

## Drugs for serious diseases (A)

ATC	Products	Active Substances	Therapeutic indications	Authorisation date (EU)	Available treatments	Superiority (only if available treatments = C)	Therapeutic effect	Therapeutic innovation
A16AA	<u>Carbaglu</u>	Carglumic Acid	Treatment of hyperammonaemia due to N-acetylglutamate synthase deficiency	24-gen-03	A		A	A
A16AB	<u>Cerezyme</u>	Imiglucerase*	Cerezyme (imiglucerase) is indicated for use as long-term enzyme replacement therapy in patients with a confirmed diagnosis of Type I Gaucher disease and who exhibit clinically significant manifestations of the disease.	17-nov-97	A		A	A
A16AX	<u>Ammonaps</u>	Sodium Phenylbutyrate	AMMONAPS is indicated as adjunctive therapy in the chronic management of urea cycle disorders, involving deficiencies of carbamyl phosphate synthetase, ornithine transcarbamylase, or argininosuccinate synthetase. It is indicated in all patients with neonatal-onset presentation (complete enzyme deficiencies, presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzyme deficiencies, presenting after the first month of life) who have a history of hyperammonaemic encephalopathy.	08-dic-99	A		A	A
A16AX	<u>Zavesca</u>	Miglustat	Treatment of mild to moderate type 1 Gaucher disease. Zavesca may be used only in the treatment of patients for whom enzyme replacement therapy is unsuitable (see sections 4.4 and 5.1).	20-nov-02	B		A	A
B01AD	<u>Ceprotin</u>	Protein C	CEPROTIN is indicated in purpura fulminans and coumarin induced skin necrosis in patients with severe congenital protein C deficiency. Furthermore CEPROTIN is indicated for short term prophylaxis in patients with severe congenital protein C deficiency if one or more of the following conditions are met: - surgery or invasive therapy is imminent - while initiating coumarin therapy - when coumarin therapy alone is not sufficient - when coumarin therapy is not feasible. Since safety and efficacy data are not available in conditions other than severe congenital protein C deficiency, use should be limited to these conditions.	16-lug-01	B		A	A
B01AD	<u>Xigris</u>	Drotrecogin Alfa (Activated) *	Xigris is indicated for the treatment of adult patients with severe sepsis with multiple organ failure when added to best standard care	22-ago-02	B		A	A
B01AX	<u>Refludan</u>	Lepirudin*	Anticoagulation in adult patients with heparin-associated thrombocytopenia (HAT) type II and thromboembolic disease mandating parenteral antithrombotic therapy. The diagnosis should be confirmed by the HIPAA (heparin induced platelet activation assay) or an equivalent test.	13-mar-97	A		A	A
H01AX	<u>Somavert</u>	Pegvisomant*	Somavert is indicated for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or radiation therapy and in whom an appropriate medical treatment with somatostatin analogues did not normalize IGF-I concentrations or was not tolerated.	13-nov-02	B		A	A

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J02AC	<u>Vfend</u>	Voriconazole**	Treatment of invasive aspergillosis. Treatment of fluconazole-resistant serious invasive Candida infections (including C. krusei). Treatment of serious fungal infections caused by Scedosporium spp. And Fusarium spp. VFEND should be administered primarily to immunocompromised patients with progressive, possibly life-threatening infections.	19-mar-02	B		A	A
J02AX	<u>CANCIDAS</u>	Caspofungin	Treatment of invasive candidiasis in non-neutropaenic adult patients. Treatment of invasive aspergillosis in adult patients who are refractory to or intolerant of amphotericin B, lipid formulations of amphotericin B and/or itraconazole. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy.	24-ott-01	B		A	A
J05	<u>Viread</u>	Tenofovir Disoproxil (As Fumarate)	Viread is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults over 18 years of age. The demonstration of benefit of Viread is based on results of one study in treatment-naïve patients, including patients with a high viral load (> 100,000 copies/ml) and studies in which Viread was added to stable background therapy (mainly tritherapy) in antiretroviral pre-treated patients experiencing early virological failure (< 10,000 copies/ml, with the majority of patients having < 5,000 copies/ml). In deciding on a new regimen for patients who have failed an antiretroviral regimen, careful consideration should be given to the patterns of mutations associated with different medicinal products and the treatment history of the individual patient. Where available, resistance testing may be appropriate. Refer to Section 5.1, "Pharmacodynamic properties".	05-feb-02	B		A	A
J05	<u>Hepsera</u>	Adefovir Dipivoxil	Treatment of chronic hepatitis B in adults with: - compensated liver disease with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active liver inflammation and fibrosis - decompensated liver disease	06-mar-03	B		A	A
J05A X	<u>Fuzeon</u>	Enfuvirtide	Fuzeon is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected patients who have received treatment with and failed on regimens containing at least one medicinal product from each of the following antiretroviral classes, protease inhibitors, non-nucleoside reverse transcriptase inhibitors and nucleoside reverse transcriptase inhibitors, or who have intolerance to previous antiretroviral regimens. In deciding on a new regimen for patients who have failed an antiretroviral regimen, careful consideration should be given to the treatment history of the individual patient and the patterns of mutations associated with different medicinal products. Where available, resistance testing may be appropriate	27 May 03	B		A	A
J05AB	<u>Vistide</u>	Cidofovir	VISTIDE is indicated for the treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS) and without renal dysfunction. Until further experience is gained, VISTIDE should be used only when other agents are considered unsuitable.	23-apr-97	B		A	A

