

Pioglitazone ban – limited impact

June 27, 2013

Quick Note

- In a surprise move the Government of India has banned Pioglitazone and its combinations in India. Pioglitazone and combinations have a market size of INR 6.5bn (FY13), which is 16% of the Anti Diabetic market in India, as per AIOCD AWACS.
- The major players in the pioglitazone market include USV, Sun Pharma, Abbott Healthcare, Micro Labs and Lupin. For Sun Pharma and Lupin the total brand sales from this segment are INR 900m and INR 400m (FY13) respectively, as per our estimates.
- We expect the Glitazone volumes will shift to other segments. Gliptins, Sulphonylurea Metformin combinations and also Insulin are expected to be key beneficiaries.
- We expect the biggest beneficiary will be the Glimepiride + Metformin combination, which is the largest selling product in the anti-diabetics segment. We note that pioglitazone is largely sold in fixed dose combinations with Glimepiride and Metformin. Also, the per tab cost of Glimepiride + Metformin (INR 4-5) is slightly lower than that of Pioglitazone + Glimepiride + Metformin (INR 5.3).
- Technically, a shift to Gliptins makes sense and most prescribers will likely do that. But there are supply constraints as the products are patented and marketed by a limited number of companies. Also Gliptins are very expensive, with costs at 3-6x those of pioglitazone combination therapy.
- Sun Pharma and Lupin have strong brand franchises across most of the products. In Glimepiride + Metformin, to which we see most of the shift happening, Sun Pharma and Lupin are the second and third largest brands. Sun Pharma and Glenmark are among the few Indian players present in Gliptins and hence would benefit from a volume switch. Lupin would also benefit from its brand presence in Insulin, which is also expected to record some volume gains based on our interaction with industry experts. Therefore the loss in pioglitazone will be made up to some extent through other segments.

Indian regulator bans pioglitazone in a surprise move

In a surprise move, the Government of India has banned Pioglitazone and its combinations in India. Pioglitazone and combinations have a market size of INR 6.5bn, which is 16% of the Anti Diabetic market in India as per AIOCD AWACS (FY13). The largest product is a combination of Pioglitazone with Metformin and Glimepiride, which accounts for 9.5% of the Diabetes Market. Glitazone and combinations as a class account for 19% of the oral antidiabetic market. The class has been slowing down compared to the other classes, as indicated in Fig 1, but still recorded a healthy 19% CAGR over FY08-13. Pioglitazone and its combinations have recorded a 24% CAGR over FY08-13.

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See Appendix A-1 for analyst certification, important disclosures and the status of non-US analysts.

Fig. 1: Oral anti- diabetic market

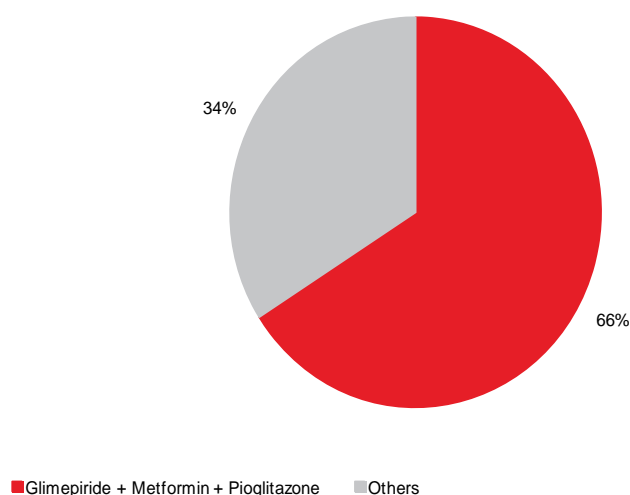
Glitazones have been growing relatively slowly

Category	Share of OAD market	FY08-FY13 CAGR	FY13 growth
Sulphonylurea+Metformin	33%	23%	18%
Gliptins and combinations	19%	NA	38%
Glitazones and combinations	19%	19%	11%
Suphonylurea	11%	11%	6%
Alphaglucoisidase inhibitor	9%	37%	35%
Metformin	8%	25%	19%

Source: AIOCD data, Nomura research

Fig. 2: Pioglitazone sales (FY13) as % of pioglitazone market

Pioglitazone is mostly sold in combination with metformin and glimepiride



Source: AIOCD data, Nomura research

Key players in pioglitazone market: USV and Sun Pharma

USV and Sun Pharma are the leading players in the segment and account for almost a third of the segment. The discontinuation of brands of pioglitazone poses a risk to brand sales worth INR 900m and INR 400m for Sun and Lupin respectively in FY13.

Fig. 3: Key players in Pioglitazone market (FY13)

Company	PTR sales (INR m)	Market share
Usv Ltd	1,034	16%
Sun Pharmaceutical Industries Ltd	947	15%
Abbott Healthcare Pvt. Ltd	612	9%
Micro Labs Ltd	490	8%
Lupin Ltd	396	6%
Mankind Pharmaceuticals Ltd.	361	6%
Eris Life Sciences Pvt Ltd	288	4%
Aristo Pharmaceuticals Pvt.Ltd	240	4%
Wockhardt Ltd	190	3%
Ipca Laboratories Pvt Ltd.	180	3%
Ranbaxy Laboratories Ltd	169	3%

Source: AIOCD data, Nomura research

How will market shape up? Glimeperide+Metformin will gain the most. Volume gain in other products will negate the impact of ban to some extent

With the exit of glitazones from the market, the volume share will be gained by other segments. Our interaction with the industry suggests that other segments like Gliptins, Insulins and sulphonylurea metformin combinations are likely to be the key beneficiaries. Technically, a shift to Gliptins makes sense and most prescribers will likely to do that, we think. But there are supply constraints as the products are patented and marketed by a limited number of companies. Also, Gliptins are very expensive with costs at 3-6x those of pioglitazone combination therapy.

Since the largest pioglitazone combination sold in India was with Glimepiride and Metformin, we expect most of the volume shift will happen to this segment. The average cost for Glimepiride Metformin combination is INR4-5, which is marginally lower than the pioglitazone + metformin + Glimepiride combination therapy, which is estimated at INR5.3.

Sun Pharma and Lupin have strong brand franchises across most of the products. In Glimepiride + Metformin, to which we see most of the shift happening, Sun Pharma and Lupin are the second- and third-largest brands. Sun Pharma and Glenmark's are among the few Indian players present in Gliptins and hence would benefit from a volume switch. Lupin would also benefit from its brand presence in Insulin, which is also expected to record some volume gains based on our interaction with the industry experts.

Fig. 4: Key players in Glimepiride + metformin market (FY13)

Company	Market share in FY13
Usv Ltd	19%
Sun Pharmaceutical Industries Ltd	11%
Lupin Ltd	9%
Intas Pharmaceuticals Ltd	8%
Sanofi-Aventis	6%

Source: AIOCD data, Nomura research

Appendix A-1

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