quantity of medicinal substances subject to the obligation introduced by this Decree by 1 January 2030. A party subject to the stockpiling obligation must stockpile 100 per cent of the total quantity of medicinal substances subject to the obligation introduced by this Decree by 1 January 2031.

Helsinki xx Month 20xx

Minister of ... First name Last name

Title First name Last name

Annex

Medicinal substances stored in mandatory stockpiles only by operators of healthcare institutions

1. alemtuzumab
2. anti-thymocyte globulin
3. asparaginase
4. basiliximab
5. BCG vaccine
6. bendamustine
7. bevacizumab
8. bleomycin
9. blinatumomab
10. bortezomib
11. busulfan
12. dacarbazine
13. dexamethasone
14. doxorubicin
15. docetaxel
16. epirubicin
17. etoposide
18. fludarabine
19. fluorouracil
20. gemcitabine
21. idarubicin
22. ifosfamide
23. irinotecan
24. calcium folinate
25. carboplatin
26. cladribine
27. melphalan
28. mesna
29. mitoxantrone
30. mitomycin
31. nivolumab
32. obinutuzumab
33. oxalic platinum
34. ondansetron
35. paclitaxel
36. pemetrexed
37. plerixafor
38. rasburicase
39. rituximab
40. cisplatin
41. cyclophosphamide
42. cytarabine
43. trastuzumab
44. tretinoin
45. vinblastine
46. vincristine

47. vinorelbine