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**Social Enterprise as Market Regulation: non-governmental
interventions in essential medicines wholesaling to low income
countries**

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Abstract

The private market for medicines, considered as a supply chain from manufacturers to end users, is notoriously subject to market failure; in rich countries it is therefore subject to stringent regulation. Yet the empirically based policy literature on access to essential medicines remains limited on how these market problems can be overcome in the supply of medicines from developing country manufacturers to the dangerously unregulated retail medicines markets suffered by the very poor across the world. This paper explores the under-studied role of social enterprise as traders and regulatory actors in the international wholesale markets for essential medicines and their impact on accessibility, quality and prices in these perverse markets, drawing on an interview survey of European-based socially oriented wholesalers supplying the medicines market for sub-Saharan Africa. The paper argues that these enterprises play an important role in regulating price and quality and hence in improving access to medicines by the poor. However they face challenging market and political conditions. The paper analyses the motivations and organisational structures that sustain social and ethical commitment in this market, drawing on theories of social enterprise and non-profit business, and surveys the challenges and constraints. It then examines the formal international and national regulatory interventions in the international markets and their effects on social enterprise, in the context of a substantial institutional divide between the medicines-related campaigning of the large international NGOs and the activities of these market-oriented social enterprises.

Keywords: social enterprise, essential medicines, markets, regulation, competition, quality, price

Introduction

'A dangerous market' (pharmacist with an international NGO)

'At every step of the supply chain there is this unequal knowledge, and people are exploited because of that lack of knowledge.' (international organisation official)

The market for medicines, considered as a supply chain from manufacturer to end user, is dangerously subject to market failure. Individual users' welfare is bedevilled by asymmetric information: users cannot effectively evaluate their own medical needs nor judge the quality of the medicines received. This lack of information generates perverse incentives for suppliers to reduce quality and to counterfeit; to sell unnecessary or inappropriate medicines to vulnerable

buyers; and to use branding to segment the market and support monopoly pricing for those able to pay (Barr 1998; Mossialos and Mrazek 2002; WHO 2004a). As a result rich countries generally employ tight regulation of both access and supply, including strong licensing and inspection of pharmacies and manufacturers, and abolition of fragmented private medicines markets between wholesalers and users in favour of prescription-only access for many drugs, negotiated price controls, and highly concentrated third party payment or reimbursement for prescribed medicinesⁱ.

In the small scale retail markets for health services and medicines that dominate the health care experience of low income people across much of South and South East Asia and sub-Saharan Africa, no such comprehensive regulatory safeguards operate. Retail fragmentation has been actively promoted in many countries since the 1980s, and government licensing and control capacities are generally weak, as are professional associations (Mujinja et al 2003; Mackintosh and Tibandebage 2002; Turshen 1999). Medicines, like other aspects of health care, are largely purchased privately and out of pocket (WHO 2004b; Mackintosh 2007). Where government regulators are energetic and efficient they can make a substantial difference to the quality of legally imported medicines circulating in the private marketⁱⁱ. However, for very large numbers of poor people in low income countries, including India, dependence on retail purchase of medicines from unregulated outlets results in poor quality medicines and advice, misuse of sometimes dangerous medicines, incomplete treatments and exclusion from treatment because of inability to pay, and severe consequences in the form of ill health, mortality and drug-resistant disease (Chaudhuri 2007; WHO 2004a, 2004b).

There is therefore widespread debate about how quality, accessibility and appropriate use of essential medicines can be improved in low income countries (WHO 2004b; Laing et al 2001). This paper argues that effective market regulation requires an appropriate combination of formal rule setting and inspection, and active market intervention, and that social enterprise at the wholesale level can and does play an important role in this process in relation to low income, hard-to-regulate markets. However, in current markets for essential medicines, the role of social enterprise is changing, as market structure shifts in response to national and international policies. The paper argues that policy towards market intervention in essential medicines should identify the regulatory role of social enterprises; should support an appropriate mix of regulatory actors; and in order to do so, should pay close attention to the impact of policy, including funding policies, on market structure and behaviour.

