COMMONWEALTH OF AUSTRALIA

National Health Act 1953

ARRANGEMENTS MADE UNDER SUBPARAGRAPH 100(1)(b)(i)

CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

No. PB 35 of 2007

I, STEPHEN DELLAR, Assistant Secretary, Pharmaceutical Evaluation Branch, Department of Health and Ageing and delegate of the Minister for Health and Ageing, pursuant to subparagraph 100(1)(b)(i) of the *National Health Act 1953*, hereby make the following Arrangements for the purpose of providing that an adequate supply of special pharmaceutical products will be available to persons who are receiving treatment with chemotherapy pharmaceuticals at public hospitals as non-admitted patients, day admitted patients or patients on discharge:

Commencement

1. (a) These Arrangements commence on 1 May 2007.

   (b) The Arrangements made on 12 March 2007 with effect from 1 April 2007 (No. PB 29 of 2007) are repealed with effect from the commencement of these Arrangements.

Definitions

2. In these Arrangements:

   (a) unless the contrary intention appears, a word or phrase will be taken to have the same meaning as in the Act, the Regulations or a declaration, determination or other instrument made under Part VII of the Act or under the Regulations;

   (b) "Act" means the *National Health Act 1953*;

   (c) "Medicare Australia CEO" means the Chief Executive Officer of Medicare Australia;

   (d) "chemotherapy pharmaceutical" means a special pharmaceutical product in relation to which, by virtue of paragraphs 5, 8 and 12, these Arrangements apply;

   (e) "Medicare Australia authority notification computer system" means a computer system operated by the Medicare Australia CEO for the purpose of receiving messages from medical practitioners and sending authorisations for supply of chemotherapy pharmaceuticals or refusals of such authorisations, having an electronic mail address approved by the Medicare Australia CEO;

   (f) "hospital" means a public hospital that is participating in the arrangements provided for in Appendix F to Australian Health Care Agreements;

   (g) "medical practitioner" means a medical practitioner, within the meaning of the *Health Insurance Act 1973*, who is affiliated with the hospital in or at which the patient is receiving treatment;

   (h) "patient" means a person receiving treatment as a non-admitted patient, a day admitted patient or a patient on discharge of the hospital of which the approved hospital authority is the governing body;

   (i) "Regulations" means the *National Health (Pharmaceutical Benefits) Regulations 1960* made under the Act.

3. Except where otherwise specified in these Arrangements, the provisions of the Act and the Regulations, and declarations, determinations and other instruments made under the Act shall apply to the prescribing and supply of chemotherapy pharmaceuticals.

Entitlement to receive chemotherapy pharmaceuticals under these Arrangements

4. Subject to these Arrangements, a person who:

   (a) is, or is to be treated as, an eligible person within the meaning of the *Health Insurance Act 1973*; and

   (b) is receiving treatment as a non-admitted patient, a day admitted patient or a patient on discharge, of a hospital as defined in paragraph 2(f); and

(c) is receiving medical treatment by a medical practitioner, within the meaning of the *Health Insurance Act 1973*, who is affiliated with the hospital in or at which the patient is receiving treatment;

is entitled to receive chemotherapy pharmaceuticals under these Arrangements without the payment or furnishing of money or other consideration other than a charge made in accordance with paragraphs 20 and 20A.

5. The special pharmaceutical products to which these Arrangements apply are the chemotherapy pharmaceuticals specified in column 1 of Schedule 1.

6. The prescribing of a chemotherapy pharmaceutical is authorised under these Arrangements only in the circumstances, if any, specified in column 2 of Schedule 1 in relation to the chemotherapy pharmaceutical.

7. The following circumstances are specified in relation to each chemotherapy pharmaceutical:

(a) where a class of persons is specified in column 2 of Schedule 1 — the chemotherapy pharmaceutical is to be supplied for the treatment of a person included in that class of persons; or

(b) where a disease or condition is specified in column 2 of Schedule 1 —

(i) if subsubparagraph (ii) does not apply — the chemotherapy pharmaceutical is to be supplied for the treatment of that disease or condition in relation to any person; or

(ii) if the disease or condition is specified in relation to a specified class of persons — that the chemotherapy pharmaceutical is to be supplied for the treatment of that disease or condition in a person included in that class of persons; or

(c) where a purpose is specified in column 2 of Schedule 1 — the chemotherapy pharmaceutical is to be supplied for that purpose.

8. Where strength, type of unit, size of unit or other particulars of form are specified in column 2 of Schedule 2 or column 2 of Schedule 3 in relation to a special pharmaceutical product, each specified form of the product is a chemotherapy pharmaceutical, and these Arrangements do not apply in relation to the special pharmaceutical product in any other form.

9. The manner of administration specified in column 3 of Schedule 2 or column 4 of Schedule 3 in relation to a chemotherapy pharmaceutical is the only manner of administration that may be directed to be used in relation to that product.

10. The maximum quantity or number of units of a chemotherapy pharmaceutical that may, in one prescription, be directed to be supplied on any one occasion is:

(a) where the name of the chemotherapy pharmaceutical is specified in column 1 of Schedule 2 — the quantity or number, if any, specified in column 4 of that Schedule in relation to the chemotherapy pharmaceutical; or

(b) where the name of the chemotherapy pharmaceutical is specified in column 1 of Schedule 3 and the chemotherapy pharmaceutical is prescribed in accordance with the provisions of column 3 of that Schedule — the quantity or number, if any, specified in column 5 of that Schedule in relation to the chemotherapy pharmaceutical.

