



# IMS Generic Publications

## PROTECTED AND UNPROTECTED MARKETS

An estimated \$116 billion of the world pharmaceuticals market belongs to the generics industry. In an increasingly complex market, the task of identifying opportunities within a crowded and competitive industry is becoming ever more difficult.

In order to take advantage of opportunities, generics companies now require consistent and detailed insight about drug usage and product protection, before they commit resources, in order for them to maximize their return on investment.

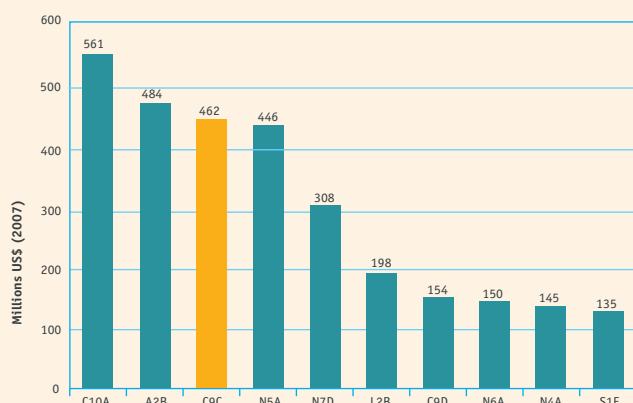
## IMS Generic Planning

### ASSESSING THE PROTECTED MARKET

IMS Generic Planning enables you to assess the protected market to identify favourable markets to enter, and to accurately predict when products will face protection expiry. The information can help you optimize development as well as locate marketing partners to enable you to achieve early entry into the market.

Using Generic Planning, you can pinpoint attractive markets in which to compete. For example you can review the data to identify the top performing therapy classes whose products are due to lose protection at a given time:

### MID-SIZE EUROPE



The above graph shows the top 10 therapy classes whose products are due to lose protection between 2008 and 2012 in the mid-size European countries. The C9C class is ranked 3rd with sales of \$462 million in 2007.

	USD/MNF MAT/12/07	USD/MNF MAT/12/07 96V
C9C ANGIOTENSIN II ANTAG, PLAIN	547	100.0
CANDESARTAN CILEXETIL	158	29.0
LOSARTAN	103	18.8
IRBESARTAN	95	17.4
VALSARTAN	90	16.4
TELMESARTAN	50	9.2
OLMESARTAN MEDOXOMIL	38	7.0
EBROSARTAN	13	2.3

The top 10 molecules in the C9C class can also be viewed. Here it can be seen that candesartan cilexetil is the top performing molecule in the region.

# IMS Generic Planning *continued*

## ASSESSING THE PROTECTED MARKET

By drilling further into the data it is possible to investigate the top performing products within the therapy class and review their performance (in US\$/KG or Standard units) in order to understand potential sales value of a given drug across different countries. The examples below show candesartan cilexetil and its associated brands in Austria, Ireland and Portugal. Note that this molecule is found in both the C9C and C9D therapy classes.

