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Predicting the Next Wave: Changes in the Global Generic Sector Implications for Manufacturers & Investors

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Agenda

- Key generic sector changes & future impact
  - Consolidation impacting generic manufacturers & U.S. customers
  - Some M&A deals are transformational
  - Increasing globalization
  - Competition
- Future developments
  - Slow down in pharma sector growth and new launches
  - Shift in new launches to categories that are technically more challenging for generics
- Predictions & Themes

Generic Leaders 1999-2004: Stable, Consolidating

Rank 1999		
1	Novartis/Sandoz	8%
2	Mylan	7%
3	Teva	7%
4	Merckle/ratiopharm	5%
5	Watson	4%

Rank 2004		
1	Teva	8%
2	Novartis/Sandoz	6%
3	Mylan	6%
4	Merckle/ratiopharm	5%
5	Hexal -now Sandoz	4%

Source: IMS

Recent M&A: Generic Leadership Shift

Rank - ProForma	2005 Generic Sales	2005 Total Sales	Rank
1 Teva/Ivax	$6.14Bn	$7.5Bn	1
2 Sandoz	$4.69Bn	$4.69Bn	2
3 Barr/Pliva	$1.56Bn	$2.35Bn	4
4 Watson/Andrx	$1.54Bn	$2.69Bn	3
5 Merckle-ratiopharm**	?	$2.01Bn	5
6 Actavis/Alpharma	$1.49Bn	$1.49Bn	6
7 Mylan/Matrix*	$1.19Bn	$1.37Bn	7
8 Stada	$931.1M	$1.28Bn	8
9 Ranbaxy	$789M	$1.18Bn	9

****Mylan acquiring 71.5% of business or $129M total sales (Matrix generic portion not broken out and therefore not included in Mylan/Matrix 2005 generic sales); **Merckle-ratiopharm is private, generic sales total unknown***

Source: Lehman Brothers estimates, public sources, 2006

Consolidation: Recent Strategic Deals

- Actavis – Amide & Alpharma
  - Created larger pure generic company with strengths in rapid development & launch in EU plus new U.S. business
  - Actavis transformation from an EU to a global player
    - Low cost FDF manufacturing scaled to EU & U.S. volumes
    - CRO & development in India
  - Actavis has a track record of smart, low cost acquisitions of troubled companies that it can integrate and run effectively
  - Pliva bid appears unsuccessful: perhaps another, smaller target in line with past pattern?

Consolidation: Recent Strategic Deals

- Teva – Ivax
  - Created world largest generic company, yet again
  - Teva's impressive track record of integration likely to again deliver strong results with the complex task of integrating Ivax's many operating units & geographies
  - Rapid simvastatin results
  - Added respiratory to Teva's branded business
- Sandoz – Hexal/Eon
  - Reverse merger created a more global, more efficient generic company under Hexal's management team
  - Hexal's strengths in Germany, U.S. appear to deliver
  - Increased US pipeline going forward
  - Indian & Lek development centers

Consolidation: Current Strategic Deals

- Barr – Pliva (if finalized)
  - Would create world's 3rd largest generic company
  - Transform leading U.S.-only generic/specialty company into a pan-U.S./European generic developer and marketer
  - Add some API capabilities
  - How will Barr's brilliant, but exclusively U.S. mgmt retain Pliva's old mgmt to build a new, competitive company?
- Mylan – Matrix
  - Potential to transform leading U.S.-only generic company into a fully integrated generic and API development & marketing powerhouse
  - Strong U.S.-India axis, EU beachhead in the Benelux
  - How will plans to retain Matrix's exceptional team & build new structure work?

M&A: Changing the Generic Landscape

- Transformational deals, if execution lives up to the transaction, will change the competitive landscape
- Multiple, smaller deals can be quickly integrated and help build a business, especially in EU
  - Ranbaxy's numerous EU acquisitions
  - Small U.S. acquisitions can achieve material revenue increases for smaller Indian companies in their local market that barely register in the U.S. market
- Other deals involve catch up games, may divert management attention & decrease combined company's ability to compete

M&A: What is Transformational?

