The need for generic policies as part of health reform

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for
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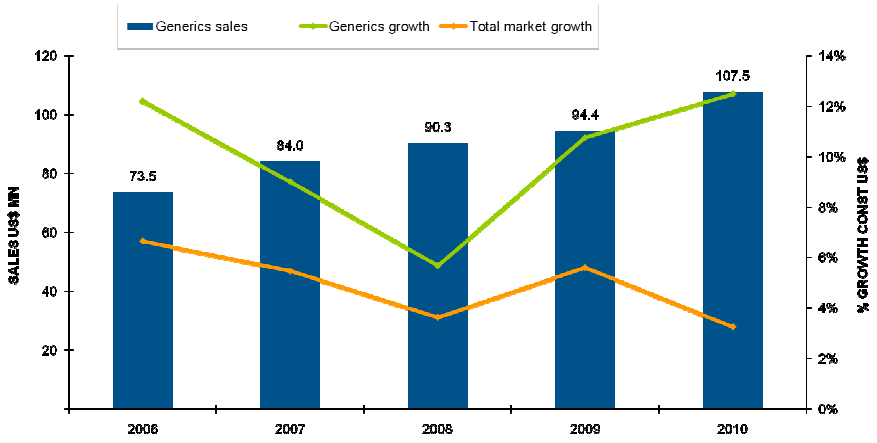
The US Generics Market reaches $107.5bn with growth four times higher than total market



Source: IMS Health, MIDAS, Market Segmentation, MAT Dec 2010, Rx only. *Market Segmentation universe

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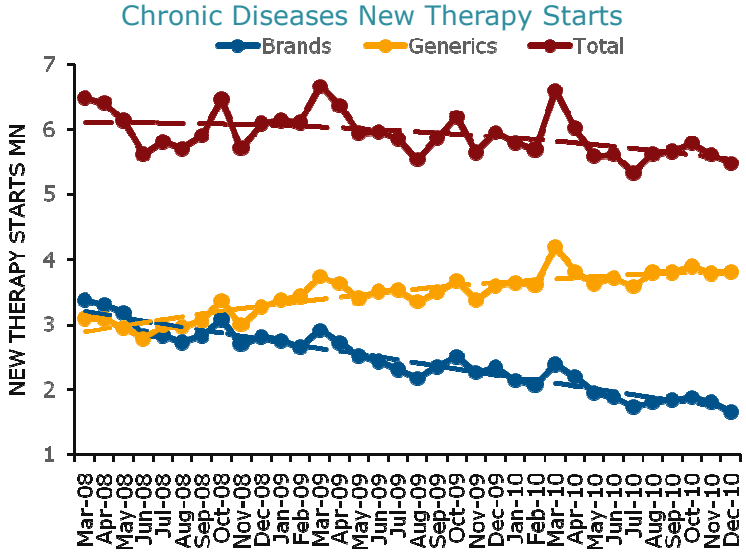
In US, fewer patients are beginning new chronic therapy treatment



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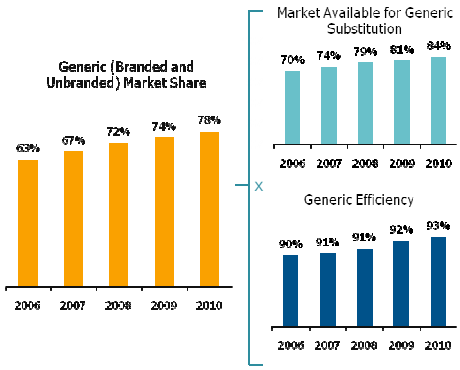
Source: IMS Health, National Prescription Audit, Dec 2010

COMPARISON OF 2010 VERSUS 2009 SPENDING

Total generic market share has risen over each of the past 5 years



Source: IMS Health, National Prescription Audit, Dec 2010

- Generic prescription share reached 78% in 2010 which was 4% higher than 2009 levels.
- This share gain is caused by a 3% gain in the available market for generics (81 to 84% in 2010) as well as a 1% gain in generic efficiency (93% vs. 92%).
- Most states allow pharmacists to substitute generics when available, others require a doctor's direct instruction or restrict substitution for specific therapies where differences between brands and generics may impact patients.
- The broad availability of discounted generics is a further positive influence on efficiency.

