

GLOBAL DRUG FACILITY (GDF) FACT BRIEF RE: GDF 2005 Tender Results and Implications



**A NEW
PERSPECTIVE
ON TB DRUG
PROCUREMENT.**

In response to recent changes in the anti TB drug market, especially concerning price increases and bottlenecks in the supply of key Active Pharmaceutical Ingredients (APIs)¹ for first line anti TB drugs, the GDF issued a new tender.

The tender, which closed in April 2005, was designed to:

- expand the GDF's supplier network and the sources of API upon which these suppliers rely, *in order to reduce the risk of supply bottlenecks*
- maintain affordable prices of high-quality anti TB drugs, *by promoting competition*
- expand buffer stocks, *to service urgent supply requests from countries*

Prior to launching the new tender through its procurement agent, UNDP/IAPSO,² GDF commissioned an in-depth analysis of the international first line anti TB drug market. The results of the analysis indicated that, among other things:

Bottlenecks in the supply of key APIs were the result of:

- an insufficient number of manufacturers able to offer first line TB drugs at the level of high-quality required by the GDF
- increasing global demand for APIs without a corresponding increase in suppliers of APIs

Increases in the prices of first line anti TB drugs were the result of:

- rising costs of API processing and finished product inputs³
- the requirement for manufactures to make new investments in order to meet the high-quality standards required by GDF, foremost among which, are those stipulated in WHO's prequalification process on access to medicines of acceptable quality

The above market challenges - which prompted GDF to launch its new tender - did affect GDF service delivery in the last quarter of 2004 and the 1st and 2nd quarters of 2005. In particular:

¹ Active Pharmaceutical Ingredients are the chemicals used in the manufacturing of drugs.

² UNDP/Interagency Procurement Services Office

³ The price of oil, which is used in the processing of APIs, has risen over the last 12 months and the price of the glucose used as an excipient in anti TB drug production, is at a 4-year high and expected to rise further.





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- For large orders of anti TB drugs (valued at US\$ 450,000 or more) GDF delivery lead times⁴ increased from 4-6 months to 6-9 months. GDF-supported countries having received or receiving large orders during the above period are Bangladesh, Democratic Republic of Congo, Democratic People's Republic of Korea, India, Myanmar, Pakistan and the Philippines.

To mitigate the impact of these delays, GDF has split large orders into smaller consignments with deliveries taking place in a staggered manner and focusing on priority products required by the programmes that need them most.

- For regular sized orders during the above period, GDF has maintained average lead times of 4 months and small emergency orders have been delivered within 2 months: Azerbaijan (4 months), Bosnia-Herzegovina (3.8 months), Burundi (3 months), Cape Verde (3 months), Central African Republic (1.2 months), Republic of Congo (3.5 months), Equatorial Guinea (2.2 months), Kosovo (3 months), Mauritania (3.4 months), Moldova (3 months), Somalia (3.6 months), Sri Lanka (1 month), Turkmenistan (3 months), Yemen (1.7 months)

Outcomes of GDF tender

The GDF is optimistic that the outcomes of the tender will stabilize the supply of high-quality anti TB drugs to countries and ensure that prices remain competitive. The results and their implications for future GDF supply are as follows:

⁴ Lead time refers to the period from the time an order is placed by UNDP/IAPSO to the time the order arrives at the port of the country of destination. The lead time DOES NOT begin at the time a contract is signed with a client since the order is ONLY placed upon receipt of monies or a bank guarantee by UNDP/IAPSO, as stipulated in the contract.





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Table 1: Outcomes of GDF Tender and Implications

<i>Results</i>	<i>Implications</i>
4 manufacturers contracted under Long Term Agreements (minimum 1 year)	Increasing the number of GDF suppliers to 4 from 3 will increase GDF supply capacity.
2 manufacturers awarded supply of each GDF product, ⁵ with a 3 rd manufacturer identified as a back-up supplier	Dividing the supply award between 2 suppliers will reduce the risk of supply chain bottlenecks and encourage better supplier performance due to competition. Moreover, having a 3rd supplier also gives GDF flexibility when approached by countries that urgently require unscheduled orders.
3 sources of Rifampicin API secured	Diversifying the API supply base from reliance on 1 source to 3 sources is a significant and positive development for GDF. It will greatly reduce the risk of capacity bottlenecks of the kind experienced in late 2004/early 2005.
Manufacturers' agreement to expand buffer stocks of priority TB drugs	Once the buffer stocks of priority TB drugs e.g. 4 drug and 2 drug fixed-dose combinations are built up (over the next 4 to 6 months) GDF will be able to service emergency and small to regular sized orders rapidly i.e. 1 to 2 month lead times.
Price increase for fixed-dose combinations ⁶ (FDCs) and price decrease for two single formulations	While prices have increased for FDCs, these prices still include the costs required to guarantee their high quality and remain well below the costs countries pay to independent suppliers of questionable quality drugs. The increases, moreover, were expected and reflect an international trend (see below). Prices for two of GDF-supplied anti TB products have fallen from previous levels. ⁷ Based on 2005 price reports, GDF prices remain lower for all drugs (except the 4FDC and Streptomycin) than the next closest international supply agent.