- Combination of U.S. sales strength, relationships with large chains/wholesalers with Indian speed, science & integrated API capabilities
  - Early, secret development of non-infringing processes
  - Increased speed: more project throughput with more affordable, high-caliber scientists
  - Low costs through low-cost science, technical and regulatory
  - Patent circumvention and blockading
  - Ability to scale up early & reduce costs by selling in India & less regulated markets

Future → **More U.S.-India M&A: Speed, margin, scale, regulatory, patent circumvention**

M&A: What is Transformational?

- Integration of API manufacturing to capture margin
  - More room to compete & take market share in U.S., EU
  - Supports greater profitability
  - Increases ability to be FTF & capture & retain market share
    - Initial filing with early internally developed API
    - Later cost reduction by outsourcing steps to China

- API business is not easy: chemistry is not punching tablets
  - Different business requires experienced management
  - Longer time lines, different risks

Future → **API integration: greater control, higher margins, less risk compared to FDF mfrs dependent on outside API**

Consolidation: U.S. Customers

- Major chain drug stores & wholesalers dominate retail pharmacy market
  - Consolidation likely to continue among retail chains
  - Regional grocery pharmacies may continue to lose share
  - Wal-Mart wants more share
- Wal-Mart & wholesaler efforts to buy direct will have limited impact on large generics with sophisticated supply chain services
- Relationships & track record on blockbuster launches with chains important & not easily built

Future → **Top generics forge closer partnerships with drug chains & Wal-Mart. Less room for new & medium sized companies**

U.S. Customers: Profiting from Generics

- "Our research shows that each generic drug garners at least $5. more in gross profit than the branded equivalent.[1]"

- Retailer gross profit margins average 10-15% on a branded drug; 50-70% for a generic[2]
- Higher profits & expected increases in generic utilization predicted to increase earnings for chains
- Increased Indian FDA filings insure competitive market for generics, even if new entrants gain little market share

Future → **Top generic co.s partnerships with drug chains include moving forward in the supply chain to capture profits**

[1] Lehman Analyst Meredith Adler, 7/28/06 report on retail drug sector; [2] Drug Store News, 8/22/05 M. Kirsche

Future: Slowdown in Pharma Sector Growth Impacts Generics

- Fewer new launches
  - New product launches estimated to average 44/year 2006-2010, vs 45/year 2001-2005 & 54/year 1999-2003
- Slowing global market growth
  - 5% a year estimated global pharma growth 2005-2010E vs 9% a year 2000-2005
  - Decline driven by:
    - Entry of lower priced generics in key categories
    - Slowdown/saturation forecasted in mature categories

10 Year Forecast → **Decrease in number of products available to generics**
Further consolidation, new entrants do not achieve scale

Source: Lehman Pharma Pipelines, 2006

Future: Fewer Launches, Fewer Traditional Generic Targets

- Necessitates development of niches even by global companies to maintain growth and profits
- Niches include:
  - Smaller markets, e.g. EU, CEE, Latin America, vet channel
  - Products with smaller sales, including specialty drugs
- Niches already becoming more competitive
  - Fewer attractive opportunities for small-medium companies

Future → **Global companies continue to acquire niche companies & to enter/acquire in smaller markets: tougher competition for small-medium & local generic/specialty companies**

Pharma Sector Growth to 2010: Fastest Growing Categories More Difficult for Generics to Penetrate

- Diabetes, +15%+/yr
  - Fastest predicted category growth to 2010
  - Driven by insulin analogs
- Vaccines, +15%+/yr
  - Biologicals, no clear generic pathway or capabilities
- Biological Anti-inflammatories, +10%+/yr
  - Driven by switching from cheap NSAIDs to biologics like Avastin, Rituxan, Herceptin
- Oncology, +15%/yr

Issue → **Vaccines & biologics projected to grow from 18% of sales in 2005 to 26% of pharma sales in 2010: where & how will multi-source vaccines & biologics be approved?**

Source: Lehman Pharma Pipelines, 2006

Pharma Sector Growth: Oncology/Hospital

- Oncology products: mostly steriles
  - Development of custom therapies changes drug delivery
  - APIs expensive, technically challenging; require containment facilities
- Hospira/Mayne to create a global, generic/specialty hospital/oncology company
  - Low cost Indian & Chinese API sourcing
  - Proprietary Abbott technology: will patents hold?