11. The maximum number of occasions, if any, on which the supply of a chemotherapy pharmaceutical may, in one prescription, be directed to be repeated is:

(a) where the name of the chemotherapy pharmaceutical is specified in column 1 of Schedule 2 — the number, if any, specified in column 5 of that Schedule in relation to the chemotherapy pharmaceutical; or

(b) where the name of the chemotherapy pharmaceutical is specified in column 1 of Schedule 3 and the chemotherapy pharmaceutical is prescribed in accordance with the provisions of column 3 of that Schedule — the number, if any, specified in column 6 of that Schedule in relation to the chemotherapy pharmaceutical.

12. The name of the manufacturer or the names of the manufacturers denoted in accordance with the following table by letters specified in column 6 of Schedule 2 or column 7 of Schedule 3 in relation to a special pharmaceutical product is or are the brand or brands under which the special pharmaceutical product may be supplied as a chemotherapy pharmaceutical, and these Arrangements do not apply to the special pharmaceutical product as marketed under any other brand:

Letters	*Manufacturer's Name*
AP	AstraZeneca Pty Ltd
AW	Arrow Pharmaceuticals Pty Limited
BQ	Bristol-Myers Squibb Pharmaceuticals A Division of Bristol-Myers Squibb Australia Pty Ltd
BX	Baxter Healthcare Pty Limited
FB	Pierre Fabre Medicament Australia Pty Limited
GK	GlaxoSmithKline Australia Pty Ltd
HX	Hexal Australia Pty Ltd
IT	InterPharma Pty Ltd
JC	Janssen-Cilag Pty Ltd
LY	Eli Lilly Australia Pty Limited
MK	Merck Sharp & Dohme (Australia) Pty Ltd
MX	Mayne Pharma Pty Ltd
NV	Novartis Pharmaceuticals Australia Pty Ltd
OA	Orphan Australia Pty Ltd
OR	Organon (Australia) Pty Limited
PF	Pfizer Pty Limited
PH	Pharmacia Australia Pty Limited
PU	Pharmacia & Upjohn Pty Limited
RE	Real-RL Division of GlaxoSmithKline Australia Pty Ltd
RO	Roche Products Pty Ltd
SE	Servier Laboratories (Aust.) Pty Ltd
SH	Schering-Plough Pty Ltd
SI	Sigma Pharmaceuticals Pty Ltd
SW	Sanofi Synthelabo Australia Pty Limited
WA	Winthrop Pharmaceuticals Division of Sanofi-Aventis Australia Pty Limited
ZP	Spirit Pharmaceuticals Pty Ltd

Prescribing of chemotherapy pharmaceuticals

13. A medication chart prepared by a medical practitioner, on which is prescribed a chemotherapy pharmaceutical for the medical treatment of a patient of the hospital who is named on the medication chart, will be taken to be a duly written prescription within the meaning of regulation 19 of the Regulations, notwithstanding that it does not comply with the requirements of paragraphs 19(1)(a) and (b) of the Regulations, provided that:

    (a) the medication chart bears the number issued by the Medicare Australia CEO, in pursuance of the function granted to him or her by subsection 18(a) of the *Medicare Australia (Functions of Chief Executive Officer) Direction 2005* made under paragraph 5(1)(d) of the *Medicare Australia Act 1973*, to the medical practitioner who prescribed the chemotherapy pharmaceutical; and

    (b) if the medication chart contains a direction, pursuant to paragraph 85A(2)(b) of the Act and subparagraph 19(1)(f)(ii) of the Regulations, that the supply of the chemotherapy pharmaceutical is to be repeated, that direction will be invalid; and

    (c) if the medication chart contains a direction for the supply of an increased quantity or number of units of the chemotherapy pharmaceutical pursuant to subsection 88(6) of the Act and regulation 24 of the Regulations, that direction will be taken to be a direction to supply the maximum quantity or number of units for that chemotherapy pharmaceutical as specified in Schedule 2 or Schedule 3, as the case may be; and

(d) if the medication chart contains a direction for the supply of a quantity or number of units of a chemotherapy pharmaceutical greater than the maximum quantity for that chemotherapy pharmaceutical as specified in column 4 of Schedule 2, or column 5 of Schedule 3, as the case may be, an authorisation has been obtained, in accordance with paragraph 15, for the supply of that greater quantity or number of units; and

(e) if the medication chart contains a direction for the supply of a chemotherapy pharmaceutical for which it is necessary to obtain the authorisation of the Medicare Australia CEO pursuant to column 2 of Schedule 1, or column 3 of Schedule 3, an authorisation has been obtained, in accordance with paragraph 14, for the supply of the chemotherapy pharmaceutical.

14. A medical practitioner who wishes to prescribe a chemotherapy pharmaceutical for which an authorisation has to be obtained pursuant to subparagraph 13(e) may:

(a) seek that authorisation in accordance with the provisions of subparagraph 14(d) of the declaration in force under subsection 85(2) of the Act; or

(b) arrange for the authorisation to be sought, on behalf of the medical practitioner, by the approved hospital authority in accordance with paragraph 16.