Regulation and the role of social enterprise

Successful market regulation operates in practice through a mixture of types of intervention (Baldwin et al 1998; Ayres and Braithwaite 1992). One type is formal rule setting, in the form of registration, licensing, inspection of facilities and firms, and proscription of certain activities such as advertisement and sale of listed medicines without prescription. A second type of complementary intervention is relational and interactive, including reinforcement of incentives

for probity, such as preferential purchase of large volumes from suppliers meeting quality hurdles, publicised delisting of suppliers whose quality is found to slip, and active working with suppliers to meet agreed standards. A third type can be characterised as 'beneficial competition' (Mackintosh and Tibandebage 2002): competitive market behaviour by efficient market suppliers and intermediaries whose probity is trustworthy – which may be public or non-governmental businesses - that creates in turn known market benchmarks for quality at accessible prices, and hence influences the behaviour of competitorsⁱⁱⁱ.

This broad characterisation of 'regulation', drawn from the socio-legal literature of interactive intervention by market actors for public purposes, includes self-regulation and the concept of 'regulatory webs' of actors and discourse (Braithwaite and Drahos 2000: 550ff). It provides a framework of analysis appropriate to the investigation of regulatory activity in perverse, partly informalised and low income markets for medicines, since its concept of diverse regulatory actors, and emphasis on the interaction between market incentives and the behaviour of these regulatory actors, encompasses questions such as, what keeps regulatory actors honest in perverse markets? How can probity and social purpose be sustained by enterprises when markets incentivise cheating? How do formal regulatory institutions interact with market behaviour of manufacturers and market intermediaries?

Markets for essential medicines in most of low income Africa are supplied predominantly by imports, although local production is increasing in importance in a number of countries. In India, a large Indian pharmaceutical industry, that is not well regulated, supplies medicines to the local market and for export (Chaudhuri 2005). Since the 1970s, social enterprises have played a role in improving quality assurance and reducing prices of imported medicines in both Africa and India. In India non-governmental organisations are involved in improving supply to government facilities, and providing reliable medicines for purchase^{iv}. In the supply chain of medicines imports to Africa, international trading organisations with a social mission have played a substantial role in providing low cost reliable medicines. And within East Africa, as elsewhere in low income Africa, faith-based, secular non-governmental and government wholesalers supply government and non-governmental non-profit facilities with medicines, achieving varying levels of cost, quality and reliability (WHO/EPN 2005).

The concept of social enterprise in this paper is an inclusive one, drawing on the United States-based literature on the behaviour of non-profit firms (Powell 1987; Anheier and Ben-Ner 2003), the European 'third sector' literature that includes co-operatives and associations (Kerlin 2006; Borzaga and Defourny 2001). The definition reflects attempts in the expanding literature on social enterprise and social entrepreneurship (Peredo and McLean 2006) to bridge this analytical divide: the paper employs Defourny's (2001:2) broad definition of social enterprises as organisations reflecting an 'entrepreneurial spirit focused on social aims', or more simply, as firms with social aims operating in markets. Only some of our surveyed social enterprises meet the US literature's criterion for non-profit status, that is, non-distribution of surplus to private

owners. Some are privately owned, some intergovernmental; government-owned autonomous trading enterprises can be included in our definition.

The paper explores four aspects of the social enterprises' regulatory role in the wholesale markets for essential medicines for low income users. These are, first, their role as trustworthy intermediaries in a market characterised by known perverse incentives to cheat. Second, social enterprise plays a market-making role in a direct sense, by bridging gaps in the supply chain. Third, the paper defines and analyses the informal regulatory role of social enterprise – market-making in a different sense – notably by creating known benchmarks for prices and quality that influence the behaviour of more commercially focused players. Fourth, social enterprise plays a more formal regulatory role, contributing the webs of shared information on manufacturing standards that substitutes in part for reliable government licensing in some parts of the world. Finally, the paper raises questions about current market restructuring, driven by the entry of very large new funding bodies from 2004, and discusses potential costs as well as benefits for low income uses of medicines.

The paper concludes by reviewing the concept of regulatory action that emerges from this analysis in the context of the existing literature on social enterprise and non-governmental public action, and suggests links to a relatively unexplored perspective on 'fair trade'. The fair trade and social enterprise literatures virtually omit pharmaceuticals^v, and fair trade practitioners focus on developing country production for rich country consumers (Paul 2005). Yet the issue of fair trading of key commodities *into* low income markets arises persistently, as in the NGO campaigning on prices of anti-retrovirals and the problem of prices and intellectual property rights for medicines under patent^{vi}. This article suggests a broader canvas for the notion of pharmaceutical fair trade^{vii}.