Chart notes

Prescriptions dispensed include retail pharmacies and longterm care facilities.

Generic prescription share represents the percentage of unbranded and branded generic prescriptions dispensed annually.

Generic availability is measured by evaluation of products at the form level that have a comparable generic available on the market in the time period.

Generic efficiency is calculated based on the percentage of generic prescribing of the generically available market.

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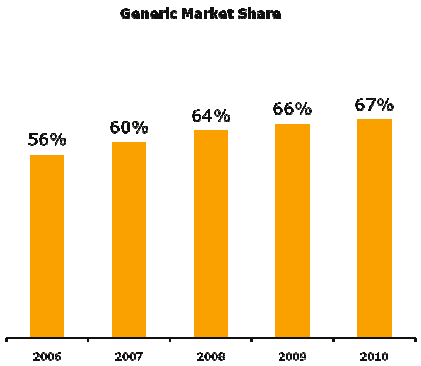
Germany generic market dynamics

Generic Share of Total Volume



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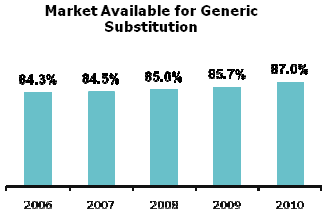

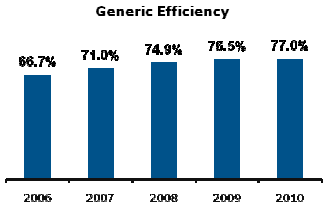

Source: IMD MIDAS, Dec 2010

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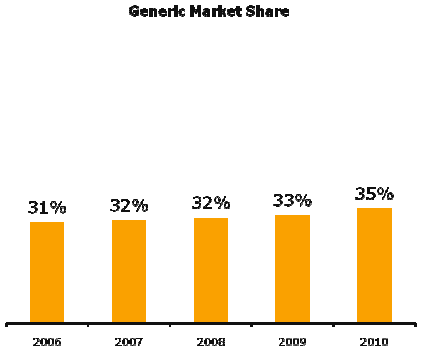
Austria generic market dynamics

Generic Share of Total Volume



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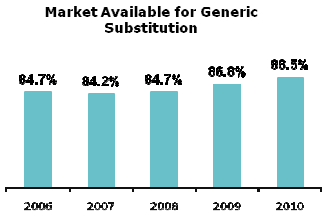

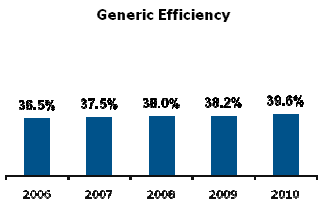

Source: IMD MIDAS, Dec 2010

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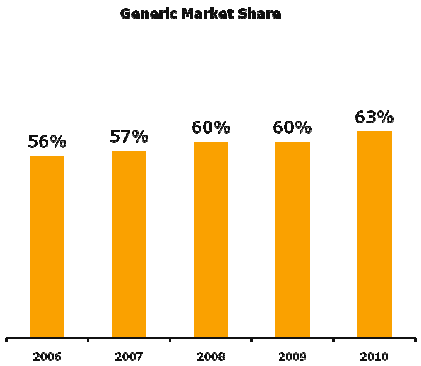
Brazil generic market dynamics

Generic Share of Total Volume



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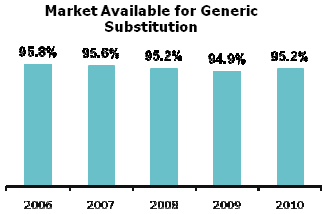