15. A medical practitioner who wishes to prescribe a quantity of a chemotherapy pharmaceutical for which an authorisation has to be obtained pursuant to subparagraph 13(d) may:

(a) seek that authorisation in accordance with the provisions of regulation 13 of the Regulations; or

(b) arrange for the authorisation to be sought, on behalf of the medical practitioner, by the approved hospital authority in accordance with paragraph 16.

16. Where, pursuant to subparagraph 14(b) or 15(b), a medical practitioner arranges for an approved hospital authority to seek an authorisation for the supply of a chemotherapy pharmaceutical, a pharmacist employed by the approved hospital authority must, on behalf of the medical practitioner, submit details of the medication chart by giving to the Medicare Australia authority notification computer system, by computer message in a manner and form approved by the Medicare Australia CEO, details of the medication chart that has been prepared and signed by the medical practitioner in accordance with regulation 19 of the Regulations, as modified by paragraph 13.

17. Where, on behalf of a medical practitioner, a pharmacist employed by an approved hospital authority submits details of a medication chart to the Medicare Australia authority notification computer system in accordance with paragraph 16, and it is received by that computer system, the computer system may send a message, in a manner and form approved by the Medicare Australia CEO, to the approved hospital authority, and:

(a) if the message indicates that authorisation has been granted, the pharmacist employed by the approved hospital authority must complete the medication chart in accordance with the instructions contained in the message; or

(b) if the message indicates that authorisation has not been granted, or the Medicare Australia authority notification computer system fails to send a message indicating whether or not authorisation has been granted, the medical practitioner may, if the medical practitioner so wishes, resubmit the details of the medication chart to the Medicare Australia CEO in accordance with the provisions of subparagraph 14(d) of the declaration in force under subsection 85(2) of the Act or regulation 13 of the Regulations, as the case may be.

18. When the Medicare Australia authority notification computer system has sent to the approved hospital authority a message indicating that authorisation has been granted, the supply of the chemotherapy pharmaceutical shall be taken to have been approved under these Arrangements.

Supply of chemotherapy pharmaceuticals under these Arrangements

19. The approved hospital authority will supply chemotherapy pharmaceuticals to the patients of the hospital as if medication charts were original prescriptions, provided that:

(a) where a medication chart contains a direction to supply more than one chemotherapy pharmaceutical, the approved hospital authority must not, pursuant to regulation 26A of the Regulations, defer the supply of one or more of the chemotherapy pharmaceuticals; and

(b) in lieu of the requirements of regulation 31 of the Regulations, a person authorised for the purpose by the approved hospital authority certifies on the medication chart that the chemotherapy pharmaceutical has been supplied and the date on which it was supplied, and signs his or her name.

Cost to patient of chemotherapy pharmaceuticals supplied under these Arrangements

20. An approved hospital authority that supplies a chemotherapy pharmaceutical may charge the person to whom the chemotherapy pharmaceutical is supplied an amount equivalent to the amount that may be charged under subsection 87(2) of the Act for the supply of a pharmaceutical benefit to the person.

20A. In addition to the amount that may be charged by an approved hospital authority under paragraph 20, an approved hospital authority which supplies a chemotherapy pharmaceutical which is:

(i) named in column 1 of Schedule 4;

(ii) in the form specified in column 2 of Schedule 4 in relation to that chemotherapy pharmaceutical;

(iii) marketed under the brand specified in column 3 of Schedule 4 in relation to that chemotherapy pharmaceutical; and

(iv) in the quantity or number of units specified in column 4 of Schedule 4 in relation to that chemotherapy pharmaceutical;

may charge the person to whom the chemotherapy pharmaceutical is supplied the amount calculated by subtracting the amount specified in column 5 of Schedule 4 in relation to that chemotherapy pharmaceutical from the amount specified in column 6 of Schedule 4 in relation to that chemotherapy pharmaceutical.

Payment to supplier of chemotherapy pharmaceuticals under these Arrangements

21. An approved hospital authority that has supplied a chemotherapy pharmaceutical is entitled to be paid by the Commonwealth the amount, if any, by which the dispensed price for the supply of the chemotherapy pharmaceutical exceeds the amount that the approved hospital authority was entitled to charge under paragraph 20.

22. The dispensed price for the supply of a chemotherapy pharmaceutical will be ascertained in accordance with the determination in force under subsection 99(4) of the Act in respect of the supply of pharmaceutical benefits by public hospitals.

23. Regulation 22 and subregulations 25(2), (3) and (4) of the Regulations do not apply to the supply of chemotherapy pharmaceuticals under these Arrangements.

Claims for payment for the supply of chemotherapy pharmaceuticals under these Arrangements

24. The approved hospital authority must prepare an electronic pharmacy record in respect of each medication chart in respect of which a chemotherapy pharmaceutical has been supplied to a patient of the hospital, and must retain that electronic pharmacy record for not less than one year after the day on which the chemotherapy pharmaceutical was supplied.

25. The electronic pharmacy record referred to in paragraph 24 must contain all information required to be included in a prescription record by Part 4 of Schedule 1 to the rules in force under subsection 99AAA(8) of the Act, as modified by paragraph 29 of these Arrangements.

26. Subject to paragraph 27, a claim by the approved hospital authority in respect of chemotherapy pharmaceuticals supplied to the patients of the hospital may be furnished unaccompanied by the medication charts in respect of which chemotherapy pharmaceuticals have been supplied to the patients of the hospital.