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J05AB	<u>Cotronak</u> , ( <u>'Rebetol</u> )	Ribavirin	Cotronak is indicated, in combination with interferon alfa-2b: · For the treatment of adult patients with chronic hepatitis C who have previously responded (with normalisation of ALT at the end of treatment) to interferon alpha therapy but who have subsequently relapsed. · For the treatment of adult patients with histologically proven chronic hepatitis C, not previously treated, without liver decompensation, with elevated ALT, who are positive for serum HCV-RNA and who have fibrosis or high inflammatory activity. Patients with only portal fibrosis (minimal fibrosis) should have a high inflammatory score.	07-mag-99	B		A	A
J05AE	<u>Norvir</u>	Ritonavir	Norvir is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infected patients (adults and children of 2 years of age and older). In protease inhibitor experienced patients the choice of ritonavir should be based on individual viral resistance testing and treatment history of patients.	26-ago-96	B		A	A
J05AE	<u>Crixivan</u>	Indinavir	CRIXIVAN is indicated in combination with antiretroviral nucleoside analogues for the treatment of HIV-1 infected adults, adolescents, and children 4 years of age and older. In adolescents and children, the benefit of indinavir therapy versus the increased risk of nephrolithiasis should particularly be considered (see 4.4 Special warnings and special precautions for use).	04-ott-96	B		A	A
J05AE	<u>Viracept</u>	Nelfinavir	VIRACEPT is indicated in antiretroviral combination treatment of human immunodeficiency virus (HIV-1) infected adults, adolescents and children of 3 years of age and older. In protease inhibitor experienced patients the choice of nelfinavir should be based on individual viral resistance testing and treatment history. Refer to Section 5.1 Pharmacodynamic properties.	22-gen-98	B		A	A
J05AE	<u>Fortovase</u> , ( <u>'Invirase</u> )	Saquinavir	Fortovase in combination with antiretroviral agents is indicated for the treatment of HIV-1 infected adult patients.	20/08/1998, (04/10/1996)	B		A	A
J05AE	<u>Agenerase</u>	Amprenavir	Agenerase is indicated for the treatment of protease inhibitor experienced HIV-1 infected adults and children above the age of 4 years, in combination with other antiretroviral agents. The choice of amprenavir should be based on individual viral resistance testing and treatment history of patients. In protease inhibitor naïve patients, Agenerase is less effective than indinavir. In heavily pretreated protease inhibitor experienced patients, the use of Agenerase has not been sufficiently studied.	20-ott-00	B		A	A
J05AE	<u>Kaletra</u>	Lopinavir/ Ritonavir	Kaletra is indicated for the treatment of HIV-1 infected adults and children above the age of 2 years, in combination with other antiretroviral agents. Most experience with Kaletra is derived from the use of the product in antiretroviral therapy naïve patients. Data in heavily pretreated protease inhibitor experienced patients are limited. There are limited data on salvage therapy of patients who have failed therapy with Kaletra. The choice of Kaletra to treat protease inhibitor experienced HIV-1 infected patients should be based on individual viral resistance testing and treatment history of patients.	20-mar-01	B		A	A

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J05AF	<u>Zerit</u>	Stavudine	Zerit is indicated in combination with other antiretroviral medicinal products for the treatment of HIV infected adults and paediatric patients over the age of 3 months.	08-mag-96	B		A	A
J05AF	<u>Epivir</u>	Lamivudine	Epivir is indicated as part of antiretroviral combination therapy for the treatment of HIV infected adults and children.	08-ago-96	B		A	A
J05AF	<u>Combivir</u>	Lamivudine/Zidovudine	Combivir is indicated in antiretroviral combination therapy for the treatment of HIV infected adults and adolescents over 12 years of age.	18-mar-98	B		A	A
J05AF	<u>Ziagen</u>	Abacavir Sulfate	Ziagen is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection. The demonstration of the benefit of Ziagen is mainly based on results of studies performed in treatment-naïve patients on combination therapy with lamivudine and zidovudine (see 5.1 Pharmacodynamic properties).	08-lug-99	B		A	A
J05AF	<u>Zeffix</u>	Lamivudine	Zeffix is indicated for the treatment of adult patients with compensated chronic hepatitis B. Hepatitis B should be documented with viral replication and histological evidence of active liver inflammation and/or fibrosis. This indication is based on the analysis of serological and histological end points that were mainly derived from studies of two years duration in HbeAg positive patients with compensated liver disease. Zeffix is also indicated in adult patients with decompensated hepatitis B.	29-lug-99	B		A	A
J05AF	<u>TRIZIVIR</u>	Abacavir / Lamivudine/ Zidovudine	Trizivir is indicated for the treatment of Human Immunodeficiency Virus (HIV) infected adults. This fixed combination replaces the three components (abacavir, lamivudine and zidovudine) used separately in similar dosages. It is recommended that treatment is started with abacavir, lamivudine, and zidovudine separately for the first 6-8 weeks (see section 4.4. Special Warnings and Precautions). The choice of this fixed combination should be based not only on potential adherence criteria, but mainly on expected efficacy and risk related to the three nucleoside analogues. The demonstration of the benefit of Trizivir is mainly based on results of studies performed in treatment naïve patients or moderately antiretroviral experienced patients with non-advanced disease. In patients with high viral load (>100.000 copies/ml) choice of therapy needs special consideration (see 5.1. Pharmacodynamic properties)."	28-dic-00	B		A	A
J05AG	<u>Viramune</u>	Nevirapine	VIRAMUNE is indicated as part of combination therapy for the antiviral treatment of HIV-1 infected patients with advanced or progressive immunodeficiency. Most of the experience with VIRAMUNE is in combination with nucleoside reverse transcriptase inhibitors. There is at present insufficient data on the efficacy of subsequent use of triple combination including protease inhibitors after VIRAMUNE therapy. Refer to Section 5.1 Pharmacodynamic properties.	05-feb-98	B		A	A

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J05AG	<u>Stocrin</u> ( <u>'Sustiva</u> )	Efavirenz**	STOCRIN is indicated in antiviral combination treatment of HIV-1 infected adults, adolescents and children 3 years of age and older. STOCRIN has not been adequately studied in patients with advanced HIV disease, namely in patients with CD4 counts < 50 cells/mm <sup>3</sup> , or after failure of protease inhibitor (PI) containing regimens. Although cross-resistance of efavirenz with protease inhibitors has not been documented, there are at present insufficient data on the efficacy of subsequent use of protease inhibitor based combination therapy after failure of regimens containing STOCRIN. For a summary of clinical and pharmacodynamic information, see 5.1 Pharmacodynamic properties: Pharmacodynamic effects	28-mag-99	B		A	A
L01CD	<u>Taxotere</u>	Docetaxel	TAXOTERE (docetaxel) in combination with doxorubicin is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have not previously received cytotoxic therapy for this condition. TAXOTERE (docetaxel) monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic therapy. Previous chemotherapy should have included an anthracycline or an alkylating agent. TAXOTERE in combination with capecitabine is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline. TAXOTERE (docetaxel) is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior chemotherapy. TAXOTERE in combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer, in patients who have not previously received chemotherapy for this condition. The use of docetaxel should be confined to units specialised in the administration of cytotoxic chemotherapy and it should only be administered under the supervision of a physician qualified in the use of anticancer chemotherapy.	27-nov-95	B		A	A
L01XC	<u>Mabthera</u>	Rituximab*	MabThera is indicated for treatment of patients with stage III-IV follicular lymphoma who are chemoresistant or are in their second or subsequent relapse after chemotherapy. MabThera is indicated for the treatment of patients with CD20 positive diffuse large B-cell non-Hodgkin's lymphoma in combination with CHOP chemotherapy (see section 5.1 Pharmacodynamic properties).	02-giu-98	B		A	A

