

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
Abiraterone Acetate	DMF # 030587	1. Australia: 2007/4681 2. Austria: 500003 3. Belgium: 118322 4. Brazil 5. Bulgaria 6. CEP: CEP 2014-128 7. China 8. Croatia 9. Czech Republic: AP: 14074SCINO0910A01 RP: 14074SCINO0910R01 10. Denmark 11. Finland 12. France: 2007-035 13. Germany: 1750 14. Ghana 15. Hungary: OGYI/3282-1/2011 16. Italy: AIN/2014/649 17. Japan: 223MF10081 223MF10107 18. Jordan 19. Kenya 20. Kosovo 21. Kyrgyzstan 22. Luxembourg 23. Malaysia 24. Mexico 25. The Netherlands: 01557 26. New Zealand: TT60-891-18-2 27. Norway: 07/8870 28. Poland: PL/DC/4003-0342/08 29. Romania 30. Singapore: 015:359 31. Slovak Republic 32. Slovenia 33. South Africa 34. Spain: AW/1949/07 35. Sweden: Dnr 2007/100 36. Switzerland: D1395 37. Thailand 38. Turkmenistan 39. Turkey 40. United Kingdom: MFD-22684-1-02509 41. Vietnam
Anastrozole USP	DMF # 018335 CDMF# DMF 2007-273	
Apixaban	DMF # 030440	
Apremilast	DMF # 032058	
Atazanavir Sulfate	DMF # 027562	
Azacitidine	DMF # 022360	1. Argentina 2. Australia: 2015/025657 3. Chile

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		4. Colombia 5. Dominican Republic 6. Ecuador 7. Namibia 8. Paraguay 9. South Africa 10. Switzerland 11. Turkey 12. Uruguay 13. Venezuela
Benazepril HCl USP	DMF # 016072	For Human 1. Austria 2. Bulgaria 3. CEP: CEP 2009-356 4. China 5. Denmark: DMF.j.no. 2215-504 6. France: 2005-071 7. Germany: B3.10-7144-09-EDMF-806 8. Greece: 1499 9. Iceland: DMF-IS-431 Benazepril Hydrochloride 10. Italy: AIN/2009/6667 11. The Netherlands: 0991 12. Poland: PL/DC-4003-0466/09 13. Portugal: 36/2006 14. Romania 15. Switzerland 16. Turkey For VMD 1. Austria 2. Belgium: DMF# 1294 3. France 4. Germany 5. Ireland: 15460006 6. Italy 7. Luxemburg 8. The Netherlands 9. Spain: BH/1934/07 10. United Kingdom: 0625 APP No: 01060-01061/2005
Bimatoprost	DMF # 027217	
Bivalirudin	DMF # 025634	1. China
Bortezomib	DMF # 025665	
Capecitabine	DMF # 024126	1. China 2. Japan: 229MF10104
Celecoxib	DMF # 030926	1. CEP: CEP 2016-320
Cladribine	DMF # 024510	
Clofarabine	DMF # 027566	
Dantrolene Sodium USP	DMF # 016118	1. China

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Decitabine	DMF # 023387 DMF # 027543	1. Brazil 2. India 3. Jordan 4. South Korea
Desmopressin Acetate	DMF # 022324	
Docetaxel USP	DMF # 020021 DMF # 030091 CDMF # DMF 2007-163	1. Albania 2. Algeria 3. Australia: 2009/007337 4. Austria: 550063 5. Bangladesh 6. Belgium: 154942 7. Bosnia and Herzegovina 8. Brazil 9. Bulgaria 10. CEP: CEP 2016-146 11. China 12. Croatia: HALMED-MF-00409 (530-09/12-12/42) 13. Cyprus: 2007-DMF-584 14. Czech Republic: AP: 11273SCINO1216A03 RP: 11273SCINO1216R03 15. Denmark: 2215-1216 16. EMA: AP: EMF-00071475 RP: EMF-00071476 17. Estonia 18. Finland 19. France: 2007-115 20. Germany: 1781 21. Greece: 1830 22. Hong Kong 23. Hungary: 25628/08/07 24. Iceland: DMF-IS-555 Docetaxel 25. India 26. Indonesia 27. Ireland 28. Israel 29. Italy: AIN/2012/2585 30. Japan: 224MF10044 224MF10192 31. Jordan 32. Kazakhstan 33. Kenya 34. Kosovo 35. Kuwait 36. Latvia 37. Lebanon 38. Liechtenstein 39. Lithuania 40. Luxemburg