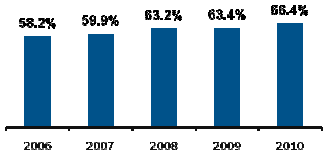

Source: IMD MIDAS, Dec 2010

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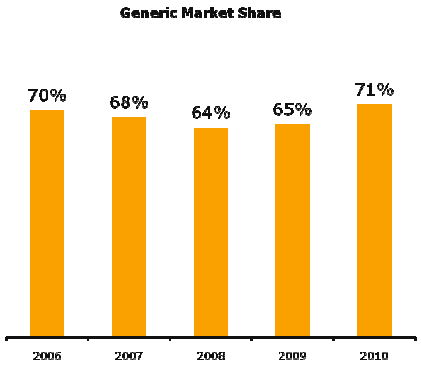
South Africa generic market dynamics

Generic Share of Total Volume



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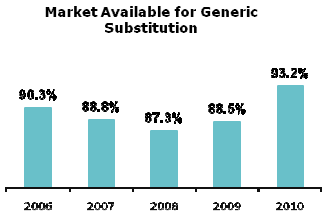

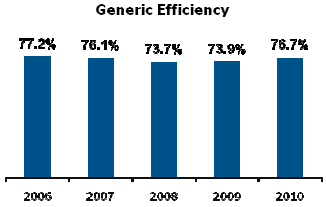

Source: IMD MIDAS, Dec 2010

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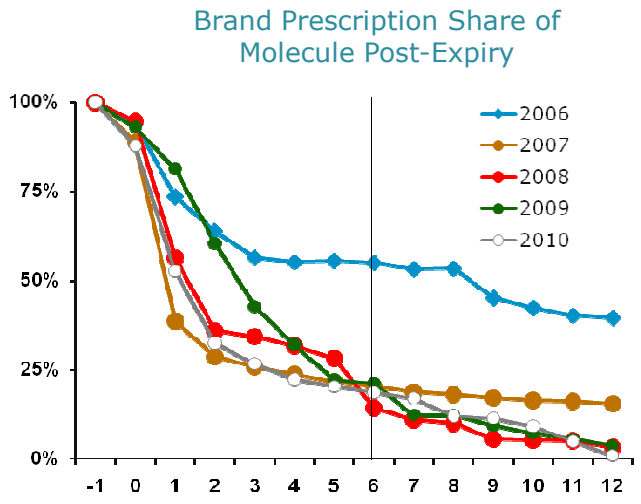
Time to market after patent expiry is a key issue

In US, Generics capture over 80% of a brand's volume within 6 months



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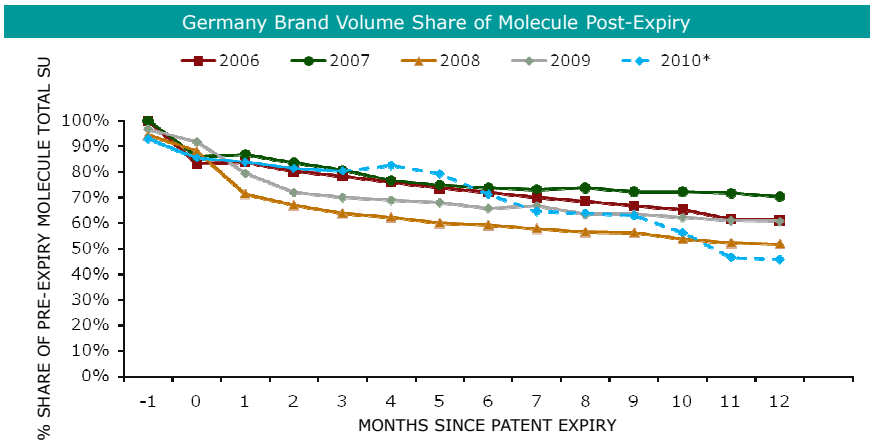
Source: IMS Health, National Prescription Audit, Dec 2010

Germany brand erosion after loss of exclusivity



Source: IMS MIDAS Monthly, Mar 2011. *2010 curve contains incomplete periods.