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L01XC	<u>Herceptin</u>	Trastuzumab*	Herceptin is indicated for the treatment of patients with metastatic breast cancer whose tumours overexpress HER2: a) as monotherapy for the treatment of those patients who have received at least two chemotherapy regimens for their metastatic disease. Prior chemotherapy must have included at least an anthracycline and a taxane unless patients are unsuitable for these treatments. Hormone receptor positive patients must also have failed hormonal therapy, unless patients are unsuitable for these treatments. b) in combination with paclitaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease and for whom an anthracycline is not suitable. Herceptin should only be used in patients whose tumours have HER2 overexpression at a 3+ level as determined by immunohistochemistry (see 4.4 Special warnings and special precautions for use and 5.1 Pharmacodynamic properties).	28-ago-00	B		A	A
L01XC	<u>MabCampath</u>	Alemtuzumab*	MabCampath is indicated for the treatment of patients with chronic lymphocytic leukaemia (CLL) who have been treated with alkylating agents and who have failed to achieve a complete or partial response or achieved only a short remission (less than 6 months) following fludarabine phosphate therapy.	06-lug-01	B		A	A
L01XD	<u>Visudyne</u>	Verteporfin	Visudyne is indicated for the treatment of patients with age-related macular degeneration with - predominantly classic subfoveal choroidal neovascularisation, - occult subfoveal choroidal neovascularisation with evidence of recent or ongoing disease progression (see section 5.1. Pharmacodynamic properties) or patients with subfoveal choroidal neovascularisation secondary to pathologic myopia.	27-lug-00	B		A	A
L01XX	<u>Hycamtin</u>	Topotecan Hydrochloride	Topotecan is indicated for the treatment of patients with metastatic carcinoma of the ovary after failure of first-line or subsequent therapy.	12-nov-96	B		A	A
L01XX	<u>TARGRETIN</u>	Bexarotene	For the treatment of skin manifestations of advanced stage CTCL patients refractory to at least one systemic treatment	29-mar-01	B		A	A
L01XX	<u>Glivec</u>	Imatinib Mesilate	Glivec is indicated for the treatment of patients with newly diagnosed Philadelphia chromosome (bcrabl) positive (Ph+) chronic myeloid leukaemia (CML) for whom bone marrow transplantation is not considered as the first line of treatment. Glivec is also indicated for the treatment of patients with Ph+ CML in chronic phase after failure of interferon-alpha therapy, or in accelerated phase or blast crisis. The effect of Glivec on the outcome of bone marrow transplantation has not been determined. Glivec is also indicated for the treatment of adult patients with Kit (CD 117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST). In adult patients, the effectiveness of Glivec is based on overall haematological and cytogenetic response rates and progression-free survival in CML and objective response rates in GIST. The experience with Glivec in children with CML is very limited (see section 5.1). There are no controlled trials demonstrating a clinical benefit or increased survival for either of the two diseases.	07-nov-01	B		A	A

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L01XX	<u>Trisenox</u>	Arsenic Trioxide	Trisenox is indicated for induction of remission and consolidation in adult patients with relapsed/refractory acute promyelocytic leukaemia (APL), characterised by the presence of the t(15;17) translocation and/or the presence of the Pro-Myelocytic Leukaemia/Retinoic-Acid Receptor-alpha (PML/RAR-alpha) gene. Previous treatment should have included a retinoid and chemotherapy. The response rate of other acute myelogenous leukaemia subtypes to Trisenox has not been examined	05-mar-02	B		A	A
L03AA	<u>Beromun</u>	Tasonermin*	As an adjunct to surgery for subsequent removal of the tumour so as to prevent or delay amputation, or in the palliative situation, for irresectable soft tissue sarcoma of the limbs, used in combination with melphalan via mild hyperthermic isolated limb perfusion (ILP).	13-apr-99	B		A	A
L04AA	<u>CellCept</u>	Mycophenolate Mofetil	CellCept is indicated in combination with cyclosporin and corticosteroids for the prophylaxis of acute transplant rejection in patients receiving allogeneic renal, cardiac or hepatic transplants.	14-feb-96	B		A	A
L04AA	<u>Simulect</u>	Basiliximab*	Simulect is indicated for the prophylaxis of acute organ rejection in de novo allogeneic renal transplantation in adult and paediatric patients (see section 4.2). It is to be used concomitantly with ciclosporin for microemulsion- and corticosteroid-based immunosuppression, in patients with panel reactive antibodies less than 80%, or in a triple maintenance immunosuppressive regimen containing ciclosporin for microemulsion, corticosteroids and either azathioprine or mycophenolate mofetil.	09-ott-98	B		A	A
L04AA	<u>Zenapax</u>	Daclizumab*	Zenapax is indicated for the prophylaxis of acute organ rejection in de novo allogeneic renal transplantation and is to be used concomitantly with an immunosuppressive regimen, including ciclosporin and corticosteroids in patients who are not highly immunised.	26-feb-99	B		A	A
L04AA	<u>Remicade</u>	Infliximab*	Rheumatoid arthritis: Remicade is indicated for: the reduction of signs and symptoms as well as the improvement in physical function in patients with active disease when the response to disease-modifying drugs, including methotrexate, has been inadequate. In this patient population, a reduction in the rate of the progression of joint damage, as measured by x-ray, has been demonstrated (see section 5.1). Efficacy and safety have been demonstrated only in combination with methotrexate. Crohn's disease: Remicade is indicated for: _ treatment of severe, active Crohn's disease, in patients who have not responded despite a full and adequate course of therapy with a corticosteroid and an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies. _ treatment of fistulising Crohn's disease, in patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy). Ankylosing spondylitis: Remicade is indicated for: Treatment of ankylosing spondylitis, in patients who have severe axial symptoms, elevated serological markers of inflammatory activity and who have responded inadequately to conventional therapy.	13-ago-99	B		A	A