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Products	US: DMF/ Canada: CDMF	EDMF or Others
		41. Macedonia 42. Malaysia 43. Malta 44. Mauritius 45. Mexico 46. Montenegro 47. Morocco 48. The Netherlands: 1620 49. New Zealand: TT60-891-18-4 50. Norway: 10/09608 51. Philippines 52. Poland: UR-DRL-4003-0031-12 53. Portugal: 178/2007 54. Romania 55. Russia 56. Saudi Arabia 57. Serbia 58. Singapore: 015:302 59. Slovak Republic 60. Slovenia 61. South Africa 62. Spain: DW/2044/07 63. Sweden: 2007/127 64. Switzerland: D1650 65. Syria 66. Thailand 67. Turkey 68. U.A.E. 69. Ukraine 70. United Kingdom: MFD-22684-1-03303 71. Vietnam 72. Zambia
Docetaxel Trihydrate USP	DMF # 020942	1. Austria: ASMF08200 2. Germany: 2108 3. Japan: 224MF10049 4. South Korea 5. Sweden: Dnr 116:2008/68075
Eflornithine HCl	DMF # 018509 CDMF # DMF 2012-174	1. France: D.M.F. n° 2005-075 2. United Kingdom: MFD-22684-2-06543
Entecavir Monohydrate	DMF # 025549 CDMF # DMF 2013-040	1. Australia: 2015/001029 2. New Zealand: TT60-891-18-10 3. Singapore: 015:863 4. Spain: AA/0003/16
Enzalutamide	DMF # 030644	
Everolimus	DMF # 029584	
Exemestane	DMF # 021175 CDMF # DMF 2011-238	1. Austria: ASMF09019 2. Belgium: 78858 3. Bosnia and Herzegovina 4. Bulgaria 5. CEP: CEP 2016-002 6. Croatia: HALMED-MF-01115

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Products	US: DMF/ Canada: CDMF	EDMF or Others
		7. Cyprus: 2009-DMF-783 8. Czech Republic: AP: 11194SCINO0316A03 RP: 11194SCINO1012R02 9. Denmark: 2215-1516 10. Estonia 11. Finland 12. France: 2009-025 13. Germany: 2227 14. Greece: 2152 15. Hong Kong 16. Hungary: 3451/80/09 17. Iceland: DMF-IS-902 Exemestane 18. Ireland 19. Israel 20. Italy: AIN/2012/3163 21. Japan: 222MF10188 22. Jordan 23. Kosovo 24. Liechtenstein 25. Latvia 26. Lithuania 27. Luxembourg 28. Macedonia 29. Malta 30. The Netherlands: 01951 31. New Zealand: TT60-891-18-7 32. Norway: 09/10256 33. Poland: UR-DRL-4003-0045-12 34. Portugal 35. Romania 36. Saudi Arabia 37. Serbia 38. Singapore: 015:539 39. Slovak Republic 40. South Africa 41. Spain: EW/2386/09 42. Sweden: Dnr 116:2009/41497 43. Switzerland: D2072 44. Turkey 45. Ukraine 46. United Kingdom: MFD-22684-1-00183
Flumazenil USP	DMF # 015592 CDMF # DMF-2004-064	1. Australia: 2008/1751 2. CEP: CEP 2006-114 3. Japan: 228MF10180 4. Mexico 5. South Korea: 20150713-73-A-313-03 6. Turkey
Fondaparinux Sodium	DMF # 027563	
Fosaprepitant Dimeglumine	DMF # 030973	
Fulvestrant USP	DMF # 022611	1. CEP: CEP 2015-338

