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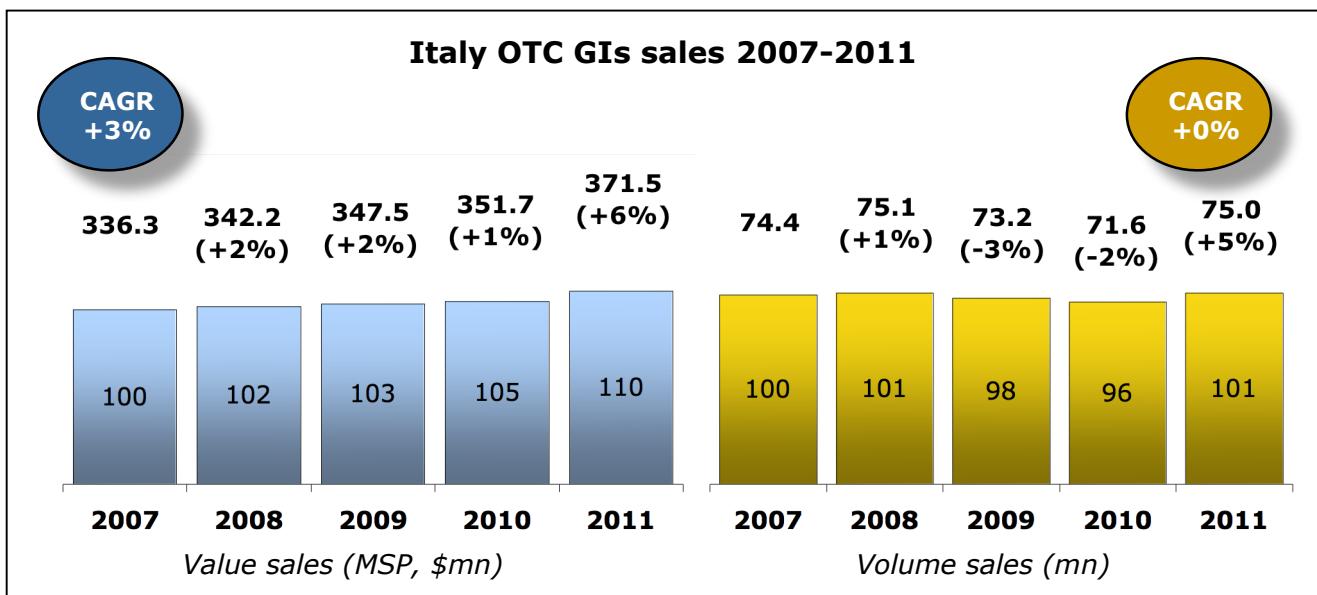
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Italy – Overview



Strong return to growth following flat period driven by launches

- Dynamic performances from top brands drove a rapid upturn for GIs in 2011 both in terms of value and volume sales
- Antacids benefited particularly from NPD; a series of line extensions via switch and launch of dominant Maalox (Sanofi) saw the brand grow rapidly ahead of its dynamic category
- The creation of the PPIs segment in late 2010 also contributed to this rapid growth; a consumer base highly receptive to innovation readily adopted brands such as Pantoloc
- The antiflatulents category saw consolidation of sales towards the top tier, with the fragmented lower tier losing share to dynamic leaders
- Laxatives category saw minor growth in value sales, but volume sales remained flat; the increasing threat to branded options of low-priced generics and increasing saturation has impacted sales

GIs sales 2011: \$371.5mn

GIs sales growth 11/10: +5.6%

GIs sales per capita 2011: \$6.11

Leading GIs marketers: Johnson & Johnson, Novartis, Sanofi, Boehringer Ingelheim, Bayer, Nathura, Aboca, Roche, Sofar, Sigma-Tau, Pfizer, Angelini, Bracco, SPA, Meda, GlaxoSmithKline, ESI, Rottapharm | Madaus, Ortis, Recordati

Forecast GIs sales 2021: \$467.5mn

Forecast GIs CAGR 21/11: +2.3%

USA – Antacids & antiflatulents

Health risks associated with PPIs dampen consumer enthusiasm

- PPIs looked to be the major success story of the GIs market in recent years, but a series of studies have cast doubts upon their safety and, despite many warnings applying only to Rx brands, sales of leading OTC brands globally have correspondingly been hit (see *PPIs chapter for further details*)
- Looking at the US specifically, the FDA has made a number of decisions in light of warnings
- In May 2010, the FDA announced a revision of labels for Rx and OTC PPIs to include new safety information about possible increased risk of hip, wrist and spine fractures associated with their use; however, in 2011 it did state that OTC PPIs are unlikely to be associated with increased risk of bone fractures
- In March 2011, the FDA announced that using prescription PPIs may cause low serum magnesium levels (hypomagnesemia), which can lead to muscle spasms, irregular heartbeat or seizures; however, the FDA did not believe that OTC PPIs carry significant risk when used according to directions
- In early 2012 the FDA began informing the public that the use of PPIs may be associated with an increased risk of Clostridium difficile-associated diarrhoea; it is working with manufacturers to include information about the increased risk of CDAD in drug labels