27. If the Medicare Australia CEO notifies the approved hospital authority that a copy of all or any of the medication charts in respect of chemotherapy pharmaceuticals supplied to the patients of the hospital is required to be submitted, the approved hospital authority must submit a copy of each such medication chart to the Medicare Australia CEO.

28. If the Medicare Australia CEO notifies the approved hospital authority that a copy of all or any of the electronic pharmacy records in respect of chemotherapy pharmaceuticals supplied to the patients of the hospital is required to be submitted, the approved hospital authority must submit a copy of each such electronic pharmacy record to the Medicare Australia CEO.

29. Information provided by electronic means to the Secretary by the approved hospital authority in respect of a claim in respect of chemotherapy pharmaceuticals supplied to the patients of the hospital will conform to the requirements of paragraph 5 of, and Schedule 1 to, the rules in force under subsection 99AAA(8) of the Act, provided that Part 4 of Schedule 1 to those rules is amended:

    (a) by omitting the specifications for the field "Prescriber Number" and substituting "Seven bytes numeric, right justified, zero filled, being the prescriber number of the prescribing medical practitioner, issued by the Medicare Australia CEO, in pursuance of the function granted to him or her by subsection 18(a) of the *Medicare Australia (Functions of Chief Executive Officer) Direction 2005* made under paragraph 5(1)(d) of the *Medicare Australia Act 1973*"; and

    (b) by omitting the field "Filler" and substituting the following field:

"Field:	Hospital patient indicator
Start:	32
End:	32
Specifications for field:	One byte alphanumeric, value 'H' to indicate that the person for whose treatment the medication chart was written was a patient of the hospital; otherwise '0' "

Dated this 30 day of March 2007.

STEPHEN DELLAR

Assistant Secretary

Pharmaceutical Evaluation Branch

Department of Health and Ageing

Delegate of the Minister for Health and Ageing

SCHEDULE 1

Column 1 *Name of chemotherapy pharmaceutical*	*Column 2* *Circumstances*
Aprepitant	In compliance with authority procedures set out in paragraph 14:
	Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy, when aprepitant is used in combination with a 5-hydroxytryptamine type 3 receptor antagonist and dexamethasone, where treatment with aprepitant is limited to an initial dose of 125 mg and 2 subsequent doses of 80 mg per cycle of cytotoxic chemotherapy, and where the cytotoxic chemotherapy to be administered to the patient includes any of the following agents:
	altretamine;
	carmustine;
	cisplatin, when a single dose constitutes a cycle of chemotherapy;
	cyclophosphamide, at a dose of 1500 mg per square metre per day or greater;
	dacarbazine;
	procarbazine, when a single dose constitutes a cycle of chemotherapy;
	streptozocin
	Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat breast cancer where cyclophosphamide and an anthracycline are to be co-administered, when aprepitant is used in combination with a 5-hydroxytryptamine type 3 receptor antagonist and dexamethasone, and where treatment with aprepitant is limited to an intial dose of 125 mg and 2 subsequent doses of 80 mg per cycle of cytotoxic chemotherapy
"BCG Immunotherapeutic" (Bacillus Calmette-Guérin/Connaught strain)	Treatment of carcinoma in situ of the urinary bladder
"BCG-Tice" (Bacillus Calmette-Guérin/Tice strain)	Primary and relapsing superficial urothelial carcinoma of the bladder
Bleomycin Sulfate	Germ cell neoplasms
	Lymphoma
Calcium Folinate	In respect of the tablet equivalent to 15 mg folinic acid:
	Antidote to folic acid antagonists
	In respect of the injection equivalent to 50 mg folinic acid in 5 mL, injection equivalent to 100 mg folinic acid in 10 mL and injection equivalent to 300 mg folinic acid in 30 mL:
	—
Carboplatin	—
Cisplatin	—
Cladribine	In compliance with authority procedures set out in paragraph 14:
	Hairy cell leukaemia
Cyclophosphamide	—
Cytarabine	—
Docetaxel	In compliance with authority procedures set out in paragraph 14:
	Adjuvant treatment of node-positive breast cancer in combination with an anthracycline and cyclophosphamide
	Advanced breast cancer after failure of prior therapy which includes an anthracycline
	Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound
	Locally advanced or metastatic non-small cell lung cancer
	Treatment of HER2 positive early breast cancer in combination with trastuzumab
Dolasetron Mesylate	Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy
Doxorubicin Hydrochloride	—
Doxorubicin Hydrochloride - Pegylated Liposomal	In compliance with authority procedures set out in paragraph 14:
	Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen
	Metastatic breast cancer, as monotherapy, after failure of prior therapy which includes capecitabine and a taxane
	Metastatic breast cancer, as monotherapy, where therapy with capecitabine or a taxane is contraindicated
Epirubicin Hydrochloride	—
Etoposide	—
Etoposide Phosphate	—
Fluorouracil	—