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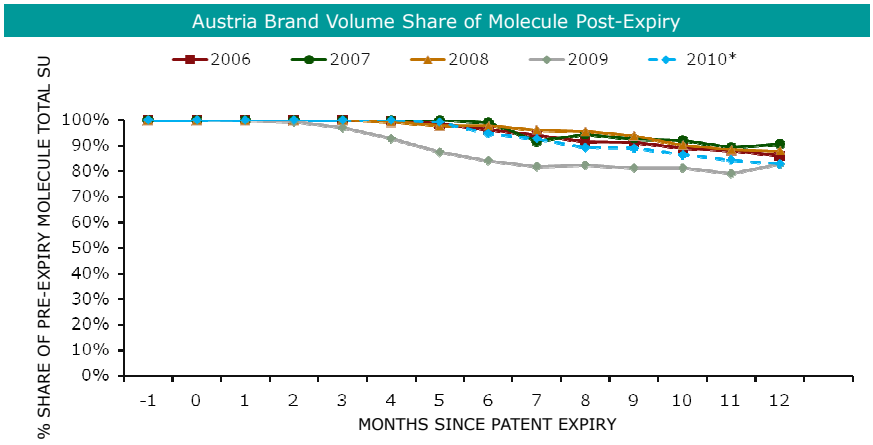
Austria brand erosion after loss of exclusivity



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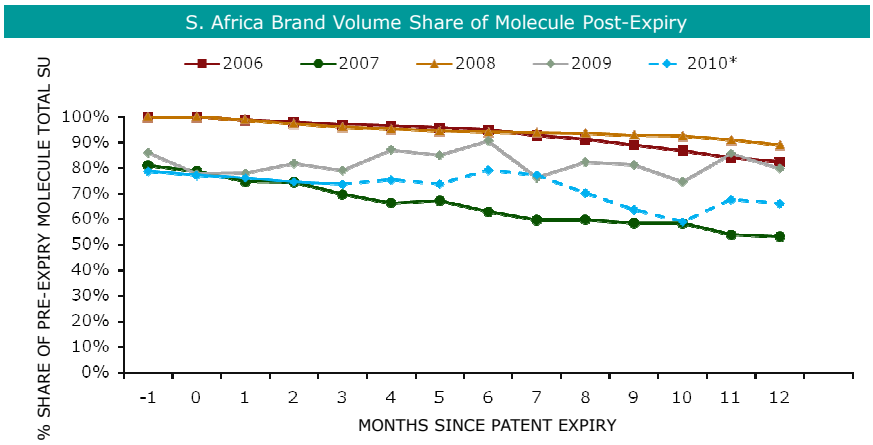
S. Africa brand erosion after loss of exclusivity



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Generic Market Shares 2010 Value & Volume Total Market - Retail

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Generic market highly segmented and countries vary greatly!

- Company generics
- Branded Generics
- INN generics

- All coexist and compete for the same space
- National Policies must adjust to the national realities

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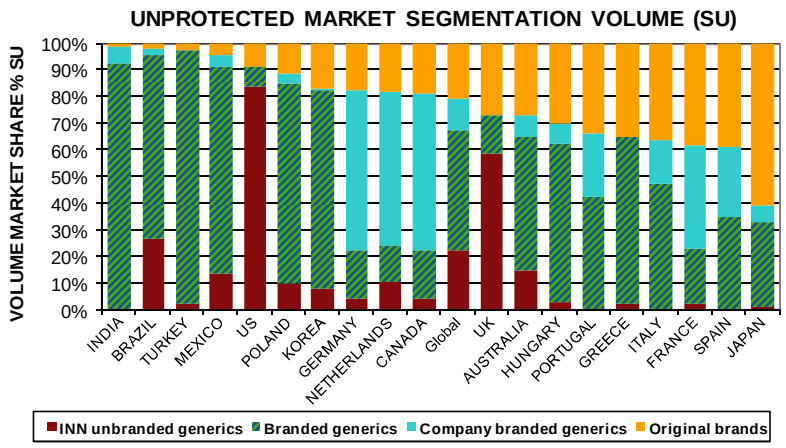
Even after patent expiration brands still retain a sizeable volume share in some countries