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L04AA	<u>Enbrel</u>	Etanercept*	Treatment of active rheumatoid arthritis in adults when the response to disease-modifying antirheumatic drugs, including methotrexate (unless contraindicated), has been inadequate. Enbrel is also indicated in the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. In this population Enbrel has been shown to slow progression of disease-associated structural damage as measured by X-ray. Treatment of active polyarticular-course juvenile chronic arthritis in children aged 4 to 17 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. Enbrel has not been studied in children aged less than 4 years. Treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug therapy has been inadequate.	03-feb-00	B		A	A
A16AB	<u>Fabrazyme</u>	Agalsidase Beta*	Indicated for long-term enzyme replacement therapy in patients with a confirmed diagnosis of Fabry disease (a-galactosidase A deficiency)	03-ago-01	A		B	A
A16AB	<u>Replagal</u>	Agalsidase Alfa*	Indicated for long-term enzyme replacement therapy in patients with a confirmed diagnosis of Fabry disease (a-galactosidase A deficiency)	03-ago-01	A		B	A
M03AX	<u>NeuroBloc</u>	Botulinum Toxin Type B	Treatment of cervical dystonia (torticollis)	22-gen-01	A		B	A
G02CX	<u>Tractocile</u>	Atosiban	Tractocile is indicated to delay imminent pre-term birth in pregnant women with: _ regular uterine contractions of at least 30 seconds duration at a rate of _ 4 per 30 minutes; _ a cervical dilation of 1 to 3 cm (0-3 for nulliparas) and effacement of _ 50%; _ age _ 18 years; _ a gestational age from 24 until 33 completed weeks; _ a normal foetal heart rate.	20-gen-00	C	C1	A	B
N05AH	<u>Zyprexa</u> , <u>(Zyprexa</u> <u>Velotab)</u>	Olanzapine	Olanzapine is indicated for the treatment of schizophrenia. Olanzapine is effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Olanzapine is indicated for the treatment of a moderate to severe manic episode; olanzapine has not been demonstrated to prevent recurrence of manic or depressive episodes (see section 5.1). ZYPREXA Powder for Solution for Injection is indicated for the rapid control of agitation and disturbed behaviours in patients with schizophrenia or manic episode, when oral therapy is not appropriate. Treatment with ZYPREXA Powder for Solution for Injection should be discontinued and the use of oral olanzapine should be initiated as soon as clinically appropriate. (Olanzapine is indicated for the treatment of schizophrenia. Olanzapine is effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Olanzapine is indicated for the treatment of moderate to severe manic episode. Olanzapine has not been demonstrated to prevent recurrence of manic or depressive episodes (see Section 5.1).)	27/09/1996, (03/02/2000)	C	C1	A	B
A16 AB05	<u>Aldurazyme</u>	Laronidase*	Long-term enzyme replacement therapy in patients with a confirmed diagnosis of Mucopolysaccharidosis I (MPS I; a-L-iduronidase deficiency) to treat the non-neurological manifestations of the disease (see section 5.1).	10 Jun 2003	B		B	B

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C01BD	<u>Tikosyn</u>	Dofetilide	Tikosyn is a Class III antiarrhythmic agent that is indicated for the following: (i) Conversion of persistent atrial fibrillation or atrial flutter to normal sinus rhythm in patients in whom cardioversion by electrical means is not appropriate and in whom the duration of the arrhythmic episode is less than 6 months (see section 5.1). (ii) Maintenance of sinus rhythm (after conversion) in patients with persistent atrial fibrillation or atrial flutter. Because TIKOSYN can cause ventricular arrhythmias, it should be reserved for patients in whom atrial fibrillation/atrial flutter is highly symptomatic and in whom other antiarrhythmic therapy is not appropriate. Dofetilide has not been shown to be effective in patients with paroxysmal atrial arrhythmias (including paroxysmal atrial fibrillation).	29-nov-99	B		B	B
J06BB	<u>Synagis</u>	Palivizumab*	For the prevention of serious lower respiratory tract disease requiring hospitalisation as caused by respiratory syncytial virus (RSV) in children who are born at 35 weeks of gestation or less and were less than 6 months of age at the onset of the RSV season, or in children who are less than 2 years of age and had required treatment for bronchopulmonary dysplasia within the last 6 months.	13-ago-99	B		B	B
L01XX	<u>Foscan</u>	Temoporfin	Palliative treatment of patients with head and neck squamous cell carcinoma failing prior therapies and unsuitable for radiotherapy, surgery or systemic chemotherapy	24-ott-01	B		B	B
L03AB	<u>Betaferon</u>	Interferon Beta - 1b***	Betaferon is indicated for the treatment of patients with relapsing remitting multiple sclerosis and two or more relapses within the last two years. Betaferon is also indicated for patients with secondary progressive multiple sclerosis with active disease, evidenced by relapses.	30-nov-95	B		B	B
L03AB	<u>Avonex, (Rebif)</u>	Interferon Beta*	AVONEX (Interferon beta-1a) is indicated for the treatment of ambulatory patients with relapsing multiple sclerosis (MS) characterized by at least 2 recurrent attacks of neurologic dysfunction (relapses) over the preceding 3-year period without evidence of continuous progression between relapses. AVONEX slows the progression of disability and decreases the frequency of relapses. AVONEX is also indicated for the treatment of patients who have experienced a single demyelinating event with an active inflammatory process if it is severe enough to warrant treatment with intravenous corticosteroids, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis (see section 5.1). AVONEX has not yet been investigated in patients with progressive multiple sclerosis, and should be discontinued in patients who develop progressive multiple sclerosis. Not all patients respond to treatment with AVONEX. No clinical criteria that would predict the response to treatment have been identified. (Rebif is indicated for the treatment of patients with multiple sclerosis and with 2 or more relapses within the last two years. Efficacy has not been demonstrated in patients with secondary progressive multiple sclerosis without ongoing relapse activity. See section 5.1.)	13/03/1997, (04/05/1998)	B		B	B
M09AX	<u>Osigraft</u>	Eptotermin Alfa***	Treatment of nonunion of tibia of at least 9 month duration, secondary to trauma, in skeletally mature patients, in cases where previous treatment with autograft has failed or use of autograft is unfeasible	17-mag-01	B		B	B

