台灣神隆股份有限公司
ScinoPharm Taiwan, Ltd.

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
Abiraterone Acetate	DMF # **030587**	
Anastrozole USP	DMF # **018335** CDMF# **DMF 2007-273**	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
Apixaban	DMF # **030440**	
Apremilast	DMF # **032058**	
Azacitidine	DMF # **022360**	1. Argentina 2. Australia: 2015/025657 3. Chile 4. Colombia

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		5. Dominican Republic 6. Ecuador 7. Paraguay 8. Switzerland 9. Turkey 10. Uruguay 11. 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
Decitabine	DMF # **023387** DMF # **027543**	1. Brazil 2. India 3. Jordan

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		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 41. Macedonia 42. Malaysia 43. Malta

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		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 7. Cyprus: 2009-DMF-783 8. Czech Republic: AP: 11194SCINO0316A03

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		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
Galantamine	DMF # **027564**	
Galantamine HBr USP	DMF # **017863** CDMF # **DMF-2005-109**	1. Australia: 2006/82637 2. Austria: ASMF11142

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		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 8. Bulgaria 9. CEP: CEP 2006-272 10. China

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		11. Colombia 12. Costa Rica 13. Croatia 14. Cyprus 15. Czech Republic: AP: 14058SCINO0406A01 RP: 14058SCINO0406R01 16. Denmark: 2215-991 17. Dominican Republic 18. EI 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 56. Romania 57. Russia 58. Saudi Arabia

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		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 26. Israel 27. Italy: AIN/2014/101 28. Japan: 218MF10990

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		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 10. France: 2008-165 11. Germany: 2232 12. Greece: 2149

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		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 USP	DMF # **015949**	1. CEP: CEP 2003-268 2. South Korea: 20050831-52-B-140-04
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 21. Finland 22. France: 2006-126

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		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: 수 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 7. Estonia 8. Finland

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		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. Sweden: Dnr 116:2010/527601 8. 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: AP: 14830SCINO1114A03 RP: 14830SCINO1114R03 10. Denmark

Summary of ScinoPharm Taiwan, Ltd. Submissions

Products	US: DMF/ Canada: CDMF	EDMF or Others
		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