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Products	US: DMF/ Canada: CDMF	EDMF or Others
Galantamine	DMF # 027564	
Galantamine HBr USP	DMF # 017863 CDMF # DMF-2005-109	1. Australia: 2006/82637 2. Austria: ASMF11142 3. Belgium 4. Brazil 5. Bulgaria 6. CEP: CEP 2011-011 7. China 8. Cyprus 9. Czech Republic: AP: 2260SCINO0412A04 RP: 2260SCINO0412R04 10. Denmark: 2215-972 11. Estonia 12. Finland 13. France: 2010-042 14. Germany: 1668 15. Greece: 2105 16. Hungary: 2383/09-11770/80/06 17. Iceland: DMF-IS-796 Galantamine Hydrobromide 18. India 19. Ireland 20. Italy: AIN/2012/1259 21. Latvia: LV/H/DMF/10/0066 22. Lithuania 23. Luxembourg 24. The Netherlands: 02191 25. New Zealand: TT60-891-18-9 26. Norway: 09/9861 27. Poland: UR.DOL.OLC.4003.0007.2012 28. Portugal: 96/2006 29. Romania 30. Slovak Republic 31. Slovenia 32. South Africa 33. South Korea 34. Spain: GH/1659/06 35. Sweden: Dnr 116:2010/506508 36. Switzerland 37. Thailand 38. Turkey 39. United Kingdom: MFD-22684-2-06735
Gefitinib	DMF # 031941	
Gemcitabine HCl	DMF # 019053 CDMF # DMF 2006-107	1. Albania 2. Armenia 3. Australia: 2006/32637 4. Austria 5. Bangladesh 6. Belgium 7. Botswana

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		8. Bulgaria 9. CEP: CEP 2006-272 10. China 11. Colombia 12. Costa Rica 13. Croatia 14. Cyprus 15. Czech Republic: AP: 14058SCINO0406A01 RP: 14058SCINO0406R01 16. Denmark: 2215-991 17. Dominican Republic 18. El Salvador 19. Estonia 20. Finland 21. France: 2006-062 22. Gabon 23. Georgia 24. Germany: 1468 25. Greece: 1563 26. Guatemala 27. Hungary: 29390/80/07 28. Iceland: DMF-IS-553 Gemcitabine Hydrochloride 29. Indonesia 30. Iran 31. Ireland 32. Israel 33. Italy 34. Japan: 221MF10023 35. Jordan 36. Kenya 37. Kosovo 38. Kuwait 39. Latvia 40. Lithuania 41. Luxembourg 42. Malta 43. Malaysia 44. Mexico 45. Morocco 46. Namibia 47. The Netherlands: DMF no.1390 48. New Zealand: TT60-891-18-3 49. Nicaragua 50. Nigeria 51. Norway: 06/6370 52. Panama 53. Poland: PL/DC-4003-0181/08 54. Portugal: 82/2006 55. Republic of Srpska

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		56. Romania 57. Russia 58. Saudi Arabia 59. Senegal 60. Serbia 61. Singapore 62. Slovak Republic 63. Slovenia 64. South Korea: 20080930-86-D-76-10 65. South Africa 66. Spain: GC/1669/06 67. Sweden: Dnr 116:2006/32449 68. Switzerland: D1213 69. Thailand 70. Tunisia 71. Turkey 72. U.A.E. 73. Ukraine 74. United Kingdom: MFD-22684-2-07951 75. Zambia 76. Zimbabwe
Granisetron HCl	DMF # 020869	1. CEP: CEP 2007-341
Ibrutinib	DMF # 030925	
Irinotecan HCl	DMF # 017312 CDMF # DMF-2004-091	1. Algeria 2. Australia: 2005/12447 3. Austria: ASMF10103 4. Bahrain 5. Belgium: 27726 6. Bosnia and Herzegovina 7. Brazil 8. Bulgaria 9. China 10. Colombia 11. Croatia 12. Cyprus 13. Czech Republic: AP: 14658SCINO1109A04 RP: 14658SCINO1109R04 14. Denmark: 2215-803 15. EMA: EMEA/ASMF/01252 16. Estonia 17. Finland 18. France: 2006-127 19. GCC 20. Germany: 1571 21. Greece: 1289 22. Hungary: OGYI/13369-1/2010 23. Iceland: DMF-IS-409 Irinotecan Hydrochloride 24. India 25. Ireland: 15640001