Column 1 *Name of chemotherapy pharmaceutical*	*Column 2* *Circumstances*
Fotemustine	In compliance with authority procedures set out in paragraph 14:
	Metastatic malignant melanoma
Gemcitabine Hydrochloride	In compliance with authority procedures set out in paragraph 14:
	Advanced breast cancer in combination with paclitaxel after failure of prior therapy which includes an anthracycline
	Advanced epithelial ovarian cancer, in combination with carboplatin, in patients who relapse more than 6 months after platinum-based therapy
	Locally advanced or metastatic non-small cell lung cancer
	Locally advanced or metastatic adenocarcinoma of the pancreas
	Locally advanced or metastatic bladder cancer, when used in combination with cisplatin
Granisetron Hydrochloride	Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy
Idarubicin Hydrochloride	Acute myelogenous leukaemia
Ifosfamide	Relapsed or refractory germ cell tumours following first-line chemotherapy
	Relapsed or refractory sarcomas following first-line chemotherapy
Interferon Alfa-2a	In respect of the injection 3,000,000 I.U. in 0.5 mL single dose pre-filled syringe:
	In compliance with authority procedures set out in paragraph 14:
	Hairy cell leukaemia
	Myeloproliferative disease with excessive thrombocytosis
	Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy
	In respect of the injection 4,500,000 I.U. in 0.5 mL single dose pre-filled syringe, injection 6,000,000 I.U. in 0.5 mL single dose pre-filled syringe and injection 9,000,000 I.U. in 0.5 mL single dose pre-filled syringe:
	In compliance with authority procedures set out in paragraph 14:
	Myeloproliferative disease with excessive thrombocytosis
	Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy
Interferon Alfa-2b	In respect of the solution for injection 18,000,000 I.U. in 1.2 mL multi-dose injection pen:
	In compliance with authority procedures set out in paragraph 14:
	Hairy cell leukaemia
	Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy
	Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy
	In respect of the solution for injection 30,000,000 I.U. in 1.2 mL multi-dose injection pen:
	In compliance with authority procedures set out in paragraph 14:
	Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy
	Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy
Irinotecan Hydrochloride Trihydrate	In compliance with authority procedures set out in paragraph 14:
	Metastatic colorectal cancer in patients with a World Health Organisation performance status of 2 or less
Mesna	Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide
Methotrexate	—
Mitozantrone Hydrochloride	—
Ondansetron	Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy
Ondansetron Hydrochloride Dihydrate	Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy
Oxaliplatin	In compliance with authority procedures set out in paragraph 14:
	Metastatic colorectal cancer in patients with a World Health Organisation performance status of 2 or less, when used in combination with fluorouracil sodium and calcium folinate
	Adjuvant treatment of stage III (Dukes C) colon cancer, in combination with fluorouracil sodium and calcium folinate, following complete resection of the primary tumour

Column 1 *Name of chemotherapy pharmaceutical*	*Column 2* *Circumstances*
Paclitaxel	In compliance with authority procedures set out in paragraph 14:
	Adjuvant treatment of node-positive breast cancer administered sequentially to an anthracycline and cyclophosphamide
	Advanced breast cancer after failure of prior therapy which includes an anthracycline
	Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound
	Primary treatment of ovarian cancer in combination with a platinum compound
	Locally advanced or metastatic non-small cell lung cancer
	Treatment of HER2 positive early breast cancer in combination with trastuzumab
Pemetrexed Disodium Heptahydrate	In compliance with authority procedures set out in paragraph 14:
	Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy
	Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where treatment with paclitaxel or docetaxel is contraindicated
	Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where intolerance to treatment with either docetaxel or paclitaxel has developed
	Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where treatment with either docetaxel or paclitaxel has been unsuccessful
	Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where transfer to docetaxel or paclitaxel is likely to result in adverse clinical consequences
Raltitrexed	In compliance with authority procedures set out in paragraph 14:
	For use as a single agent in the treatment of advanced colorectal cancer
Rituximab	In compliance with authority procedures set out in paragraph 14:
	Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma
	Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma
	Treatment of previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy
	Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma, in combination with chemotherapy
Temozolomide	In respect of the capsule 5 mg, capsule 20 mg and capsule 100 mg:
	In compliance with authority procedures set out in paragraph 14:
	Glioblastoma multiforme concomitantly with radiotherapy
	Recurrence of anaplastic astrocytoma following standard therapy
	Recurrence of glioblastoma multiforme following standard therapy
	Glioblastoma multiforme following radiotherapy
	In respect of the capsule 250 mg:
	In compliance with authority procedures set out in paragraph 14:
	Recurrence of anaplastic astrocytoma following standard therapy
	Recurrence of glioblastoma multiforme following standard therapy
	Glioblastoma multiforme following radiotherapy
Thiotepa	—
Topotecan Hydrochloride	In compliance with authority procedures set out in paragraph 14:
	Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound
Tropisetron Hydrochloride	Management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy
Vinblastine Sulfate	—
Vincristine Sulfate	—
Vinorelbine Tartrate	In compliance with authority procedures set out in paragraph 14:
	Advanced breast cancer after failure of prior therapy which includes an anthracycline
	Locally advanced or metastatic non-small cell lung cancer