GP example - [ GPWIDS ] - IMS Dataview	GP brochure visual 2 [ GPWIDS ] - IMS Dataview	GP example - [ GPWIDS ] - IMS Dataview																																																																																																															
<table><thead><tr><th>Retrieve Data</th><th>Market</th><th>Redefine</th></tr></thead><tbody><tr><td colspan="3">Measure: USD/MNF MAT/12/07</td></tr><tr><td colspan="3">AUSTRIA</td></tr><tr><td>C9C - ANGIOTEN-II ANTAG, PLAIN</td><td>37,581,993</td><td></td></tr><tr><td>CANDESARTAN CILEXETIL</td><td>17,559,556</td><td></td></tr><tr><td>EST PROTECTION EXP DATE 2012/04</td><td>17,559,556</td><td></td></tr><tr><td>BLOPRESS</td><td>11,790,604</td><td></td></tr><tr><td>ATACAND</td><td>5,768,062</td><td></td></tr><tr><td>C9D - ANGIOTEN-II ANTAG, COMB</td><td>20,122,437</td><td></td></tr><tr><td>CANDESARTAN CILEXETIL</td><td>20,122,437</td><td></td></tr><tr><td>EST PROTECTION EXP DATE 2014/06</td><td>20,122,437</td><td></td></tr><tr><td>BLOPRESS PLUS</td><td>13,322,886</td><td></td></tr><tr><td>ATACAND PLUS</td><td>6,799,551</td><td></td></tr></tbody></table>	Retrieve Data	Market	Redefine	Measure: USD/MNF MAT/12/07			AUSTRIA			C9C - ANGIOTEN-II ANTAG, PLAIN	37,581,993		CANDESARTAN CILEXETIL	17,559,556		EST PROTECTION EXP DATE 2012/04	17,559,556		BLOPRESS	11,790,604		ATACAND	5,768,062		C9D - ANGIOTEN-II ANTAG, COMB	20,122,437		CANDESARTAN CILEXETIL	20,122,437		EST PROTECTION EXP DATE 2014/06	20,122,437		BLOPRESS PLUS	13,322,886		ATACAND PLUS	6,799,551		<table><thead><tr><th>Retrieve Data</th><th>Market</th><th>Redefine</th></tr></thead><tbody><tr><td colspan="3">Measure: USD/M</td></tr><tr><td colspan="3">IRELAND RETAIL</td></tr><tr><td>C9C - ANGIOTEN-II ANTAG, PLAIN</td><td>6,258,269</td><td></td></tr><tr><td>CANDESARTAN CILEXETIL</td><td>4,294,707</td><td></td></tr><tr><td>EST PROTECTION EXP DATE 2012/04</td><td>4,294,707</td><td></td></tr><tr><td>ATACAND</td><td>4,294,707</td><td></td></tr><tr><td>C9D - ANGIOTEN-II ANTAG, COMB</td><td>1,960,562</td><td></td></tr><tr><td>CANDESARTAN CILEXETIL</td><td>1,960,562</td><td></td></tr><tr><td>EST PROTECTION EXP DATE 2014/06</td><td>1,960,562</td><td></td></tr><tr><td>ATACAND PLUS</td><td>1,960,562</td><td></td></tr></tbody></table>	Retrieve Data	Market	Redefine	Measure: USD/M			IRELAND RETAIL			C9C - ANGIOTEN-II ANTAG, PLAIN	6,258,269		CANDESARTAN CILEXETIL	4,294,707		EST PROTECTION EXP DATE 2012/04	4,294,707		ATACAND	4,294,707		C9D - ANGIOTEN-II ANTAG, COMB	1,960,562		CANDESARTAN CILEXETIL	1,960,562		EST PROTECTION EXP DATE 2014/06	1,960,562		ATACAND PLUS	1,960,562		<table><thead><tr><th>Retrieve Data</th><th>Market</th><th>Redefine</th></tr></thead><tbody><tr><td colspan="3">Measure: USD/MNF MAT/12/07</td></tr><tr><td colspan="3">PORTUGAL RETAIL</td></tr><tr><td>C9C - ANGIOTEN-II ANTAG, PLAIN</td><td>35,398,366</td><td></td></tr><tr><td>CANDESARTAN CILEXETIL</td><td>20,303,246</td><td></td></tr><tr><td>EST PROTECTION EXP DATE 2012/10</td><td>20,303,246</td><td></td></tr><tr><td>BLOPRESS</td><td>11,537,504</td><td></td></tr><tr><td>ATACAND</td><td>9,785,742</td><td></td></tr><tr><td>C9D - ANGIOTEN-II ANTAG, COMB</td><td>15,095,140</td><td></td></tr><tr><td>CANDESARTAN CILEXETIL</td><td>15,095,140</td><td></td></tr><tr><td>EST PROTECTION EXP DATE 2014/06</td><td>15,095,140</td><td></td></tr><tr><td>BLOPRESS 16/12.5MG</td><td>8,709,560</td><td></td></tr><tr><td>HYTACAND</td><td>6,385,580</td><td></td></tr></tbody></table>	Retrieve Data	Market	Redefine	Measure: USD/MNF MAT/12/07			PORTUGAL RETAIL			C9C - ANGIOTEN-II ANTAG, PLAIN	35,398,366		CANDESARTAN CILEXETIL	20,303,246		EST PROTECTION EXP DATE 2012/10	20,303,246		BLOPRESS	11,537,504		ATACAND	9,785,742		C9D - ANGIOTEN-II ANTAG, COMB	15,095,140		CANDESARTAN CILEXETIL	15,095,140		EST PROTECTION EXP DATE 2014/06	15,095,140		BLOPRESS 16/12.5MG	8,709,560		HYTACAND	6,385,580	
Retrieve Data	Market	Redefine																																																																																																															
Measure: USD/MNF MAT/12/07																																																																																																																	
AUSTRIA																																																																																																																	
C9C - ANGIOTEN-II ANTAG, PLAIN	37,581,993																																																																																																																
CANDESARTAN CILEXETIL	17,559,556																																																																																																																
EST PROTECTION EXP DATE 2012/04	17,559,556																																																																																																																
BLOPRESS	11,790,604																																																																																																																
ATACAND	5,768,062																																																																																																																
C9D - ANGIOTEN-II ANTAG, COMB	20,122,437																																																																																																																
CANDESARTAN CILEXETIL	20,122,437																																																																																																																
EST PROTECTION EXP DATE 2014/06	20,122,437																																																																																																																
BLOPRESS PLUS	13,322,886																																																																																																																
ATACAND PLUS	6,799,551																																																																																																																
Retrieve Data	Market	Redefine																																																																																																															
Measure: USD/M																																																																																																																	
IRELAND RETAIL																																																																																																																	
C9C - ANGIOTEN-II ANTAG, PLAIN	6,258,269																																																																																																																
CANDESARTAN CILEXETIL	4,294,707																																																																																																																
EST PROTECTION EXP DATE 2012/04	4,294,707																																																																																																																
ATACAND	4,294,707																																																																																																																
C9D - ANGIOTEN-II ANTAG, COMB	1,960,562																																																																																																																
CANDESARTAN CILEXETIL	1,960,562																																																																																																																
EST PROTECTION EXP DATE 2014/06	1,960,562																																																																																																																
ATACAND PLUS	1,960,562																																																																																																																
Retrieve Data	Market	Redefine																																																																																																															
Measure: USD/MNF MAT/12/07																																																																																																																	
PORTUGAL RETAIL																																																																																																																	
C9C - ANGIOTEN-II ANTAG, PLAIN	35,398,366																																																																																																																
CANDESARTAN CILEXETIL	20,303,246																																																																																																																
EST PROTECTION EXP DATE 2012/10	20,303,246																																																																																																																
BLOPRESS	11,537,504																																																																																																																
ATACAND	9,785,742																																																																																																																
C9D - ANGIOTEN-II ANTAG, COMB	15,095,140																																																																																																																
CANDESARTAN CILEXETIL	15,095,140																																																																																																																
EST PROTECTION EXP DATE 2014/06	15,095,140																																																																																																																
BLOPRESS 16/12.5MG	8,709,560																																																																																																																
HYTACAND	6,385,580																																																																																																																