Research methods

The findings are based on semi-structured interviewing of the main non-governmental intermediaries in the wholesale markets for essential medicines for sub-Saharan Africa. The interviewees' organisations were located through web searches and initial interviews with key informants in Europe with long experience in these markets. The list was then snowballed by asking each organisation interviewed about their main competitors. We also interviewed key international funding bodies and UN organisations named by the main trading players as important market influences. The snowballing confirms that the interviews include most of the socially oriented trading organisations operating at some scale in this market^{viii}.

Table 1 categorises the European-based organisations interviewed. In several organisations there were multiple interviewees. The organisations include for-profit enterprises with explicit social goals as well as those constituted as non-profit enterprises and non-profit trading arms of charities and inter-governmental bodies. The two largest among the independent wholesalers had turnover of around \$100mn per year; one UN purchaser was larger, one smaller. The other firms were smaller, as was one charity; the other charity would not provide their purchasing

volume. Of the UN bodies and charities, all but one procured medicines for their own projects and also for others in the non-profit and government sectors in developing countries; none sold into high income countries. Interviews in Europe were conducted during late 2005 and 2006, and recorded and transcribed.

Table 1 Organisations interviewed by category: all European/international

Type of organisation	Number of organisations interviewed
Non-profit wholesaler	2
For-profit wholesaler	3
Charity purchasing and distributing medicines	2
UN body purchasing and distributing medicines	2
UN body with a regulatory role	1
Other international body purchasing or funding medicines	1
Other international NGO distributing medicines or campaigning	2

Trust and social enterprise in dangerous medicines markets : assuring quality

Over the years I've seen a lot of funny things happening – also from reputable companies. (Non-profit company procurement expert) ^{ix}

Medicines markets can be, and often are, dangerous. Medicines are hard for users to assess in terms of quality: individual users cannot be sure that they are being supplied with medicines that are appropriate to their needs, and that the item supplied is indeed what it says on the label. Skilled intermediaries are required to prescribe needed medicines and to certify the reliability of the medicines supplied. Furthermore, potential intermediaries who might play this role have some evident reasons to cheat. Manufacturers gain by keeping costs down – an incentive to reduce quality – as do commercial wholesalers. Clinicians who also sell medicines are in a particularly complicated position: they have an incentive to over-supply and over-charge, but on the other hand they are also not in a position to be certain about the quality of a batch of medicines they supply.

There is therefore an acute need for supply systems that can guarantee reliable medicines quality, for users and for reputable clinicians and retailers. In principle this information can be made available – medicine batches can be traced and tested for quality. But quality assurance and quality control are expensive and complex, and, in a cumulative regress, they require the quality assessors to be themselves trustworthy.

This situation creates a niche that social enterprise can potentially fill. The economic literature on non-profit enterprises argues that the non-profit form reduces firms' market incentives to cheat by suppressing the profit-seeking motive (Hansmann 1987). In health services^x the US literature examines the extent to which non-profits in the hospital sector provide higher quality services than commercial firms (better outcomes, full range of services, more prevention) and provide more charitable (unpaid) care (Irvin 2000; Rosenau and Linder 2003). Similarly, the literature on faith-based health facilities care in Africa argues that they may (and sometimes do) provide better quality care than both government and commercial sectors because of a religious values-driven commitment to patients (Tibandebage and Mackintosh 2005; Gilson 2003; Leonard 2000).

When they came back [from mission work in Africa] the owner and his wife started the business in their garage. It was a charity, a pure charity. [commercial firm manager describing the business' origins]

Social enterprises can play this role of trustworthy supplier in developing country medicines markets if they can sustain a deserved reputation for probity. In the international supply chain of medicines to Africa, the largest independent nongovernmental non-profit wholesaler – the International Dispensary Association (IDA), based in Amsterdam – pioneered this role in 1972. It was established with the involvement of student campaigners at a time when the concept of essential medicines lists was also coming to the fore, and became the most successful of several non-profit initiatives of the time. Others established in that era included Christian missionary-linked charities supplying medicines to mission facilities in Africa. Some have survived. One charitable supplier was later taken over by a commercial firm^{xi}. The origins of the cultural values of these organisations are thus a mix of political engagement and religious missionary-linked commitment.