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N03AX	<u>Keppra</u>	Levetiracetam	Adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in patients with epilepsy	29-set-00	B		B	B
N04BC	<u>Mirapexin</u> , ( <u>Sifrol</u> ), ( <u>Daquiran</u> )	Pramipexole	MIRAPEXIN tablets are indicated for treatment of the signs and symptoms of idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or "on off" fluctuations)., [DAQUIRAN tablets are indicated for treatment of the signs and symptoms of advanced idiopathic Parkinson's disease in combination with levodopa, i.e. over the course of the disease, when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or "on off" fluctuations).]	23/02/1998, (14/10/1997), [27/10/1997]	B		B	B
N04BX	<u>Comtess</u> , ( <u>Comtan</u> )	Entacapone	Entacapone is indicated as an adjunct to standard preparations of levodopa/benserazide or levodopa/carbidopa for use in patients with Parkinson's disease and end-of-dose motor fluctuations, who cannot be stabilised on those combinations.	16/09/1998, (22/09/1998)	B		B	B
R07AX	<u>INOmax</u>	Nitric Oxide	INOmax, in conjunction with ventilatory support and other appropriate agents, is indicated for the treatment of newborns <sup>3</sup> 34 weeks gestation with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension, in order to improve oxygenation and to reduce the need for extracorporeal membrane oxygenation.	01-ago-01	B		B	B
S01EC	<u>Azopt</u>	Brinzolamide	AZOPT is indicated to decrease elevated intraocular pressure in: _ ocular hypertension _ open-angle glaucoma as monotherapy in patients unresponsive to beta-blockers or in patients in whom betablockers are contra-indicated, or as adjunctive therapy to beta-blockers.	09-mar-00	B		B	B
S01EX	<u>Travatan</u>	Travoprost	Decrease of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma who are intolerant or insufficiently responsive to another intraocular pressure lowering medication, as monotherapy or as adjunctive therapy	27-nov-01	B		B	B
S01EX	<u>Lumigan</u>	Bimatoprost	Reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension. As monotherapy in patients: insufficiently responsive to first-line therapy, intolerant or contra-indicated to first-line therapy.As adjunctive therapy to	08-mar-02	B		B	B
V03AC	<u>Ferriprox</u>	Deferiprone	Treatment of iron overload in patients with thalassemia major for whom deferoxamine therapy is contra-indicated or who present serious toxicity with deferoxamine therapy	25-ago-99	B		B	B
N06DA	<u>Prometax</u> , ( <u>Exelon</u> )	Rivastigmine	Symptomatic treatment of mild to moderately severe Alzheimer's dementia	04/12/1998, (12/05/1998)	A		C	B

ATC	Products	Active Substances	Therapeutic indications	Authorisation date (EU)	Available treatments	Superiority (only if available treatments = C)	Therapeutic effect	Therapeutic innovation
N07XX	<u>Rilutek</u>	Riluzole	Riluzole is indicated to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS). Clinical trials have demonstrated that RILUTEK extends survival for patients with ALS (See 5.1 Pharmacodynamics properties). Survival was defined as patients who were alive, not intubated for mechanical ventilation and tracheotomy-free. There is no evidence that riluzole exerts a therapeutic effect on motor function, lung function, fasciculations, muscle strength and motor symptoms. Riluzole has not been shown to be effective in the late stages of ALS. Safety and efficacy of riluzole has only been studied in ALS. Therefore, riluzole should not be used in patients with any other form of motor neurone disease.	10-giu-96	A		C	B
D03	<u>Regranex</u>	Becaplermin*	REG GRAN EX is indicated, in association with other good wound care measures, to promote granulation and thereby the healing of full-thickness, neuropathic, chronic, diabetic ulcers less than or equal to 5 cm <sup>2</sup> .	29-mar-99	C	C1	C	C
L01AX	<u>Temodal</u>	Temozolomide	Temodal capsules are indicated for the treatment of patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.	26-gen-99	B		C	C
L01CD	<u>Paxene</u>	Paclitaxel	treatment of patients with advanced AIDS-related Kaposi's sarcoma (KS) who have failed prior liposomal anthracycline therapy	19-lug-99	B		C	C
L01XX	<u>Panretin</u>	Alitretinoin	Panretin gel is indicated for the topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma (KS) when: <ul style="list-style-type: none"> <li>- lesions are not ulcerated or lymphoedematous, and</li> <li>- treatment of visceral KS is not required, and</li> <li>- lesions are not responding to systemic antiretroviral therapy, and radiotherapy or chemotherapy are not appropriate.</li> </ul>	11-ott-00	B		C	C
A10AB	<u>NovoRapid</u>	Insulin Aspart*	Diabetes mellitus	07-set-99	C	C2	A	Pharm
A10AB	<u>Humalog</u> , ( <u>Liprolog</u> ), ( <u>Humalog Mix</u> )	Insulin Lispro*	For the treatment of adults and children with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. Humalog is also indicated for the initial stabilisation of diabetes mellitus.	30/04/1996, (01/08/2001), [18/05/2001]	C	C2	A	Pharm
A10AD	<u>NovoMix 30</u>	Insulin Aspart*	Treatment of patients with diabetes mellitus	01-ago-00	C	C2	A	Pharm
A10AE	<u>Lantus</u> , ( <u>Optisulin</u> )	Insulin Glargine*	For the treatment of adults, adolescents and children of 6 years or above with diabetes mellitus, where treatment with insulin is required., ('Diabetes mellitus, where treatment with insulin is required.)	09/06/2000, (27/06/2000)	C	C2	A	Pharm

ATC	Products	Active Substances	Therapeutic indications	Authorisation date (EU)	Available treatments	Superiority (only if available treatments = C)	Therapeutic effect	Therapeutic innovation
A10BG	<u>NYRACTA</u> , ( <u>VENVIA</u> ), ( <u>VANDIA</u> )	Rosiglitazone	Rosiglitazone is indicated only in oral combination treatment of type 2 diabetes mellitus in patients with insufficient glycaemic control despite maximal tolerated dose of oral monotherapy with either metformin or a sulphonylurea: - in combination with metformin only in obese patients; - in combination with a sulphonylurea only in patients who show intolerance to metformin or for whom metformin is contraindicated.	11-lug-00	C	C2	A	Pharm
A10BG	<u>Glustin</u> , ( <u>Actos</u> )	Pioglitazone	Pioglitazone is indicated only in oral combination treatment of type 2 diabetes mellitus in patients with insufficient glycaemic control despite maximal tolerated doses of oral monotherapy with either metformin or a sulphonylurea: in combination with metformin only in obese patients; in combination with a sulphonylurea only in patients who show intolerance to metformin or for whom metformin is contraindicated.	10/10/2000, (13/10/2000)	C	C2	A	Pharm
A10BX	<u>NovoNorm</u> , ( <u>Prandin</u> )	Repaglinide	Repaglinide is indicated in patients with Type 2 diabetes (Non Insulin-Dependent Diabetes Mellitus (NIDDM)) whose hyperglycaemia can no longer be controlled satisfactorily by diet, weight reduction and exercise. Repaglinide is also indicated in combination with metformin in Type 2 diabetes patients who are not satisfactorily controlled on metformin alone. Treatment should be initiated as an adjunct to diet and exercise to lower the blood glucose in relation to meals.	17/08/1998, (29/01/2001)	C	C2	A	Pharm
A10BX	<u>Trazec</u> , ( <u>Starlix</u> )	Nateglinide	Combination therapy with metformin of type 2 diabetes patients inadequately controlled despite a maximally tolerated dose of metformin alone	03-apr-01	C	C2	A	Pharm
B01AD	<u>Rapilysin</u>	Reteplase*	Rapilysin is indicated for the thrombolytic treatment of suspected myocardial infarction with persistent ST elevation or recent left Bundle Branch Block within 12 hours after the onset of AMI symptoms.	29-ago-96	C	C2	A	Pharm
B01AD	<u>Metalyse</u> , ( <u>Tenecteplase Boehringer Ingelheim Pharma KG</u> )	Tenecteplase*	Metalyse is indicated for the thrombolytic treatment of suspected myocardial infarction with persistent ST elevation or recent left Bundle Branch Block within 6 hours after the onset of AMI symptoms	23-feb-01	C	C2	A	Pharm
B01AX	<u>Revasc</u>	Desirudin*	Prevention of deep venous thrombosis in patients undergoing elective hip or knee replacement surgery.	09-lug-97	C	C2	A	Pharm
B03XA	<u>Aranesp</u> , ( <u>Nespo</u> )	Darbepoetin Alfa*	Treatment of anaemia associated with chronic renal failure in adults and paediatric subjects ≥ 11 years of age. Treatment of anaemia in adult cancer patients with solid tumours (non-haematological malignancies) receiving chemotherapy.	08-giu-01	C	C2	A	Pharm
C02KX	<u>Tracleer</u>	Bosentan	Treatment of pulmonary arterial hypertension (PAH) to improve exercise capacity and symptoms in patients with grade III functional status. Efficacy has been shown in: Primary PAH PAH secondary to scleroderma without significant interstitial pulmonary disease	15-mag-02	C	C2	A	Pharm