Future

- **Hospital sales: generic & brand may blur if generics innovate in drug delivery & customized medicine**
- **Technology in delivery/device; generics will need to evolve from vial & syringe suppliers**

Pharma Sector: Globalization

- Expected slowing growth in major markets, increasing competition from India, China
- China & India integrated into global market
  - M&A in EU by Indian & U.S./Global companies
  - India as base for aggressive, internationally focused API & FDF companies with high caliber science
  - China as outsource supplier of APIs, intermediates, has rapidly growing domestic market
- EU will remain fragmented longer

Future → **Slowing growth, stronger global companies via organic & inorganic growth will increase competition in all markets**

Increasing Competition to Supply the U.S.

- Indian companies targeting U.S. and EU
  - China often in the Indian supply chain
  - Direct FDF sales ~2-5 years behind, fewer cos. ready
- Newer Indian companies, especially API mfrs used to lower margins, attempting to sell FDF
- U.S. customers mostly using competition to negotiate better prices from top generic suppliers
  - Most new entrants still have minimal market share
  - Ranbaxy not new, fully global, competes as a U.S. company

Result →

- **Margins pressured throughout supply chain**
- **New entrants gain little meaningful FDF market share**

Increasing Competition from India

- Other than APIs, no Indian companies other than Ranbaxy, DRL & Sun/Caraco gaining meaningful market share in U.S. FDF market
- Alliance products hard to measure
  - FDF market share included in U.S. partner's name
- 72 Indian companies have U.S. DMFs
- Cipla, DRL, Ranbaxy, Matrix, Sun, Wockhardt and Lupin each have more than 25 active DMFs
- ANDAs filed in 2003-2005 period getting approved 2006 onward. Will the picture change?

Trend → **Large increases in DMFs submitted and cited in ANDAs, FDF as yet limited share except Ranbaxy**