⁵ Except for Streptomycin 1g

⁶ And for Ethambutol 400mg and Streptomycin 1g

⁷ Pyrazinamide 400mg and Isoniazid 300mg





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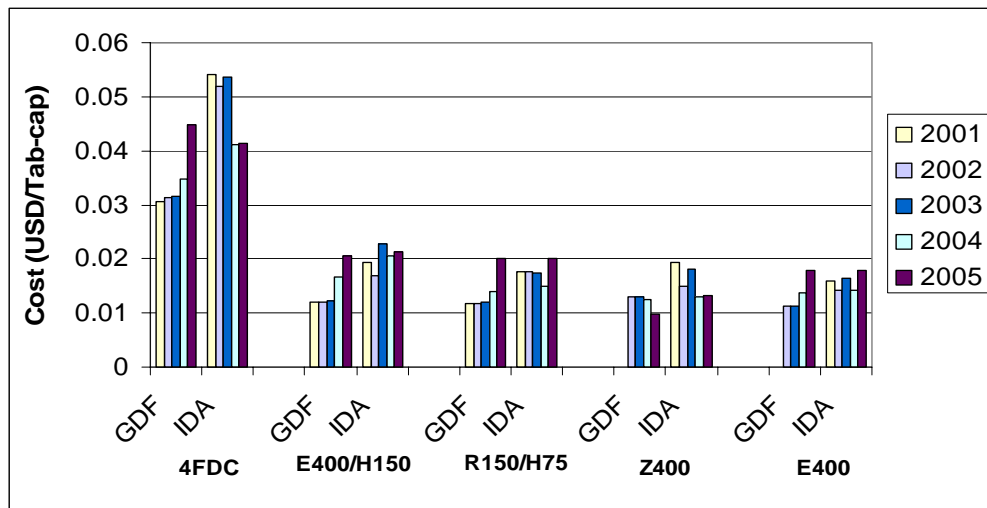
International Prices and Trends

The table and bar graph below display how GDF prices (for a sub-set of commonly supplied GDF anti TB drugs) compare to those of the International Dispensary Association (IDA), which is currently the most appropriate comparator agency based on range of products supplied and market position.

Table 2: GDF product prices compared to those of IDA (price per tablet in US\$)

Product	Source/Year	2001	2002	2003	2004	2005	% Difference
R150/H75	GDF	0.0118	0.0118	0.0119	0.0139	0.02006	GDF 1% lower
	IDA	0.0176	0.0176	0.0175	0.015	0.02009	
E400/H150	GDF	0.012	0.0121	0.0122	0.0166	0.02056	GDF 3% lower
	IDA	0.0194	0.0169	0.0227	0.0206	0.02119	
4FDC	GDF	0.0305	0.0314	0.0316	0.0347	0.04488	IDA 8% lower
	IDA	0.0541	0.052	0.0537	0.0412	0.04147	
Z400	GDF		0.013	0.0131	0.0125	0.00975	GDF 36% lower
	IDA	0.0194	0.015	0.0181	0.0129	0.0133	
E400	GDF		0.0112	0.0113	0.0137	0.01783	GDF 6% lower
	IDA	0.0159	0.0142	0.0164	0.0141	0.01795	

Bar Graph: International anti TB drug price trends 2001 - 2005 (select products)



Notes:

Tab = tablet; Cap = capsule

Sources of prices: for years 2001-2003, MSH Drug Price Indicator Guide (<http://erc.msh.org>); for year 2004: GDF Catalogue 2004 and IDA Catalogue, Dec. 2004; for year 2005: GDF Catalogue 2004 and IDA Catalogue, Jan. 2004

4FDC = Four fixed-dose combination tablets (rifampicin 150 mg; isoniazid 75 mg; pyrazinamide 400 mg; ethambutol 275 mg)

R: rifampicin; H: isoniazid; E: Ethambutol

IDA price not next closest for E400/H150 in 2003. Price of Missionpharma A/S

(<http://www.missionpharma.com>) was the next closest for E400/H150 in 2003.

Additional information on GDF and IDA products and prices:

- GDF's prices reflect guaranteed prices for 1 year, thus there is an associated risk factor from the suppliers built into GDF's prices.
- GDF's FDCs (plus E400) are film coated. Film coating is a manufacturing process that adds to GDF costs but is required by GDF as it enhances the integrity and durability of FDC tablets and (plus E400).
- GDF's prices do not include the cost of independent quality control and preshipment inspection.
- IDA's prices are valid per quarter.
- IDA's FDCs (plus E400) are not film-coated.
- IDA's prices include the cost of quality control.





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The GDF welcomes the fall in prices from 2004 levels of two of its catalogue products (Pyrazinamide and Isoniazid) and is confident that the price increases for the other products will have, at best, minimal consequences for countries and NTP programs benefiting from GDF services. While a complete 6 month patient treatment using the 4FDC and R150/H75 can no longer be bought for US\$12 to 14, the new price range of US\$ 15 to 17 remains very affordable, especially considering that many countries have paid and continue to pay through other procurement arrangements, US\$ 50 or more for the same course of treatment.

Moreover, it should be remembered that the main goal of the GDF is not rock-bottom prices, but rather, ensuring access to *high quality* drugs at *affordable, sustainable prices*.

Conclusion

The past 6 months have been a challenging period for GDF, but GDF has demonstrated that it responds best when challenged. The outcomes of the GDF tender will allow continued access to low cost, high quality drugs for all GDF clients and reflect how GDF's proactive stance enables it to respond quickly and efficiently to market dynamics. In the months ahead the GDF will focus on implementing the outcomes of this tender so as to realize its full benefit. It will do this within the broader context of its supply mandate of ensuring that affordable, quality TB drugs are bundled with the technical assistance and drug management support of Stop TB partners that are so critical to their effective use.

For a full list of the anti TB drugs supplied by GDF and their prices please refer to the GDF website at:

http://www.stoptb.org/gdf/drugsupply/drugs_available.asp

For further information on the GDF and regular updates on GDF performance indicators, service developments, news stories and more, please visit the GDF website at: www.stoptb.org/gdf.