ATC	Products	Active Substances	Therapeutic indications	Authorisation date (EU)	Available treatments	Superiority (only if available treatments = C)	Therapeutic effect	Therapeutic innovation
J01D	<u>Invanz</u>	Ertapenem	Treatment of the following infections in adults when caused by bacteria known or very likely to be susceptible to ertapenem and when parenteral therapy is required: <ul style="list-style-type: none"> <li>· Intra-abdominal infections</li> <li>· Community acquired pneumonia</li> <li>· Acute gynaecological infections</li> </ul> Consideration should be given to official guidance on the appropriate use of antibacterial agents	18-apr-02	C	C2	A	Pharm
J01FA	<u>Levviax</u> , ( <u>Ketek</u> )	Telithromycin	When prescribing Ketek, consideration should be given to official guidance on the appropriate use of antibacterial agents. Ketek is indicated for the treatment of the following infections: In patients of 18 years and older: <ul style="list-style-type: none"> <li>- Community-acquired pneumonia, mild or moderate,</li> <li>- Acute exacerbation of chronic bronchitis,</li> <li>- Acute sinusitis,</li> <li>- Tonsillitis/pharyngitis caused by Group A beta streptococci, as an alternative when beta lactam antibiotics are not appropriate.</li> </ul> In patients of 12 to 18 years old: Tonsillitis/pharyngitis caused by Group A beta streptococci, as an alternative when beta lactam antibiotics are not appropriate	09-lug-01	C	C2	A	Pharm
L01BC	<u>Xeloda</u>	Capecitabine	Xeloda is indicated for: <ul style="list-style-type: none"> <li>- first line monotherapy of metastatic colorectal cancer.</li> <li>- as combination therapy with docetaxel in the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline.</li> <li>- as monotherapy for the treatment of patients with locally advanced or metastatic breast cancer after failure of taxanes and an anthracycline-containing chemotherapy regimen or for whom further anthracycline therapy is not indicated.</li> </ul>	02-feb-01	C	C2	A	Pharm
L01BC	<u>DepoCyte</u>	Cytarabine	Intrathecal treatment of lymphomatous meningitis. In the majority of patients such treatment will be part of symptomatic palliation of the disease.	11-lug-01	C	C2	A	Pharm
L01DB	<u>Caelyx</u>	Doxorubicin-Hcl	Caelyx is indicated: <ul style="list-style-type: none"> <li>-As monotherapy for patients with metastatic breast cancer, where there is an increased cardiac risk.</li> <li>-For the treatment of advanced ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen.</li> <li>-For the treatment of AIDS-related Kaposi's sarcoma (KS) in patients with low CD4 counts (&lt; 200 CD4 lymphocytes/mm<sup>3</sup>) and extensive mucocutaneous or visceral disease. Caelyx may be used as first-line systemic chemotherapy, or as second line chemotherapy in AIDS-KS patients with disease that has progressed with, or in patients intolerant to, prior combination systemic chemotherapy comprising at least two of the following agents: a vinca alkaloid, bleomycin and doxorubicin (or other anthracycline).</li> </ul>	21-giu-96	C	C2	A	Pharm
L01DB	<u>Myocet</u>	Doxorubicin	Myocet, in combination with cyclophosphamide, is indicated for the first line treatment of metastatic breast cancer in women.	13-lug-00	C	C2	A	Pharm

ATC	Products	Active Substances	Therapeutic indications	Authorisation date (EU)	Available treatments	Superiority (only if available treatments = C)	Therapeutic effect	Therapeutic innovation
L03AA	<u>Neupopeg</u> , ( <u>'Neulasta</u> )	Pegfilgrastim*	Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).	22-ago-02	C	C2	A	Pharm
L03AB	<u>ViraferonPeg</u> , ( <u>PegIntron</u> )	Peginterferon Alfa-2b*	ViraferonPeg is indicated for the treatment of adult patients with histologically proven chronic hepatitis C who have elevated transaminases without liver decompensation and who are positive for serum HCV-RNA or anti-HCV. The best way to use ViraferonPeg in this indication is in combination with ribavirin. This combination is indicated in naïve patients as well as in patients who have previously responded (with normalisation of ALT at the end of treatment) to interferon alpha monotherapy but who have subsequently relapsed. Interferon monotherapy, including ViraferonPeg, is indicated mainly in case of intolerance or contraindication to ribavirin. Please refer also to the ribavirin Summary of Product Characteristics (SPC) when ViraferonPeg is to be used in combination with ribavirin.	29/05/2000, (25/05/2000)	C	C2	A	Pharm
L03AB	<u>PEGASYS</u>	Peginterferon Alfa-2a*	Pegasys is indicated for the treatment of histologically-proven chronic hepatitis C in adult patients with elevated transaminases and who are positive for serum HCV-RNA, including patients with compensated cirrhosis. The optimal way to use Pegasys in patients with chronic hepatitis C is in combination with ribavirin. This combination is indicated in naive patients as well as in patients who have previously responded to interferon alpha therapy and subsequently relapsed after treatment was stopped. Monotherapy is indicated mainly in case of intolerance or contraindication to ribavirin.	20-giu-02	C	C2	A	Pharm
L04AA	<u>Arava</u>	Leflunomide	Leflunomide is indicated for the treatment of adult patients with active rheumatoid arthritis as a "disease-modifying antirheumatic drug" (DMARD). Recent or concurrent treatment with hepatotoxic or haematotoxic DMARDs (e.g. methotrexate) may result in an increased risk of serious adverse reactions; therefore, the initiation of leflunomide treatment has to be carefully considered regarding these benefit/risk aspects. Moreover, switching from leflunomide to another DMARD without following the washout procedure (see section 4.4) may also increase the risk of serious adverse reactions even for a long time after the switching.	02-set-99	C	C2	A	Pharm
L04AA	<u>Kineret</u>	Anakinra*	Kineret is indicated for the treatment of the signs and symptoms of rheumatoid arthritis in combination with methotrexate, in patients with an inadequate response to methotrexate alone.	08-mar-02	C	C2	B	Pharm
M05BC	<u>InductOs</u>	Dibotermine Alfa*	InductOs is indicated for the treatment of acute tibia fractures in adults, as an adjunct to standard care using open fracture reduction and intramedullary nail fixation.	09-set-02	C	C2	B	Pharm
N06DX	<u>Ebixa</u> , ( <u>'Axura</u> )	Memantine	Treatment of patients with moderately severe to severe Alzheimer's disease	15/05/2002, (17/05/2002)	C	C2	C	Pharm