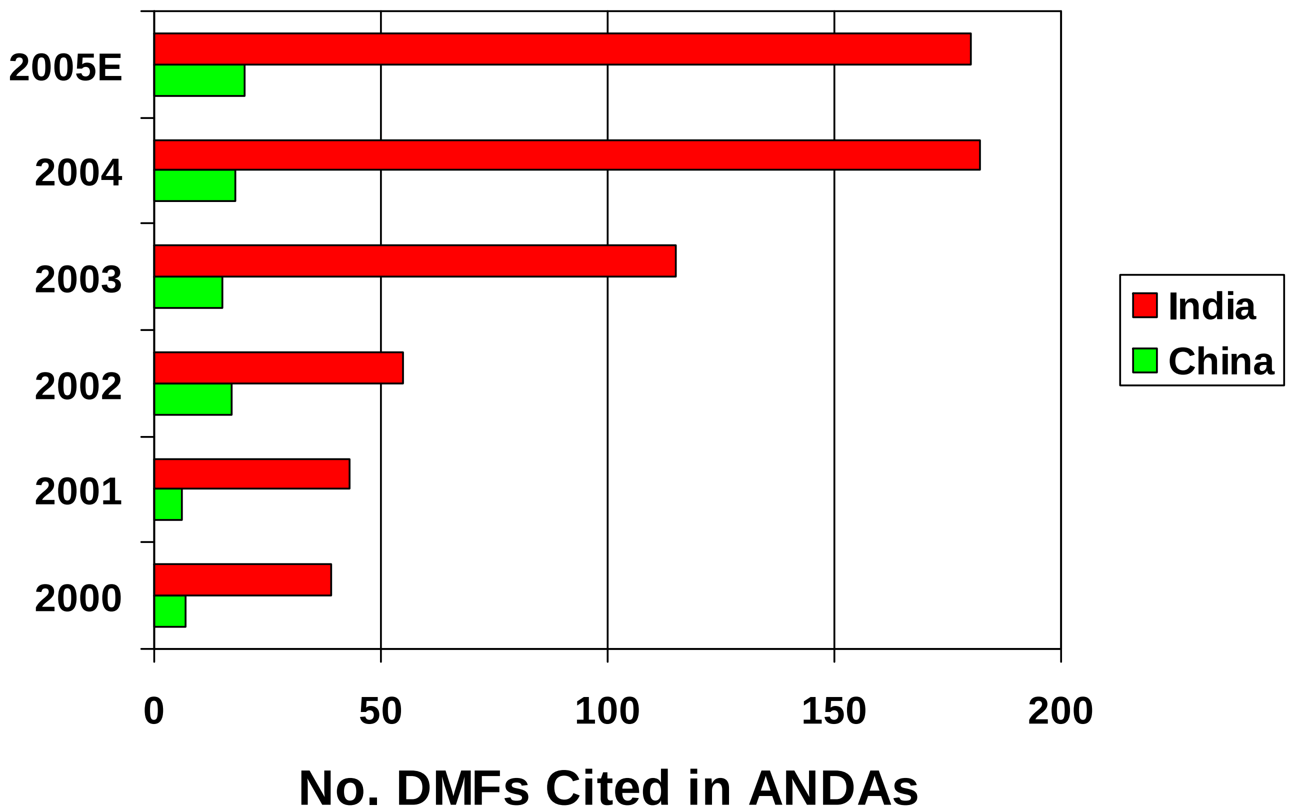
Measuring Competition: FDA Inspections

FIRM TYPE	2003	2004	2005	China ’05	India ’05
API	92	130	135	14	20
API/FDF	28	26	28		3
FDF	35	69	60		7
Intermediate	2	2	3		
Contract Labs	20	24	23		3
Contract Micronizers	1	2	0		
Contract Sterilizers	3	0	1		
Drug Repackers	4	6	5	1	
TOTALS	185	259	255	15	33
Growth %		40%	-2%	6% of total	13% of total

Trend → **Increase in overseas FDF inspections; China and India have increasing roles, change is incremental**

Source: US FDA’s Gary Buhler, presentation at GPhA API Conference, 3/2006

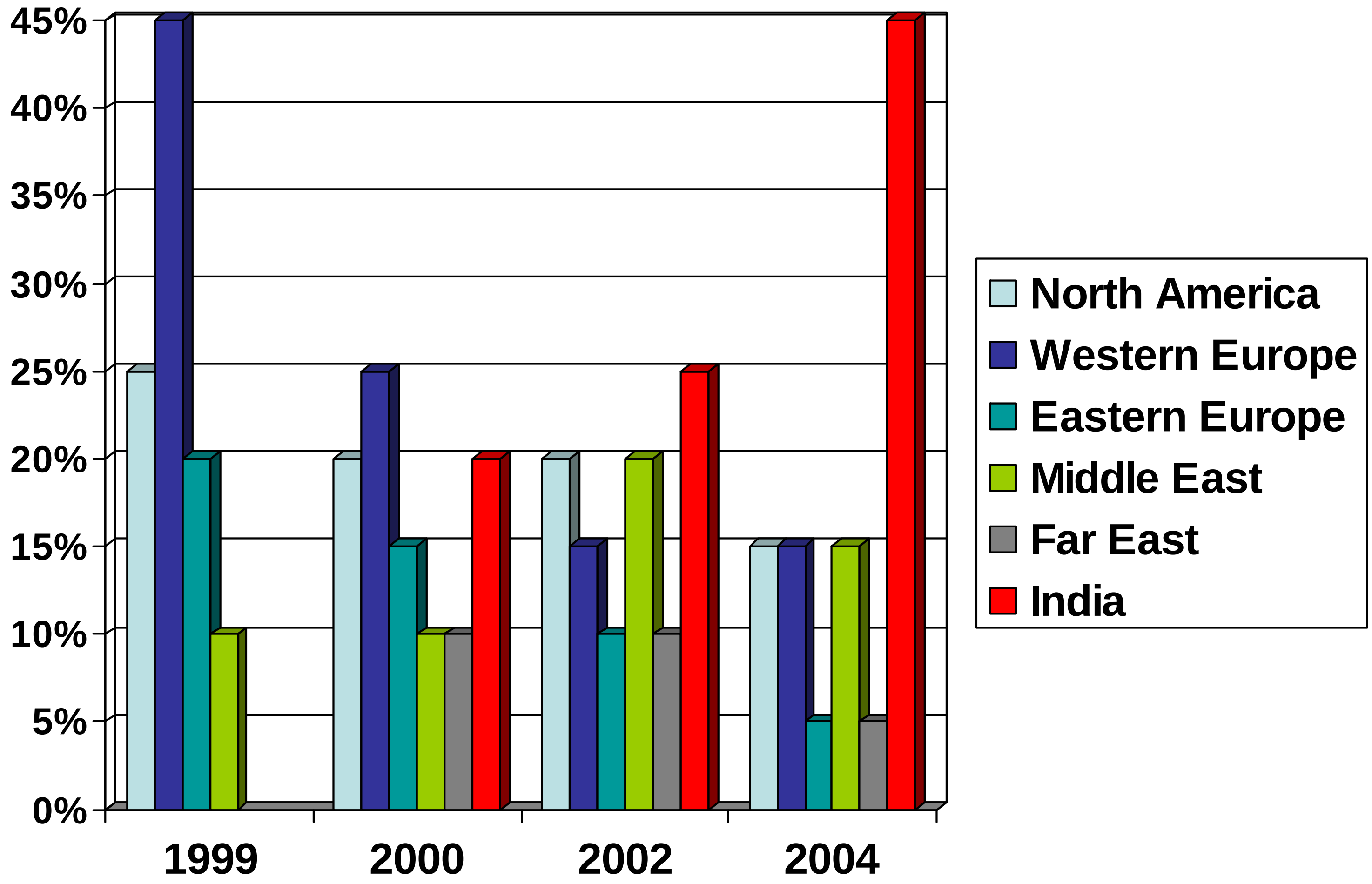
Measuring Competition: More Indian DMFs/APIs Cited in ANDAs