Our mission is to improve access, and to deliver high quality essential medicines and medical supplies at lowest possible price to only these [developing] countries (non-profit firm manager)

A key value-added of these firms, that gives them their market niche, was, and remains, quality assurance of essential medicines. IDA supplies mainly branded generics: that is, they buy and quality-assure medicines, now 80% sourced in India, packaged by manufacturers with IDA labels, and supply only to low and middle income country government or non-profit buyers:

Our logistics buyer..... told me.... if the doctors would see that they are getting IDA products, they would be happy ... for them it's really trust and guarantee of quality [IDA manager]

IDA quality assurance and quality control include approving manufacturing sites for each product, and testing all batches in-house^{xii}. Only one other (commercial) firm branded some of their bought-in generic medicines and also tested batches en route to Europe. Other competitors said in interview that the IDA quality control was the most extensive among

international wholesalers in this market, though not all competitors thought batch testing was the best route to ensuring quality.

We are fairly young, dynamic people really committed to doing a good job, a professional piece of work, and having fun at the same time [private firm]

By the early 1980s commercial competitors had joined this market. All those interviewed are family-dominated or entrepreneurial businesses, which either concentrate wholly on the medicines market for developing countries, or maintain a separate division – with its own culture and management – to pursue that trade. All claimed a social mission that resembled that of the non-profit traders. Two had their origins in the non-profit sector : in one case a commercial firm had bought the charitable business and kept a nucleus of committed staff, segregating the activity physically away from the ‘*purely commercial*’ culture of the rest of the firm. In another, a founder of a non-profit business had moved on to start a competing business on a commercial basis. A third had taken out the African business from a commercial wholesaler, and decided to establish it independently, but as a family business:

He ended up doing it as a private company because that was easier than to make it a foundation^{xiii}

The nature of company culture was thus a common response to the question of how these organisations seek to sustain a practice of delivering high quality in this market. Each firm, or separate division, focused only on supplying low and middle income countries, and largely or entirely on supplying non-profit and government buyers, both international and national. One commercial wholesaler expresses its key objective as ‘*expanding the availability of generic pharmaceuticals worldwide*’. All emphasised that this is a large market, but with rather few major players, so reputation is key to repeat business and problems are hard to hide. One commercial firm saw their youthful multinational workforce as key to a culture of commitment to good quality. Another said the focus on developing country and non-profit markets was key. The commercial firms did sell to private buyers as well as non-profit, charitable and government buyers, but it was a small part of the business of those interviewed; the non-profit wholesalers sold only to the non-governmental non-profit, charitable and government buyers.

A key challenge for all the wholesaling firms over the last decade has been to rethink their purchasing, supply and quality assurance roles in the light of the emerging dominance of Indian manufacturers in the essential medicines market. In the early 1990s, a major niche for European-based intermediaries was quality control of Indian-sourced medicines. IDA when interviewed continued to test all their Indian-purchased medicines in Europe, as they had done for many years:

We buy a lot of products in India, we bring them down here and then we have here pharmacists who check the quality and control..... We do it all in Holland. (IDA manager)

Most other firms did not do this level of quality testing, regarding it as both financially unviable, and also as unnecessary. As a commercial company interviewee put it:

We do not re-analyse all batches, because then we would certainly be non-profit!

The firms interviewed undertook a mix of five quality assurance strategies:

- inspecting and re-inspecting suppliers' manufacturing plants and processes in India or elsewhere outside Europe;
- reliance on WHO 'pre-qualification'^{xiv} of specific products from specific manufacturing sites (based on inspections);
- immensely detailed attention to paperwork for batches purchased, including tracking back documentation of the source of active ingredients;
- procurement of European-registered medicines, including those Indian-sourced;
- and moving upstream into manufacturing themselves in India.

Of the five independent wholesalers interviewed, two non-profits and one commercial firm did their own repeated inspections of manufacturing sites: one used only suppliers they had approved themselves, while two accepted some forms of WHO prequalification but otherwise undertook their own inspections. One of the UN purchasing bodies interviewed also did inspections itself or contracted for them, as did one of the international charities interviewed. The other UN body, the other international charity and one commercial firm did no inspections, either buying only from European sources, accepting only 'pre-qualified' sources, or using a 'procurement agent'^{xv} who would do the technical quality assurance. A commercial firm explained that Indian manufacturers were now buying European generic manufacturing firms, to gain UK product licences also for their own Indian-sourced products and thus reducing the relative prices of UK-licensed products. The role of pre-qualification is discussed further below, as is the move into manufacturing.

Firms differed on whether their competitors' quality strategies truly assured safety, and there were mutual accusations of cutting corners in the competitive market conditions discussed further below. Enterprises with a social mission are subject to the same market pressures as others, especially when the market requires rapid response to change.