Source: IMS Health, MIDAS, Market Segmentation, MAT Dec 2010, Rx only. *Market Segmentation universe

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Total potential cost savings and average percentage savings that could be obtained from switching private sector consumption from originator brands to lowest-priced generics, for a limited basket of medicines

Country (n= number of medicines)	Total potential cost savings (2008 USD)	Average percentage savings across individual medicines*
China, public hospitals (n=4)	**$86,492,276**	**65.1%**
Colombia (n=9)	**$3,229,092**	**88.7%**
Ecuador (n=12)	**$3,066,407**	**63.2%**
Indonesia (n=9)	**$6,405,597**	**84.2%**
Jordan (n=11)	**$887,262**	**55.9%**
Kuwait (n=6)	**$64,261**	**9.3%**
Lebanon (n=8)	**$4,397,432**	**67.5%**
Malaysia, private hospital and retail sectors (n=10)	**$7,419,942**	**67.2%**

Source WHR 2010 Chapter 4

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Components of a generics policy Prerequisite: Quality assurance recognized by prescribers & patients

"Generics policies" is a broad term comprising a heterogeneous set of specific practices, including:

- Fast track registration: abbreviated and less costly registration procedure for generics, Bolar provision
- Procurement of medicines under INN or generic name;
- Encouraged or mandatory prescribing by generic name;
- Generic substitution by pharmacists;
- Information and incentives for generic utilization to prescribers, pharmacists and consumers;
- Selective financing of generics in positive lists, reference price systems, procurement by tendering, IPR policies.

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Conclusions

- In all but high income countries out of pocket payment is the most frequent form of payment for medicines
- When health insurance is introduced and covers medicines they need to have generic policies in place
- Where people have to pay out of pocket generic policies individuals can reduce costs by about 60% and this could make the difference between death or impoverishment and survival.

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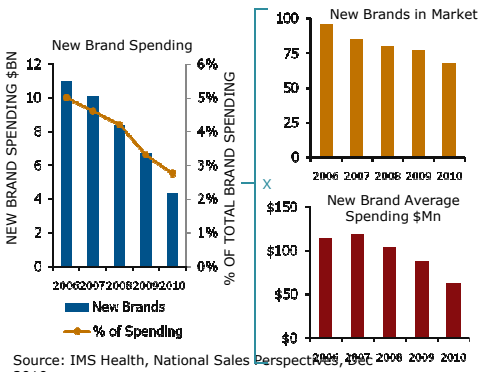
COMPARISON OF 2010 VERSUS 2009 SPENDING

New brands accounted for 2.8% of spending

New Brand Spending



Source: IMS Health, National Sales Perspectives, Dec 2010

- Total drug spending on products that have been available to patients for less than 24 months has dropped to $4.0Bn in 2010, down from $6.7Bn the prior year, and $11.0Bn in 2006.
- Spending on new medicines is now 2.8% of total brand spending, down from 5.0% in 2006.
- The number of products in this group totaled 69 in 2010, down from 96 in 2006, reflecting the decline in products emerging from research and development laboratories and receiving regulatory approval.
- Average spending per new branded product was $62Mn in 2010, down from $114Mn in 2006, reflecting a shift in the mix of new products toward orphan drugs and products with the same mechanism of action as existing products.

Chart notes:
New brands defined as brands launched in the prior 24 months where sales are reported in NSP.

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Data, methods and caveats

- Standard units instead of prescriptions used as volume measure to calculate generics share and brand erosion after loss of exclusivity (LOE)
- Pricing of generics and no-longer-protected brands after LOE varies significantly by country and results in a different volume balance between generics and brands

	USA	Germany	S Africa	Brazil
Brand Capture by generic (volume)	90%	75%	30%	50%
Price Differential	-90%	-40%	-26%	-35%
Time to Impact (months)	12	24	12	12

- The number of generic competitors available after LOE varies by country; fewer products produce less brand erosion
- Intellectual property protection enforcement is not at the same level in all countries; generics prior to a brand's LOE are more likely to be available in pharmerging markets than in the developed markets
- Country-specific epidemiology needs guide different policies and market dynamics related to unmet medical need (i.e. antiretroviral drugs in South Africa)

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But implementation may be difficult:

Public advertisement, Guatemala, 2006 and 2010

"I have diabetes. If my medication fails, I could suffer a diabetic coma."