The key to developing a successful strategy based on product expiry is being able to predict when and where products will lose protection. IMS Generic Planning provides full protection expiry dates which can show when the various forms of a given drug (e.g. candesartan cilexetil) are due to lose protection in each country. The Protection expiry date is based on product and is the date when a product is estimated to lose all types of protection including Patents, SPCs, CCPs, data and other exclusivities. The following table shows information on candesartan cilexetil taken directly from the database, and shows the different expiry dates which are available to view.

Market	Molecule Product Patent Expiry	SPC Date	Data Exclusivity Expiry	Branded Product Protection Expiry
Austria	04/2011	04/2012	04/2003	04/2012
Ireland	04/2011	04/2012	04/2003	04/2012
Portugal	01/2011	10/2012	04/2003	10/2012

Companies involved in generics can therefore use this information to accurately predict expiration events and plan their development and commercial strategy accordingly.

## More questions answered by IMS Generic Planning

- What forms of risperidone are still protected?
- When will these forms lose protection?
- What is the value of the protected market?

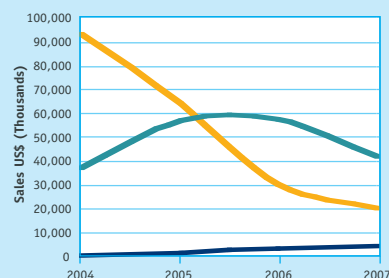
# IMS Generic Market Analyzer

## ASSESSING THE CURRENT UNPROTECTED MARKET

Apart from the benefits of IMS Generic Planning to predict opportunities arising from future events, data is also available to analyse and understand the current unprotected market and its competitive landscape. One important activity required is to gather information from past launches of generics to devise strategy and understand market conditions. The information available through IMS Generic Market Analyzer can be used to produce analysis similar to the following example which shows the relative success of generic amlodipine in four countries following the protection expiry of Norvasc:

### Successful launch of generic product

#### GERMANY

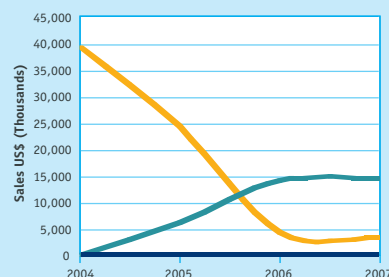


First Launch (NORVASC) Protection Expiry 03/2004

Generic products launched 0-3 months post protection expiry

Generic products launched >3 months post protection expiry

#### SWITZERLAND



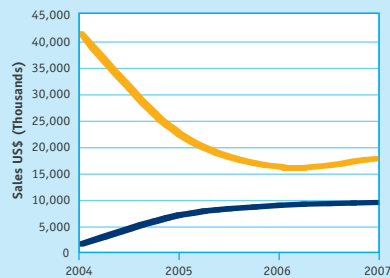
First Launch (NORVASC) Protection Expiry 03/2005

Generic products launched 0-3 months post protection expiry

Generic products launched >3 months post protection expiry

### Less successful launch of generic product

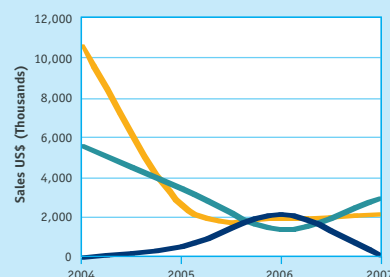
#### BELGIUM



First Launch (AMLOR) Protection Expiry 03/2004

Generic products launched >3 months post protection expiry

#### NORWAY



First Launch (NORVASC) Protection Expiry 03/2004

Generic products launched 0-3 months post protection expiry

Generic products launched >3 months post protection expiry

IMS Generic Market Analyzer can also be used to evaluate the market share of generic products across regions or specific countries, in order to understand the competition.

Amlodipine (table on right) accounts for over 47% of sales for 2007 within the unprotected C8A category for the Western Europe & USA where sales for generic amlodipine topped US\$783 million.

	KG MAT/12/07 (Thousands)	USD/MNF MAT/12/07 (Millions)	KG MAT/12/07 %/v (Absolute)	USD/MNF MAT/12/07 %v (Absolute)
Western Europe & USA	614.1	4,661	---	100.0
C8A - CALCIUM ANTAGONIST PLAIN	614.1	4,661	100.0	100.0
AMLODIPINE	30.0	2,207	6.2	47.3
NON-GENERIC PRODUCTS	14.4	1,424	37.9	64.5
GENERIC PRODUCTS	23.6	783	62.1	35.5

## More questions answered by IMS Generic Market Analyzer

- What forms of risperidone are already facing generic competition?
- What is the current value of the generic market?
- Which companies have already launched risperidone products?
- What is the size in terms of KG and SU?

#### ABOUT IMS

Operating in more than 100 countries, IMS Health is the world's leading provider of market intelligence to the pharmaceutical and healthcare industries. With \$2.2 billion in 2007 revenue and more than 50 years of industry experience, IMS offers leading-edge market intelligence products and services that are integral to clients' day-to-day operations, including portfolio optimization capabilities; launch and brand management solutions; sales force effectiveness innovations; managed care and consumer health offerings; and consulting and services solutions that improve ROI and the delivery of quality healthcare worldwide. Additional information is available at: <http://www.imshealth.com>

#### IMS HEALTH®

##### EUROPE & WORLDWIDE

7 Harewood Avenue  
London  
NW1 6JB UK  
Tel: +44 (0)20 3075 5888

##### THE AMERICAS

IMS Health  
660 West Germantown Pike  
Plymouth Meeting, PA 19462  
USA  
Tel: 1.800.523.5333

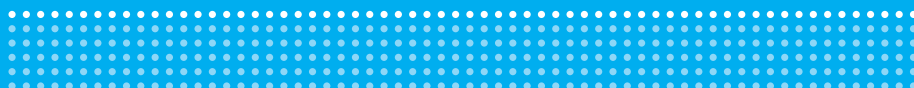
##### ASIA-PACIFIC

10 Hoe Chiang Road  
Keppel Towers # 23-01/02  
Singapore 089315  
Tel: 65-6227-3006

##### JAPAN

Toranomon Towers Office  
4-1-28 Toranomon  
Minato-ku, Tokyo 105-0001  
Japan  
Tel: 81 3 5425 9000

[www.imshealth.com](http://www.imshealth.com)



**ims** | INTELLIGENCE.  
APPLIED.