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Products	US: DMF/ Canada: CDMF	EDMF or Others
		26. Israel 27. Italy: AIN/2014/101 28. Japan: 218MF10990 29. Jordan 30. Kosovo 31. Kuwait 32. Latvia 33. Lithuania 34. Luxembourg 35. Macedonia 36. Malta 37. Mexico 38. Moldova 39. Montenegro 40. Morocco 41. The Netherlands: DMF no.01260 42. New Zealand: TT60-891-18-1 43. Norway: 04/12049 44. Philippines 45. Poland: PL/DC-4003-0099/10 46. Portugal: 159/2004 47. Romania 48. Saudi Arabia 49. Serbia 50. Singapore: 015:179 51. Slovak Republic 52. Slovenia 53. South Africa 54. Spain: IC/1366/04 55. Sweden: Dnr 116:2006/67704 56. Switzerland: D1443 57. Thailand 58. Tunisia 59. Turkey 60. Turkmenistan 61. U.A.E. 62. Ukraine 63. United Kingdom: MFD-22684-2-05756 64. Vietnam
Lapatinib Ditosylate	DMF # 030043	
Letrozole	DMF # 019139	1. Albania 2. Armenia 3. Australia: 2010/005693 4. Austria 5. Belgium: 80862 6. CEP: CEP 2008-127 7. Czech Republic: AP: 13754SCINO0808A00 RP: 13754SCINO0808R00 8. Denmark: 2215-1515 9. Finland

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Products	US: DMF/ Canada: CDMF	EDMF or Others
		10. France: 2008-165 11. Germany: 2232 12. Greece: 2149 13. Hong Kong 14. Hungary: 3415/80/09 15. Indonesia 16. Italy: AIN/2009/299 17. Japan: 226MF10063 18. Malaysia 19. The Netherlands: 01950 20. New Zealand: 892-18-6 21. Norway: 09/10249 22. Poland: PL/DC-4003-0022/09 23. Saudi Arabia 24. Singapore 25. Slovak Republic 26. Sweden: Dnr 116:2009/41494 27. Switzerland: D1765 28. Thailand 29. Turkey 30. U.A.E
Leuprolide Mesylate	DMF # 026770	
Levonorgestrel USP	DMF # 017067 CDMF # DMF 2009-138	1. Japan: 221MF10292 2. New Zealand: TT60-891-18-8
Octreotide Acetate	DMF # 030131	
Omeprazole		1. CEP: CEP 2003-268
Ondansetron HCl USP	DMF # 015990 CDMF # 2005-133	
Paclitaxel USP	DMF # 016676 DMF # 027567 CDMF # DMF 2010-174	1. Algeria 2. Argentina 3. Australia: 2007/9595 4. Austria: ASMF10087 5. Belgium: 1160 6. Brazil 7. Bulgaria 8. CEP: CEP 2009-209 CEP 2015-278 9. Chile 10. China 11. Colombia 12. Costa Rica 13. Croatia 14. Cyprus 15. Czech Republic: AP: 13163SCINO0906A00 RP: 13163SCINO0906R00 16. Denmark: 2215-1079 17. Dominican Republic 18. Ecuador 19. EMA 20. Estonia