Market making in difficult contexts: logistics and supply chain management

The five independent wholesalers interviewed found their market niche by linking their quality assurance role as social enterprises to the conventional wholesaling roles of assemblage and logistics. This can be understood as a market-making function within their 'social' segment of the essential medicines market: the supply of the medicines sold or distributed by government and non-governmental non-profit dispensaries, pharmacies and facilities in low and middle income countries. Their presence as trusted intermediaries is essential in creating rapid and

reliable supply chains, alongside the direct procurement activities of the big charities and United Nations bodies.

The wholesalers' main customers fall into three categories. First, governments, in the shape of government buying agencies or semi-autonomous or autonomous Central Medical Stores. Second, international emergency relief agencies such as the International Red Cross Red Crescent (ICRC) and UN bodies including UNICEF which buy from the wholesalers to supply their own projects and activities; the UN bodies also buy directly from manufacturers to supply their projects and others'. And third, non-governmental organisations, including church-supported buying agencies and charities, which buy and resell to faith based and secular NGO facilities and dispensers – and indeed on occasions to government facilities.

This is a market characterised by patchy market information, and uneven buying and handling capability among governments, in a context riven by many conflict and emergency situations. The wholesalers can assemble complete parcels or kits of a list of required items, rapidly and at high volume, generally from a number of different manufacturers, and ensure delivery. The main firms stock large warehouses with a range of essential items – for example, IDA can supply 750 items from stock – and hence can respond rapidly to emergency procurement needs. This ties up substantial working capital: one interviewee gave a minimum of US\$5 million needed to stock a warehouse to the size required be an effective player in this market.

All the wholesaling firms also purchase to order, to supply for example, countries' Central Medical Stores and faith-based pooled-purchasing organisations. These activities may depend upon winning tenders, which are often aid funded and may be highly price sensitive. Another form of purchasing to order is to act as a procurement agent for a large buyer: for example, the Global TB Facility appoints a single procurement agent for its TB drugs. A third is repeat-supply to a large international buyer such as the International Red Cross Red Crescent (ICRC). For example, one firm's current work was divided roughly 60% sales to government purchasers, 20% NGO buyers including small and large mission customers in Africa and big international NGOs; 15% United Nations; 5% other. The balance varies among firms and over time.

This market changes rapidly, and firms are having to adapt quickly to find new market-making niches. The big pressures are: the rise of Indian manufacturers to a dominance of perhaps 80% by volume of the essential medicines export trade to Africa^{xvi}; the entry of large new funding bodies (notably the Global Fund for HIV/AIDS, TB and Malaria (henceforth the 'Global Fund') and PEPFAR^{xvii}); and associated pressure to undertake more tasks in the supply chain to customers.

Price competition and the move to India

It has become decreasingly viable for these firms to base their wholesaling in Europe, given that much of the essential medicines trade is between India and other low and middle income countries, notably across the Indian Ocean to Africa. The linking of quality assurance to logistics – and the past history of supply from Europe – had combined as described to create a market

structure in which European wholesaling played a key role. However since the mid- to late-1990s, Indian manufacturers have increasingly succeeded in supplying directly to large buyers such as government Central Medical Stores, by passing European wholesalers. This has generated intense price competition for large tenders, as Indian manufacturers' competition has squeezed wholesalers' margins.

The big European-based wholesalers were therefore, when interviewed, in the process of moving much of their warehousing and logistics from Europe to India in an effort to cut their costs. The move is also driven by increasing stringency of regulations concerning import of medicines into the EU. The move has been difficult, and at least one firm was losing money during the process. We were surprised however to find that the problems do not arise from competition by Indian *wholesalers*. None of our interviewees could identify an Indian wholesaling competitor in this niche market, one commenting that this was odd, given the Indian entrepreneurial flair. No Indian wholesaling firm appears to have yet established itself as a trustworthy intermediary to undertake the QA/QC-logistics combination of services that the big purchasers require. The European companies moving to India found problems however in dealing with the complexity of legal and tax issues concerning the rules for foreign companies operating in Free Economic Zones in India.

The lack of Indian wholesaler competition did not lessen pressure on the European firms to reduce costs. Once one firm drives down wholesale costs by moving out of Europe, the others are forced to follow or face rising losses as they lose tenders to competitors. All the main independent firms were struggling with the challenge of sustaining quality control – and reputation for quality – while drastically lowering costs.

In this line of business you cannot have heavy overheads in Europe. ...It [moving the 'logistics platform' to India] is a major, major challenge. (commercial firm)

Only a UN agency or a major international charity buying for their own projects, with rather more protection from intense price competition, seemed likely to retain substantial European warehousing.