SCHEDULE 2

Column 1 *Name of chemotherapy pharmaceutical*	*Column 2* *Form (strength, type, size, etc.)*	*Column 3* *Manner of adminis-tration*	*Column 4* *Maxi-mum quantity*	*Column 5* *Maxi-mum number of repeats*	*Column 6* *Brand*
Aprepitant	Pack containing 1 capsule 125 mg and 2 capsules 80 mg	Oral	1	..	MK
"BCG Immunotherapeutic" (Bacillus Calmette-Guérin/ Connaught strain)	Single dose set comprising 1 vial powder for intravesical administration containing 6.6 to 19.2 x 10^8 CFU and 1 vial diluent 3 mL	Intravesical administration	3	1	SW
"BCG-Tice" (Bacillus Calmette-Guérin/Tice strain)	Vial containing powder for intravesical administration approximately 5 x 10^8 CFU	Intravesical administration	3	1	OR
Bleomycin Sulfate	Powder for injection 15,000 I.U.	Injection	10	..	BQ, MX, SI
Calcium Folinate	Tablet equivalent to 15 mg folinic acid	Oral	10	..	MX
	Injection equivalent to 50 mg folinic acid in 5 mL	Injection	5	5	IT, MX, PF
	Injection equivalent to 100 mg folinic acid in 10 mL	Injection	10	1	IT, PF
	Injection equivalent to 300 mg folinic acid in 30 mL	Injection	4	1	MX
Carboplatin	Solution for I.V. injection 50 mg in 5 mL	Injection	2	..	IT, MX, PU
	Solution for I.V. injection 150 mg in 15 mL	Injection	6	..	IT, MX, PU
	Solution for I.V. injection 450 mg in 45 mL	Injection	2	..	IT, MX, PU
Cisplatin	I.V. injection 10 mg in 10 mL	Injection	1	..	PU
	I.V. injection 50 mg in 50 mL	Injection	1	..	MX, PU
	I.V. injection 100 mg in 100 mL	Injection	1	..	IT, MX
Cladribine	Injection 10 mg in 5 mL vial	Injection	7	..	OA
	Solution for I.V. infusion 10 mg in 10 mL single use vial	Injection	7	..	JC
Cyclophosphamide	Powder for injection 500 mg (anhydrous)	Injection	2	..	BX
	Powder for injection 1 g (anhydrous)	Injection	1	..	BX
	Powder for injection 2 g (anhydrous)	Injection	1	..	BX
Cytarabine	Injection 100 mg in 5 mL vial	Injection	10	1	PU
Docetaxel	Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL and 1 single use vial solvent 1.5 mL	Injection	2	..	SW
	Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL and 1 single use vial solvent 6 mL	Injection	1	..	SW
Dolasetron Mesylate	Tablet 200 mg	Oral	2	..	SW
	I.V. injection 100 mg in 5 mL ampoule	Injection	1	..	SW
Doxorubicin Hydrochloride	Solution for I.V. injection or intravesical administration 10 mg in 5 mL single dose vial	Injection or intravesical administration	4	..	IT, MX, PH
	Solution for I.V. injection or intravesical administration 20 mg in 10 mL single dose vial	Injection or intravesical administration	4	..	PH
	Solution for I.V. injection or intravesical administration 50 mg in 25 mL single dose vial	Injection or intravesical administration	3	..	IT, MX, PH
	Solution for I.V. injection or intravesical administration 100 mg in 50 mL single dose vial	Injection or intravesical administration	1	..	IT
	Solution for I.V. injection or intravesical administration 200 mg in 100 mL single dose vial	Injection or intravesical administration	1	..	IT

Column 1 *Name of chemotherapy pharmaceutical*	*Column 2* *Form (strength, type, size, etc.)*	*Column 3* *Manner of administration*	*Column 4* *Maximum quantity*	*Column 5* *Maximum number of repeats*	*Column 6* *Brand*
Doxorubicin Hydrochloride - Pegylated Liposomal	Suspension for I.V. infusion 20 mg in 10 mL vial	Injection	1	..	SH
	Suspension for I.V. infusion 50 mg in 25 mL vial	Injection	1	..	SH
Epirubicin Hydrochloride	Solution for injection 10 mg in 5 mL	Injection or intravesical administration	4	..	IT, PH
	Solution for injection 20 mg in 10 mL	Injection or intravesical administration	4	..	PH
	Solution for injection 50 mg in 25 mL	Injection or intravesical administration	4	..	IT, MX, PH
	Powder for injection 50 mg	Injection or intravesical administration	4	..	MX
	Solution for injection 100 mg in 50 mL	Injection or intravesical administration	2	..	IT, MX
	Solution for injection 200 mg in 100 mL	Injection or intravesical administration	1	..	IT
Etoposide	Solution for I.V. infusion 100 mg in 5 mL vial	Injection	5	..	IT, MX
Etoposide Phosphate	Powder for I.V. infusion 113.6 mg, vial	Injection	5	..	BQ
	Powder for I.V. infusion 1.136 g, vial	Injection	1	..	BQ
Fluorouracil	Injection 500 mg in 10 mL	Injection	10	..	IT, MX
	Injection 1000 mg in 20 mL	Injection	5	..	IT
Fotemustine	Powder for injection 208 mg with solvent	Injection	1	4	SE
Gemcitabine Hydrochloride	Powder for I.V. infusion equivalent to 200 mg gemcitabine	Injection	4	2	LY
	Powder for I.V. infusion equivalent to 1 g gemcitabine	Injection	2	2	LY
Granisetron Hydrochloride	Tablet equivalent to 2 mg granisetron	Oral	2	..	MX
	Concentrated injection equivalent to 3 mg granisetron in 3 mL ampoule	Injection	1	..	MX
Idarubicin Hydrochloride	Capsule 5 mg	Oral	3	..	PH
	Capsule 10 mg	Oral	3	..	PH
	Solution for I.V. injection 5 mg in 5 mL single use vial	Injection	3	..	PH
	Solution for I.V. injection 10 mg in 10 mL single use vial	Injection	6	..	PH
Ifosfamide	Powder for I.V. injection 1 g in single dose vial	Injection	5	5	BX
	Powder for I.V. injection 2 g in single dose vial	Injection	5	5	BX
Interferon Alfa-2a	Injection 3,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	15	4	RO
	Injection 4,500,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	5	4	RO
	Injection 6,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	5	4	RO
	Injection 9,000,000 I.U. in 0.5 mL single dose pre-filled syringe	Injection	5	4	RO
Interferon Alfa-2b	Solution for injection 18,000,000 I.U. in 1.2 mL multi-dose injection pen	Injection	3	4	SH
	Solution for injection 30,000,000 I.U. in 1.2 mL multi-dose injection pen	Injection	3	5	SH
Irinotecan Hydrochloride Trihydrate	I.V. injection 40 mg in 2 mL vial	Injection	1	3	MX, PU
	I.V. injection 100 mg in 5 mL vial	Injection	2	3	MX, PU