"I don't take chances. I only use originals"

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Total potential cost savings and average percentage savings that could be obtained from switching private sector consumption from originator brands to lowest-priced generics, for a limited basket of medicines

Country (n= number of medicines)	Total potential cost savings (2008 USD)	Average percentage savings across individual medicines*
Morocco (n=6)	**$3,175,435**	**51.8%**
Pakistan (n=9)	**$12,606,083**	**51.2%**
Peru (n=11)	**$2,520,356**	**78.7%**
Philippines (n=9)	**$9,415,319**	**57.1%**
South-Africa (n=7)†	**$3,461,600**	**78.9%**
Thailand (n=7)	**$1,348,669**	**75.7%**
Tunisia (n=3)	**$280,001**	**25.8%**
Ukraine (n=4)	**$458,892**	**52.3%**
United Arab Emirates (n=12)	**$10,671,587**	**53.0%**

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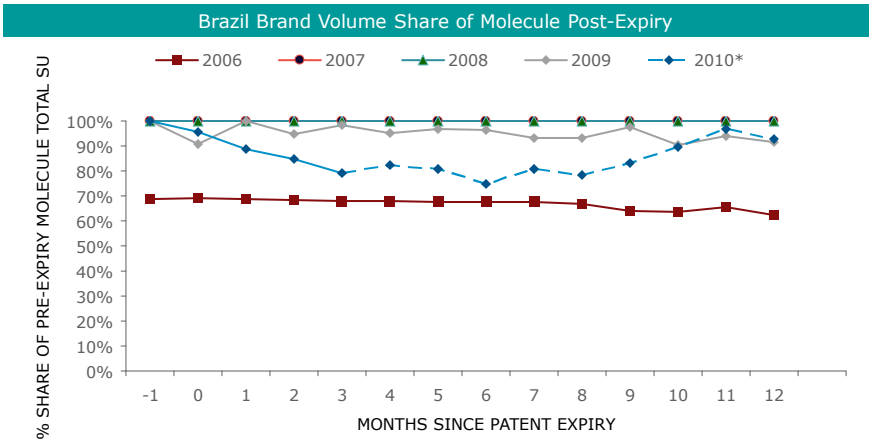

Source: IMS MIDAS Monthly, Mar 2011. *2010 curve contains incomplete periods.

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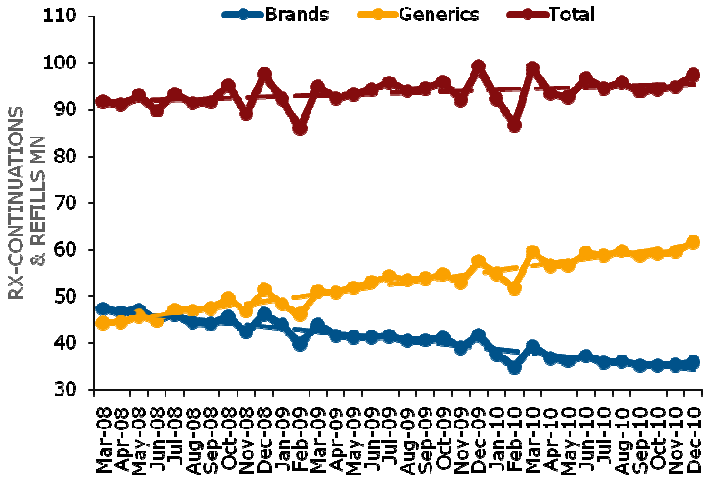
In US, continuing therapies grew slowly as brands continued to decline

Chronic Disease Continuations and Refills



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Source: IMS Health, National Prescription Audit, Dec 2010