ATC	Products	Active Substances	Therapeutic indications	Authorisation date (EU)	Available treatments	Superiority (only if available treatments = C)	Therapeutic effect	Therapeutic innovation
V03AE	<u>Renagel</u>	Sevelamer	Renagel is indicated for the control of hyperphosphataemia in adult patients on haemodialysis. Renagel should be used within the context of a multiple therapeutic approach, which could include calcium supplements, 1,25 - dihydroxy Vitamin D3 or one of its analogues to control the development of renal bone disease.	28-gen-00	C	C2	C	Pharm
V10BX	<u>Quadramet</u>	Quadramet - Samarium [153 Sm] Lexidronam Pentasodium	QUADRAMET is indicated for the relief of bone pain in patients with multiple painful osteoblastic skeletal metastases which take up technetium [99mTc]-labelled biphosphonates on bone scan. The presence of osteoblastic metastases which take up technetium [99mTc]-labelled biphosphonates should be confirmed prior to therapy.	05-feb-98	C	C2	C	Pharm
A10AB	<u>Velosulin, (Actrapid)</u>	Insulin Human (Rdna) *	Treatment of diabetes mellitus	07-ott-02	C	C3	A	Tech
A10AC	<u>Insuman</u>	Insuman Basal - Human Insulin*	Diabetes mellitus where treatment with insulin is required. Insuman Rapid is also suitable for the treatment of hyperglycaemic coma and ketoacidosis, as well as for achieving pre-, intra- and postoperative stabilisation in patients with diabetes mellitus.	21-feb-97	C	C3	A	Tech
A10AC	<u>Monotard, (Protaphane), (Insulatard)</u>	Insulin Human (Rdna) *	Treatment of diabetes mellitus	7 Oct 2002	C	C3	A	Tech
A10AD	<u>Mixtard, (Actraphane)</u>	Insulin Human (Rdna) *	Treatment of diabetes mellitus	07-ott-02	C	C3	A	Tech
A10AE	<u>Ultratard</u>	Insulin Human (Rdna) *	Treatment of diabetes mellitus	7 Oct 2002	C	C3	A	Tech
A16AA	<u>Cystagon</u>	Mercaptamine Bitartrate	CYSTAGON is indicated for the treatment of proven nephropathic cystinosis. Cysteamine reduces cystine accumulation in some cells (e.g. leukocytes, muscle and liver cells) of nephropathic cystinosis patients and, when treatment is started early, it delays the development of renal failure. CYSTAGON treatment should be initiated under the supervision of a physician experienced in the treatment of cystinosis.	23-giu-97	C	C3	A	Tech
B02BD	<u>NovoSeven</u>	Factorviii*	Bleeding episodes and surgery in patients with inherited or acquired haemophilia with inhibitors to coagulation factors VIII or IX > 10 BU or in patients with antibody titer < 10 BU who are expected to have a high $\alpha$ -ibavirina $\alpha$ response to factor VIII or factor IX.	23-feb-96	C	C3	A	Tech
B02BD	<u>BeneFIX</u>	Nonacog Alpha*	Treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency).	27-ago-97	C	C3	A	Tech
B02BD	<u>ReFacto</u>	Moroctocog Alfa*	Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). ReFacto does not contain von Willebrand factor and hence is not indicated in von Willebrand's disease.	13-apr-99	C	C3	A	Tech

ATC	Products	Active Substances	Therapeutic indications	Authorisation date (EU)	Available treatments	Superiority (only if available treatments = C)	Therapeutic effect	Therapeutic innovation
B02BD	<u>Helixate</u> <u>NexGen</u> ( <u>KOGENATE</u> <u>Bayer</u> )	Recombinant Coagulation Factor VIII (Octocog Alfa) *	Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). This preparation does not contain von Willebrand factor and is therefore not indicated in von Willebrand's disease.	04-ago-00	C	C3	A	Tech
B02BD	<u>Nonafact</u>	Human Coagulation Factor IX	Treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency)	03-lug-01	C	C3	A	Tech
B03XA	<u>NeoRecormon</u>	Epoetin Beta*	Treatment of anaemia associated with chronic renal failure (renal anaemia) in patients on dialysis. Treatment of symptomatic renal anaemia in patients not yet undergoing dialysis. Prevention of anaemia of prematurity in infants with a birth weight of 750 to 1500 g and a gestational age of less than 34 weeks. Prevention and treatment of anaemia in adult patients with solid tumours and treated with platinum-based chemotherapy prone to induce anaemia (cisplatin: 75 mg/m2/cycle, carboplatin: 350 mg/m2/cycle). Treatment of anaemia in adult patients with multiple myeloma, low grade non-Hodgkin's lymphoma or chronic lymphocytic leukaemia, who have a relative erythropoietin deficiency and are receiving anti-tumour therapy. Deficiency is defined as an inappropriately low serum erythropoietin level in relation to the degree of anaemia. Increasing the yield of autologous blood from patients in a pre-donation programme. Its use in this indication must be balanced against the reported increased risk of thromboembolic events. Treatment should only be given to patients with moderate anaemia (Hb 10 – 13 g/dl [6.21 – 8.07 mmol/l], no iron deficiency) if blood conserving procedures are not available or insufficient when the scheduled major elective surgery requires a large volume of blood (4 or more units of blood for females or 5 or more units for males).	16-lug-97	C	C3	A	Tech
B03XA	<u>Dynepo</u>	Epoetin Delta*	Treatment of anaemia in patients with chronic renal failure. It may be used in patients on dialysis and in patients not on dialysis.	18-mar-02	C	C3	A	Tech
L02BA	<u>Fareston</u>	Toremifene	First line hormone treatment of hormone-dependent metastatic breast cancer in postmenopausal patients. Fareston is not recommended for patients with oestrogen receptor negative tumours.	14-feb-96	C	C3	A	Tech
L03AB	<u>Infergen</u>	Interferon Alfacon-1*	Treatment of patients of 18 years and older with histologically proven chronic hepatitis and serum markers for hepatitis C virus (HCV) infection e.g. those who have elevated serum $\alpha$ 1 levels without decompensated liver disease. Consideration should be given to current official guidance on the appropriate use of interferons for the treatment of patients with chronic hepatitis c	01-feb-99	C	C3	A	Tech