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		21. Finland 22. France: 2006-126 23. Germany: 1572 24. Greece: 1747 25. Hungary: OGYI/15658-1/2010 26. Iceland: DMF-IS-518 Paclitaxel 27. India 28. Ireland 29. Italy: AIN/2006/4877 30. Japan: 223MF10128 31. Kosovo 32. Latvia 33. Lithuania 34. Luxembourg 35. Macedonia 36. Malta 37. Mexico 38. Morocco 39. The Netherlands: 01457 40. New Zealand: TT60-891-18-5 41. Norway: 10/11255 42. Oman 43. Poland: PL/DC/4003-4012-2006 [DMF] 44. Romania 45. Panama 46. Philippines 47. Portugal: 249/2006 48. Singapore: 015:203 49. Slovak Republic 50. Slovenia 51. South Africa 52. South Korea: 20110531-68-A-250-11 53. Spain: PW/1792/06 54. Sweden: Dnr 116:2006/67384 55. Switzerland: D1287 56. Thailand 57. Turkey 58. U.A.E. 59. United Kingdom: MFD-22684-1-07369 60. Venezuela
Pemetrexed	DMF # 029821	
Pemetrexed Disodium	DMF # 024327	1. South Korea: 승 5616-2-ND
Regadenoson	DMF # 028939	1. China
Riluzole	DMF # 015252	1. Australia: E17-11942 2. Austria: 550238 3. Belgium 4. Bulgaria 5. Czech Republic: AP: 10929SCINO0413A01 RP: 10929SCINO0413R01 6. Denmark: 2215-1295

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Products	US: DMF/ Canada: CDMF	EDMF or Others
		7. Estonia 8. Finland 9. France: 2007-188 10. Germany: 1900 11. Greece: 1911 12. Hungary: 53565/80/09 13. Iceland 14. Ireland 15. Israel 16. Italy: AIN/2013/2202 17. Latvia 18. Lithuania 19. Luxembourg 20. Malta 21. The Netherlands: 1706 22. Norway: 07/16260 23. Poland: UR-DRL-4003-0024-13 24. Portugal: 200/2007 25. Romania 26. Russia 27. Slovak Republic: 07/5141 28. Slovenia 29. Spain: RW/2088/07 30. Sweden: Dnr 116:2007/86907 31. Switzerland: D55975 32. Turkey 33. United Kingdom: MFD-22684-1-02874
Roflumilast	DMF # 026764	
SN38	DMF # 021183	
Tamsulosin HCl USP	DMF # 018717	1. CEP: CEP 2011-004 2. China
Topiramate USP	DMF # 017035 CDMF # DMF 2009-202	1. China 2. Czech Republic: AP: 10722SCINO1107A00 RP: 10722SCINO1107R00 3. EMA 4. Israel 5. Poland 6. Singapore 7. South Korea 8. Sweden: Dnr 116:2010/527601 9. United Kingdom: MFD-22684-1-02932
Topotecan HCl	DMF # 020810 CDMF # DMF 2008-107	1. Albania 2. Australia: 2009/008572 3. Austria: ASMF 08070 4. Belgium: 84172 5. Bosnia and Herzegovina 6. Bulgaria 7. Croatia 8. Cyprus: 2009-DMF-842 9. Czech Republic:

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Products	US: DMF/ Canada: CDMF	EDMF or Others
		AP: 14830SCINO1114A03 RP: 14830SCINO1114R03 10. Denmark 11. Egypt 12. EMA: EMEA/ASMF/01159 13. Estonia 14. Finland 15. France: 2008-045 16. Germany: 1977 17. Greece: 2026 18. Hungary: 18195/80/08 19. Iceland: DMF-IS-832 Topotecan Hydrochloride 20. India 21. Ireland 22. Israel 23. Italy: AIN/2014/398 24. Kosovo 25. Kuwait 26. Latvia 27. Lithuania 28. Luxembourg 29. Macedonia 30. Malta 31. Mexico 32. Montenegro 33. Morocco 34. The Netherlands: 01748 35. Norway 36. Poland: PL/DC-4003-0138/08 37. Portugal 38. Romania 39. Russia 40. Saudi Arabia 41. Serbia 42. Singapore: 015:487 43. Slovak Republic 44. Slovenia 45. Spain: TH/2157/08 46. South Korea: 20120703-207-I-40-01 47. Sweden: Dnr 116:2008/21194 48. Switzerland: D1565 49. Syria 50. Turkey 51. U.A.E. 52. Ukraine 53. United Kingdom: MFD-22684-2-07090 54. Zimbabwe
Travoprost	DMF # 023423	
Zoledronic acid	DMF # 022688	1. Japan: 225MF10047