Interviewees explained why and to what extent manufacturers' direct sales to big purchasers compete effectively with wholesalers. Where purchasers are large, efficient and well informed, and where they develop over time relationships with suppliers perceived as reliable, those direct buying relations may take over, whether through tendering or through repeat orders from a suppliers' list. One wholesaler commented on the learning process by the large buyers:

What we were mainly doing is telling these guys where it [the product] is coming from, so we are educating our customers

The manufacturers also benefit from wholesaler investment. For example, the wholesaler may do the work of registering a manufacturer's product in an African market:

And then you know, when everything is registered, which takes a long time ... costs you a lot of money ... then they start selling directly.

Or the manufacturer allows the wholesaler to establish the company's reputation:

Because we put the quality on [that is, assure quality] we have, of course, a higher price. And then what they do, we make the market and then they come in and take over.

However, a manufacturer may find the selling process to Africa countries to be more complex than they want to handle:

We have examples where some of our manufacturers say, OK, now we go directly [to Central Medical Stores] ... then after one year they come back and say, "OK, can we work with you again?" ... It's the hassle.

If we want to survive then we have to get away from the open direct competition with manufacturers (commercial firm)

One strategy for diversifying was into manufacturing, through joint ventures with Indian firms. Two commercial firms were taking this route, to reduce their dependence on other manufacturers, to learn about manufacturing, and to increase flexibility in supplying customers. But the main implication of manufacturers' competition is that independent wholesalers can add the most value – hence find their main markets – where buyers require the assembling of large lots of different medicines, whether emergency supplies, kits for primary health facilities, or large complex tenders by Central Medical Stores. A CMS might find they would need to buy from 100 manufacturers; to avoid that they may 'bundle' the order into lots, which manufacturers with limited product lines will find expensive to supply, and the tender will be won by a wholesaler.

Crisis situations, new funding streams and supply chain management

..where we get involved, is where others – mmm - are not very keen. (UN agency procurement arm)

Many of the organisations interviewed can also do many aspects of supply chain management for the delivery of medicines right down to the facility within recipient countries. The UN agencies, like the big NGOs, may particularly be involved where governmental procurement and delivery capacity has broken down. Thus the UNDP plays a major role in procurement and supply chain management in situations such as the Democratic Republic of Congo. IAPSO, the UNDP procurement agency, can take over procurement temporarily where local procurement capacity is found to be weak. The UNDP is the 'recipient of last resort' under the Global Fund:

It means when there's no-one else capable of doing it, UNDP gets the job!

Increasingly the independent wholesalers are strengthening their ability to undertake these supply chain strengthening functions within recipient countries, seeing a market opportunity.

We are very good in the post-war countries or in the countries where there is ... disorganisation. When the country is getting more mature, then we are losing market share.

One non-profit trader had established a separate organisation from its wholesaler to undertake such supply chain management and consultancy activities. One of the commercial firms was involved in a complex project that included support for local manufacturing firms in a conflict-ridden country, including raw materials supply to manufacturers and local assemblage and delivery of local and imported supplies. One non-profit firm that acts only as a procurement agent – not as a stock-holding wholesaler – has a long history of also supporting procurement capacity development, including training.

Another reason for increasing emphasis on supply chain management is the entry into the market from 2004 onwards of major new funders, including the Global Fund and PEPFAR. In pharmaceuticals, both have a strong focus on supply of a narrow range of items to the user, and both create employment for agents to procure on their behalf or on behalf of the country recipients of their funds. Both focus on HIV/AIDS, and the Global Fund also on TB and Malaria; together they have generated a huge increase in the funds flowing through the market, with major reorganising effects, forcing the existing firms and agencies to rethink their roles. PEPFAR has also brought into the market new players, within its Supply Chain Management System (SCMS), some based in the USA, which are seen by some existing firms as major new competition. The UNDP set up IAPSO, its procurement arm, in 2004, to support UNDP offices' capacity in pharmaceuticals procurement using Global Fund resources, including help to put supply chain management processes in place within countries.

One major organisational impact has been on the independent activity of the established wholesalers. They have had, as one commercial firm explained, to choose between a shift to competing for a major role as procurement agents for the big funds, or being sidelined into a much more minor market role. They compete for large contracts that can sharply increase the scale of their activity year on year if won, and as procurement agents they are constrained to operate within restrictive rules for Global Fund or PEPFAR procurement, discussed further below. A non-profit wholesaler distinguished three types of business, the 'core' business of supplying orders, including for example repeat orders for international organisations dealing with continuing emergencies or post-conflict situations; supply as a result of winning tenders, which is a large but unstable element of activity; and acting as procurement agent for a large funder. The last activity is an expanding market segment, with a few organisations competing hard for big contracts.