Column 1 *Name of chemotherapy pharmaceutical*	*Column 2* *Form (strength, type, size, etc.)*	*Column 3* *Manner of administration*	*Column 4* *Maximum quantity*	*Column 5* *Maximum number of repeats*	*Column 6* *Brand*
Mesna	Solution for I.V. injection 400 mg in 4 mL ampoule	Injection	15	5	BX
	Solution for I.V. injection 1 g in 10 mL ampoule	Injection	15	5	BX
Methotrexate	Injection 5 mg in 2 mL vial	Injection	5	..	MX
	Injection 50 mg in 2 mL vial	Injection	5	..	MX, PU
	Solution concentrate for I.V. infusion 500 mg in 5 mL vial	Injection	1	..	IT
	Solution concentrate for I.V. infusion 500 mg in 20 mL vial	Injection	1	..	MX
	Solution concentrate for I.V. infusion 1000 mg in 10 mL vial	Injection	1	..	IT, MX
	Solution concentrate for I.V. infusion 5000 mg in 50 mL vial	Injection	1	..	IT
Mitozantrone Hydrochloride	Injection equivalent to 10 mg mitozantrone in 5 mL	Injection	1	..	PU
	Injection equivalent to 20 mg mitozantrone in 10 mL	Injection	1	..	BX, MX, PU
	Injection equivalent to 25 mg mitozantrone in 12.5 mL	Injection	1	..	BX, PU
Ondansetron	Wafer 4 mg	Oral	4	..	GK, HX, RE
	Wafer 8 mg	Oral	4	..	GK, HX, RE
Ondansetron Hydrochloride Dihydrate	Tablet equivalent to 4 mg ondansetron	Oral	4	..	AW, GK, HX, RE
	Tablet equivalent to 8 mg ondansetron	Oral	4	..	AW, GK, HX, RE
	I.V. injection equivalent to 4 mg ondansetron in 2 mL ampoule	Injection	1	..	GK, HX, RE
	I.V. injection equivalent to 8 mg ondansetron in 4 mL ampoule	Injection	1	..	GK, HX, RE
Oxaliplatin	Solution concentrate for I.V. infusion 50 mg in 10 mL vial	Injection	1	2	SW
	Powder for I.V. infusion 50 mg	Injection	1	2	IT, MX, WA, ZP
	Solution concentrate for I.V. infusion 100 mg in 20 mL vial	Injection	1	2	SW
	Powder for I.V. infusion 100 mg	Injection	1	2	IT, MX, WA, ZP
Paclitaxel	Solution concentrate for I.V. infusion 30 mg in 5 mL vial	Injection	5	..	BQ, IT, MX
	Solution concentrate for I.V. infusion 100 mg in 16.7 mL vial	Injection	2	..	BQ, IT, MX
	Solution concentrate for I.V. infusion 150 mg in 25 mL vial	Injection	2	..	BQ, IT, MX
	Solution concentrate for I.V. infusion 300 mg in 50 mL vial	Injection	1	..	BQ, IT, MX
Pemetrexed Disodium Heptahydrate	Powder for I.V. infusion equivalent to 500 mg pemetrexed, vial	Injection	2	2	LY
Raltitrexed	Powder for I.V. infusion 2 mg in single use vial	Injection	3	2	AP
Rituximab	Solution for I.V. infusion 100 mg in 10 mL vial	Injection	2	3	RO
	Solution for I.V. infusion 500 mg in 50 mL vial	Injection	1	3	RO

Column 1 *Name of chemotherapy pharmaceutical*	*Column 2* *Form (strength, type, size, etc.)*	*Column 3* *Manner of adminis-tration*	*Column 4* *Maxi-mum quantity*	*Column 5* *Maxi-mum number of repeats*	*Column 6* *Brand*
Temozolomide	Capsule 5 mg	Oral	15	2	SH
	Capsule 20 mg	Oral	15	2	SH
	Capsule 100 mg	Oral	15	2	SH
	Capsule 250 mg	Oral	5	5	SH
Thiotepa	Powder for injection 15 mg	Injection or intravesical administration	2	1	SI
Topotecan Hydrochloride	Powder for I.V. infusion equivalent to 4 mg topotecan, vial	Injection	5	1	GK
Tropisetron Hydrochloride	Capsule equivalent to 5 mg tropisetron	Oral	2	..	NV
	I.V. injection equivalent to 5 mg tropisetron in 5 mL ampoule	Injection	1	..	NV
Vinblastine Sulfate	Solution for I.V. injection 10 mg in 10 mL vial	Injection	5	..	MX
Vincristine Sulfate	I.V. injection 1 mg in 1 mL vial	Injection	10	..	MX, PU
Vinorelbine Tartrate	Solution for I.V. infusion equivalent to 10 mg vinorelbine in 1 mL vial	Injection	16	2	FB, IT, MX
	Solution for I.V. infusion equivalent to 50 mg vinorelbine in 5 mL vial	Injection	4	2	FB, IT, MX