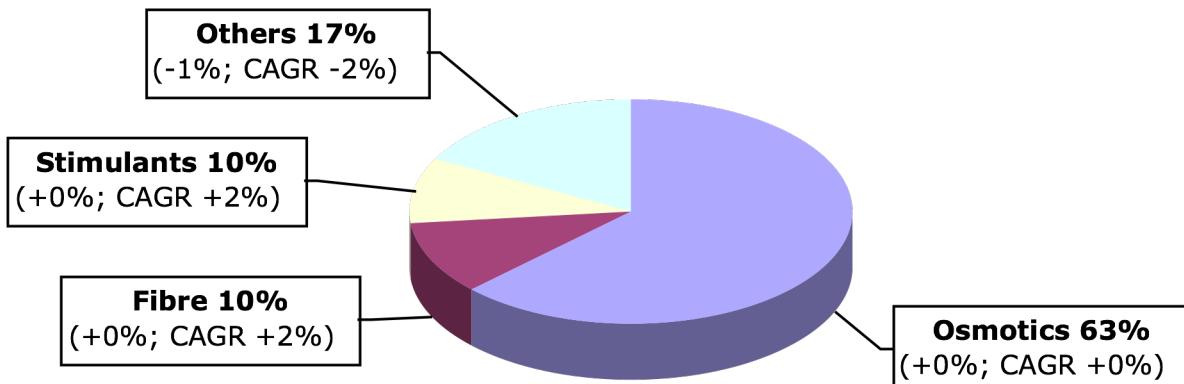
- Tums was the real success story of 2011, with growth nearly reaching +20%
- Success can be attributed to GSK's A+P efforts and a repositioning of Tums, with a variety of campaigns highlighting how the antacid is a faster-acting solution than PPIs and provides immediate relief
- With this new positioning GSK can target a considerable audience, from those who suffer from occasional heartburn to those who require quick relief while waiting for PPI medication to take full effect (which can take between 1-4 days)
- GSK focused its A+P efforts on Tums Ultra, supporting the maximum strength (calcium carbonate 1,000mg) version with a range of "Food Fight" TV ads and an integrated Facebook campaign
- High-strength options Tums Ultra and Tums Extra now account for just over two-thirds of total brand turnover and outpaced the rest of the line



"Fight back fast" tagline highlights Tums' speed of action

France – Laxatives

France OTC laxatives sales by segment 2011
(MSP, \$mn)



Pie reflects identified brands, worth \$181.4mn

- While ispaghula husk-based Spagulax has benefited from the downturn for osmotic laxatives, fibre-based laxatives have been on the 15% reimbursement list since 2010, affecting prescription sales
- Norgine's naturally-formulated semi-ethical Normacol has been particularly affected; the brand has steadily declined 2007-11
- A number of other semi-ethical laxatives including Sanofi's stool-softener Lubentyl and Techni-Pharma's suppository Eductyl were also downgraded to "orange prescription" (15% reimbursement) status in 2010
- No.1 pure OTC laxative Microlax rectal solution has seen steady growth, although consumers remain unwilling to embrace self-selection in this category
- Microlax is supported by TV and internet ads using the tagline "Make peace with your belly", and was extended in 2011 with a 4-count unidose pack, available for self-selection
- The pure OTC segment may yet benefit from the reimbursement cuts for semi-ethical laxatives; BI's Dulcolax continued to grow thanks to a higher-than-average adspend in 2010
- J&J's other major pure OTC laxative, Lansöyl oral gel, was made eligible for self-selection in 2010



Germany – Antidiarrhoeals

- Brand website shows a woman using Tannacomp at the popular tourist destination the pyramids in Cairo, targeting Germans who holiday in foreign countries
- Fourth-placed Kohle-Compretten is formulated with activated carbon; A+P material claims brand “fights the causes of diarrhoea and not only the symptoms”
- Also claims to provide “natural help”
- Saline, potassium chloride and glucose combination remedies Oralpaedon and Elotrans have a solid presence
- Herbal brand Myrrhinil Intest (chamomile, myrrh) posted growth, but does not challenge the leading brands; however, continued consumer interest in natural remedies may see brand move up rankings



Ad for Tannacomp with slogan
"Diarrhoea? Tannacomp helps fast!"

Probiotics strong competition for traditional antidiarrhoeals

- Probiotic antidiarrhoeals (*sales tracked in VMS*) form a large segment and provide strong competition for conventional antidiarrhoeals
- However, a number of leading probiotic brands struggled for growth 2007-10 (although had strong year in 2011)
- No.1 probiotic Perenterol (UCB for Biocodex) posted sales of \$16mn in 2011
- In 2011, the brand was extended with a 30-pack version with individual doses of the extra-strength formulation, positioned as ideal for a family to take on holiday
- A+P material for the brand included a travellers' diarrhoea risk card (*see right*), showing on a map of the world the regions where the risk of getting diarrhoea is highest
- Mutaflor (Ardeypharm) and Symbioflor (Symbiopharm) were placed No.2 & 3 in 2011 with sales of \$11mn and \$9mn respectively
- Ardeypharm positions Mutaflor for holidaymakers but also claims it is effective for newborns