Informal regulatory roles: benchmarking prices and quality

The concept of 'informal regulation' can be thought of as a discursively produced informal governance structure for a market. Informal regulatory norms can be thought of, not so much as firms' behavioural regularities, but rather as something akin to a 'script' rooted in past

experience of expectations fulfilled and in a shared discourse concerning market behaviour^{xviii}. In the pharmaceutical markets, corporate culture has been more influential than state rule-making in shaping risk and outcomes (Braithwaite and Drahos 2000:383). I consider here just one aspect of social enterprise wholesalers' informal regulatory impact on the market for essential medicines: their role as benchmark and 'beneficial competitor'.

The concept is examined with reference to the social benchmark firm in this market: the International Dispensary Association (IDA). In every interview with competitors, buyers and with most international organisations, the firm was mentioned unprompted, and several aspects of strategy were explained with reference to IDA. Thus an organisation supplying donated drugs began to explain their niche by saying: '*we are not sort of, we are not an IDA*' meaning not a non-profit wholesaler nor very large within the market.

All the firms were asked what difference commercial or non-profit status made in this market. The commercial firms each defined themselves in relation to IDA. On product range:

we tend to be quite flexible in the range of articles we supply, which is not similar to what IDA does in maintaining a fixed list of essential drugs which they claim to be very good value, in some cases they are [commercial firm]

On prices:

The thing is our prices are, compared to other organisations like IDA ...relatively high.
[Charity buying and supplying medicines to the FBO sector in Africa]

The commercial players interviewed had all been spun off from, or had originally worked closely with, the non-profit and charitable organisations. Two saw the relation with IDA as shaping their mission and strategy:

we share a lot of history you know in the beginning back from 75 to 78 we, you know, there was a very close co-operation between IDA and [ourselves] [commercial firm]

- while later, the relationship became more competitive. Two private companies had cooperated for a while in buying, in order to get the volumes that would allow them to compete:

because the big, big company in the business was IDA [commercial firm]

One commercial firm argued – slightly tongue-in-cheek – that as far as:

the commercial aggressive approach is concerned I would say eh, for many years IDA has been by the most aggressive player in the business.

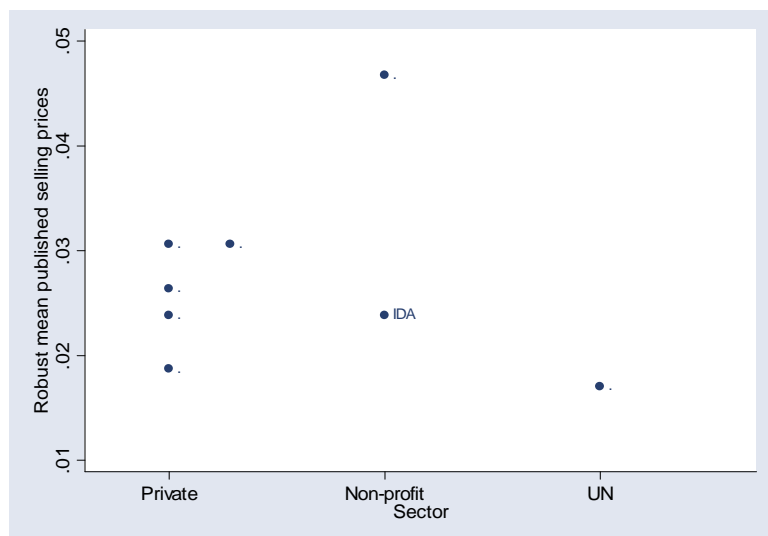
A charitable trading company manager argued from the other side of the fence that their own role in the market, as well as that of IDA, had influenced the behaviour of the commercial firms, notably on quality:

our wholesalers are used to our high quality expectations, so I think in a way we triggered the market, although we are the minor playerAnd the same goes for IDA.

A manager of a commercial firm spun off from a charity wondered whether IDA was truly a 'charity' or not.