SCHEDULE 3

Column 1 Name of chemo-therapy pharma-ceutical	*Column 2 Form (strength, type, size, etc.)*	*Column 3 Purposes*	*Column 4 Manner of adminis-tration*	*Column 5 Maximum quantity*	*Column 6 Maximum number of repeats*	*Column 7 Brand*
Interferon Alfa-2a	Injection 3,000,000 I.U. in 0.5 mL single dose pre-filled syringe	In compliance with authority procedures set out in paragraph 14: Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy	Injection	15	5	RO
	Injection 4,500,000 I.U. in 0.5 mL single dose pre-filled syringe	In compliance with authority procedures set out in paragraph 14: Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy	Injection	5	5	RO
	Injection 6,000,000 I.U. in 0.5 mL single dose pre-filled syringe	In compliance with authority procedures set out in paragraph 14: Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy	Injection	5	5	RO
	Injection 9,000,000 I.U. in 0.5 mL single dose pre-filled syringe	In compliance with authority procedures set out in paragraph 14: Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy	Injection	5	5	RO
Interferon Alfa-2b	Solution for injection 18,000,000 I.U. in 1.2 mL multi-dose injection pen	In compliance with authority procedures set out in paragraph 14: Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy	Injection	3	5	SH
Pemetrexed Disodium Heptahydrate	Powder for I.V. infusion equivalent to 500 mg pemetrexed, vial	In compliance with authority procedures set out in paragraph 14: Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where treatment with paclitaxel or docetaxel is contraindicated Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where intolerance to treatment with either docetaxel or paclitaxel has developed Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where treatment with either docetaxel or paclitaxel has been unsuccessful Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy, where transfer to docetaxel or paclitaxel is likely to result in adverse clinical consequences	Injection	2	2	LY

Column 1 Name of chemo-therapy pharma-ceutical	*Column 2 Form (strength, type, size, etc.)*	*Column 3 Purposes*	*Column 4 Manner of adminis-tration*	*Column 5 Maximum quantity*	*Column 6 Maximum number of repeats*	*Column 7 Brand*
Rituximab	Solution for I.V. infusion 100 mg in 10 mL vial	In compliance with authority procedures set out in paragraph 14: Treatment of previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma, in combination with chemotherapy	Injection	2	7	RO
	Solution for I.V. infusion 500 mg in 50 mL vial	In compliance with authority procedures set out in paragraph 14: Treatment of previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma, in combination with chemotherapy	Injection	1	7	RO
Temozolomide	Capsule 5 mg	In compliance with authority procedures set out in paragraph 14: Recurrence of anaplastic astrocytoma following standard therapy Recurrence of glioblastoma multiforme following standard therapy Glioblastoma multiforme following radiotherapy	Oral	5	5	SH
	Capsule 20 mg	In compliance with authority procedures set out in paragraph 14: Recurrence of anaplastic astrocytoma following standard therapy Recurrence of glioblastoma multiforme following standard therapy Glioblastoma multiforme following radiotherapy	Oral	5	5	SH
	Capsule 100 mg	In compliance with authority procedures set out in paragraph 14: Recurrence of anaplastic astrocytoma following standard therapy Recurrence of glioblastoma multiforme following standard therapy Glioblastoma multiforme following radiotherapy	Oral	5	5	SH

SCHEDULE 4

Column 1 *Name of chemotherapy pharmaceutical*	*Column 2* *Form (strength, type, size, etc.)*	*Column 3* *Brand*	*Column 4* *Relevant quantity or number of units*	*Column 5* *Manufacturer's price* *$*	*Column 6* *Price claimed by manufacturer* *$*
Bleomycin Sulfate	Powder for injection 15,000 I.U.	MX	1	44.33	84.20
		SI	10	443.25	842.02
		BQ	10	443.25	910.80
Calcium Folinate	Injection equivalent to 50 mg folinic acid in 5 mL	MX	1	25.59	25.60
		PF	10	205.31	205.51
	Injection equivalent to 100 mg folinic acid in 10 mL	IT	1	23.62	23.63
Ondansetron	Wafer 4 mg	GK	4	28.38	28.95
	Wafer 8 mg	GK	4	44.45	45.03
Ondansetron Hydrochloride Dihydrate	Tablet equivalent to 4 mg ondansetron	GK	4	28.38	28.95
	Tablet equivalent to 8 mg ondansetron	GK	4	44.45	45.03
	I.V. injection equivalent to 4 mg ondansetron in 2 mL ampoule	GK	1	16.00	16.58
	I.V. injection equivalent to 8 mg ondansetron in 4 mL ampoule	GK	1	25.42	25.99
Pemetrexed Disodium Heptahydrate	Powder for I.V. infusion equivalent to 500 mg pemetrexed, vial (unless authorisation is obtained in accordance with paragraph 14 for a purpose specified in column 3 of Schedule 3)	LY	1	1395.59	1594.95