- Many DMFs cited multiple times in multiple ANDAs
- Some ANDAs citing Indian DMFs support FDF products via partnerships

Source: FDA Office of Generic Drugs, August 2005

Indicator of Competition: Increase in Reviewed DMFs from India Received by FDA



Source: Paul Schwartz, Ph.D., FDA Office of Generic Drugs, GPhA API Conference 3/15/05

Limited Future Competition: Bio Generics Have Barriers to Entry

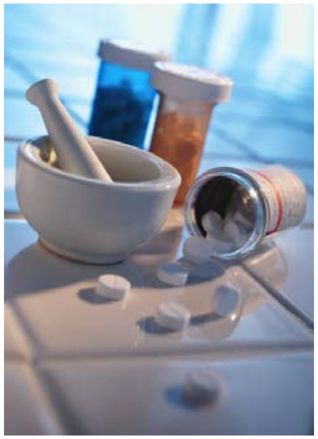
- Unclear regulatory pathway, even nomenclature must be defined (INN issue)
- Specialized manufacturing parameters for ‘API’
- May be a branded generic type business model
  - Education of prescribers & patients may be required
  - Business model similar to Barr’s, good fit with Pliva
  - Teva’s biologics capabilities & brand experience
  - Sandoz experience with branded generics in EU markets

Future → **Barriers to entry support profitable market & growth for limited number of sophisticated, global companies**

Branded Pharma Competitive Impact

- Delaying tactics, patent strategies & authorized generics will continue, requiring sophisticated legal & development resources to fight
- Innovation in delivery, personalized medicine, greater complexity of patient data & communications, biologicals will continue to change the landscape
- Authorized generics may be combined with other strategies to retain market share based on TRxs by brand companies
- Medicare Part D impact still new, may raise the bar for new therapies & support generic utilization

Generics: Size, Breadth, Sophistication Important to Compete



- Large companies with high performing R&D & access to API have advantages in delivering broad, deep pipelines to meet the needs of U.S. chains and wholesalers & other markets
- Sophisticated supply chain management & a track record required to achieve meaningful sales to major chains and wholesalers in the U.S.
  - Other companies will take their place in the supply chain
- M&A key to achieving scale, geographic reach & lower costs by global companies
- M&A key for leading Indian and other overseas companies positioning themselves for U.S. & EU markets

Key Themes

- Leading U.S. players have remained stable and consolidated their positions: Teva, Sandoz, Mylan, Barr will continue to perform
- Regional companies have become global, & will compete effectively: Ranbaxy, Actavis
- Top performance requires high caliber, often Indian, R&D & integrated API capabilities
- Achieving significant scale in U.S. difficult for new entrants without M&A to combine low cost R&D & U.S. marketing strength
- Niches are complex & important to the top companies, leaving less room for small-medium generic companies

Thank you

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