ATC	Products	Active Substances	Therapeutic indications	Authorisation date (EU)	Available treatments	Superiority (only if available treatments = C)	Therapeutic effect	Therapeutic innovation
L03AB	<u>IntronA</u>	Interferon Alfa – 2b*	<p>Chronic Hepatitis B: Treatment of adult patients with chronic hepatitis B associated with evidence of hepatitis B viral replication (presence of HBV-DNA and HbeAg), elevated ALT and histologically proven active liver inflammation and/or fibrosis.</p> <p>Chronic Hepatitis C: Treatment of adult patients with histologically proven chronic hepatitis C who have elevated transaminases without liver decompensation and who are positive for serum HCV-RNA or anti-HCV.</p> <p>The best way to use IntronA in this indication is in combination with <input type="checkbox"/>ibavirina.</p> <p>Hairy Cell Leukaemia: Treatment of patients with hairy cell leukaemia.</p> <p>Chronic Myelogenous Leukaemia:</p> <p>Monotherapy: Treatment of adult patients with Philadelphia chromosome or bcr/abl translocation positive chronic myelogenous leukaemia. Clinical experience indicates that a haematological and cytogenetic major/minor response is obtainable in the majority of patients treated. A major cytogenetic response is defined by &lt; 34 % Ph+ leukaemic cells in the bone marrow, whereas a minor response is <math>\geq</math> 34 %, but &lt; 90 % Ph+ cells in the marrow.</p> <p>Combination therapy: The combination of interferon alfa-2b and cytarabine (Ara-C) administered during the first 12 months of treatment has been demonstrated to significantly increase the rate of major cytogenetic responses and to significantly prolong the overall survival at three years when compared to interferon alfa-2b monotherapy.</p> <p>Multiple Myeloma: As maintenance therapy in patients who have achieved objective remission (more than 50 % reduction in myeloma protein) following initial induction chemotherapy. Current clinical experience indicates that maintenance therapy with interferon alfa-2b prolongs the plateau phase; however, effects on overall survival have not been conclusively demonstrated.</p> <p>Follicular Lymphoma: Treatment of high tumour burden follicular lymphoma as adjunct to appropriate combination induction chemotherapy such as a CHOP-like regimen. High tumour burden is defined as having at least one of the following: bulky tumour mass (&gt; 7 cm), involvement of three or more nodal sites (each &gt; 3 cm), systemic symptoms (weight loss &gt; 10 %, fever &gt; 38°C for more than 8 days, or nocturnal sweats), splenomegaly beyond the umbilicus, major organ obstruction or compression syndrome, orbital or epidural involvement, serious effusion, or leukaemia.</p> <p>Carcinoid Tumour: Treatment of carcinoid tumours with lymph node or liver metastases and with "carcinoid syndrome".</p> <p>Malignant Melanoma: As adjuvant therapy in patients who are free of disease after surgery but are at high risk of systemic recurrence, e.g., patients with primary or recurrent (clinical or pathological) lymph node involvement.</p>	09-mar-00	C	C3	A	Tech
L03AB	<u>Viraferon</u>	Interferon Alfa – 2b*	<p>Chronic Hepatitis B: Treatment of adult patients with chronic hepatitis B associated with evidence of hepatitis B viral replication (presence of HBV-DNA and HbeAg), elevated ALT and histologically proven active liver inflammation and/or fibrosis..</p> <p>Chronic Hepatitis C: Treatment of adult patients with histologically proven chronic hepatitis C who have serum markers for virus C replication, e.g., those who have elevated transaminases without liver decompensation and who are positive for serum HCV-RNA or anti-HCV.</p> <p>The efficacy of interferon alfa-2b in the treatment of hepatitis C is enhanced when combined with <input type="checkbox"/>ibavirina</p>	09-mar-00	C	C3	A	Tech

ATC	Products	Active Substances	Therapeutic indications	Authorisation date (EU)	Available treatments	Superiority (only if available treatments = C)	Therapeutic effect	Therapeutic innovation
L04AA	<u>Rapamune</u>	Sirolimus	Rapamune is indicated for the prophylaxis of organ rejection in adult patients of low to moderate immunological risk receiving a renal transplant. It is recommended that Rapamune be used initially in combination with cyclosporine microemulsion and corticosteroids for 2 to 3 months. Rapamune may be continued as maintenance therapy with corticosteroids only if cyclosporine can be progressively discontinued (refer to sections 4.2 and 5.1).	13-mar-01	C	C3	A	Tech
H01AC	<u>NutropinAg</u>	Somatotropin*	Long-term treatment of children with growth failure due to inadequate endogenous growth hormone secretion. Long-term treatment of growth failure associated with Turner syndrome. Treatment of prepubertal children with growth failure associated with chronic	16-feb-01	C	C3	B	Tech
M01AH	<u>Kudeg</u> , ('Valdyn'), ('Bextra')	Valdecoxib	Symptomatic relief in the treatment of osteoarthritis or rheumatoid arthritis. Treatment of primary dysmenorrhoea.	27-mar-03	C	C3	B	Tech
H05BA	<u>Forcaltonin</u>	Calcitonin (Salmon) ***	Treatment of Paget's disease and hypercalcemia in malignancy	11-gen-99	C	C3	C	Tech
M05BA	<u>Destara</u> , ('Bondronat')	Ibandronic Acid	Treatment of tumour-induced hypercalcaemia with or without metastases.	25-giu-96	C	C3	C	Tech
M05BA	<u>Zometa</u>	Zoledronic Acid	Prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in patients with advanced malignancies involving bone. 'Treatment of tumour-induced hypercalcaemia (TIH).	20-mar-01	C	C3	C	Tech

\* Biotechnological developed drugs (SEE ANNEX PART "A" - EEC 2309/93)

\*\* Drugs approved in special circumstances