This extensive commentary represents, not considered judgements on IDA so much as eloquent evidence of its key role in the market, as the dominant example of the weight of a social trader in influencing the strategy of others. IDA has long published its price lists, and these prices were acting as benchmarks before the publishing of the WHO/HAI price research (discussed further below). Both commercial and non-profit actors thought the biggest non-profit actor had acted as a benchmark in both price and quality terms. Published international price reference data (MSH/WHO 2006) supports this idea of IDA as a benchmark firm. The data show that, for twelve of our tracer medicines^{xix} for which all of the participating firms provided prices, IDA was at the lower end but not the lowest; the commercial sector had a substantial price spread, mainly more expensive than IDA; the UN agency (UNFPA) participating was the cheapest; and one other non-profit firm, which buys only European medicines, was consistently the most expensive (illustrating the competitive pressure to move to Indian suppliers) (Figure 1)

Figure 1: Dotplot: international reference prices of twelve tracer medicines, robust mean price by firm and sector, 2006.



Source MSH/WHO (2006)

The commercial firms and IDA's non-profit competitors all argued that they brought particular skills and value added to the market, and there were, as illustrated, criticisms of IDA. But IDA appears to have acted as a market maker – the first big independent player – and as a benchmark firm and beneficial competitor in the market, helping to keep down prices and put a floor under quality by providing a 'fall back' with known prices and reliable quality. This benchmark role – of which the IDA has been the leading, not the only example – has influenced both the expectations of buyers and the culture of other firms in this market.

Formal standards and market information: regulatory impact in a relational market

International standard setting and market information

Market regulation is a politically contested concept. The international discourse on regulation of essential drugs makes a strong distinction between formal standard setting and intervention in the market. A UN agency procurement expert explained:

We are not a technical agency. WHO is a technical agency, they set norms and standards. We follow the WHO norms and standards in the medicines area

This role derives from the WHO's international responsibilities for medicines quality:

WHO is the unique agency that deals with quality of medicines.....[this] is a WHO mandate from 48 onwards. (WHO interviewee^{xx})

Since 2000, there has been some substantial reworking of the interaction between the social enterprises in this market, the WHO and the other UN agencies, and the big funding bodies, notably the Global Fund and PEPFAR.

The WHO's market influence is rooted in its championing of the essential medicines concept:

In 1977 the essential medicines list was first developed. That was a group of experts coming together and persuading WHO that there was such an idea as an essential medicines concept. At the time it was an absolute bombshell and caused tremendous upsets. (WHO interviewee)

The initiative to create an essential medicines list generated a three way debate between WHO, industry and NGOs, most notably at a conference in 1985 that hammered out a compromise:

That the public sector was left to the WHO and the private sector was left to industry, was more or less the outcome (WHO interviewee)

Essential medicines lists, based on the WHO lists, are now used in over 150 countries^{xxi}. Their rationale is to promote effective, appropriate and cost-effective use of medicines, notably in low and middle income countries.

The WHO has worked with NGOs, non-profit organisations and social enterprises in influencing the essential medicines market in a number of ways, including a series of initiatives that have hugely increased published information about wholesale medicines prices. It has worked since 2000 with Management Sciences for Health, a US non-profit organisation, to produce the annual *International Drug Price Indicator Guide*^{xxii}. This report lists procurement prices obtained by a number of developing country procurement organisations, and the selling prices in the price lists of the main wholesalers in this market. Jointly with Health Action International (HAI), an energetic campaigning and networking health NGO based in the Netherlands, WHO has also promoted and published a price survey methodology and a major series of comparative surveys of pricing of essential medicines in a number of developing countries^{xxiii}, and has put the results

on the web. In addition, the WHO reports, on its website, data obtained through the Global Price Reporting Mechanism on manufacturers' prices for HIV/AIDS drugs bought by international funding bodies and procurement agents^{xxiv}. These publicly accessible databases broke new ground in including data by manufacturer, moving from publicising the previous year's benchmark prices in the *Price Indicator Guide*, to more detailed breakdowns of observed prices by medicine and source.

It's a very big market, very transparent' (non-profit firm, commenting on the impact of the Global Fund)

These initiatives have hugely increased the information available on market prices, and have been largely accepted by the industry^{xxv}. The data particularly focus on the medicines for HIV/AIDS, tuberculosis and malaria that are the Global Fund targets, but the price surveys extend to a broader range of essential medicines. The huge rise in funding from the Global Fund and PEPFAR has underpinned this increase in market information, by imposing some requirements for reporting associated with the rise in demand. The price reporting has also shifted from reporting wholesaler prices in the *Indicator Guide* to reporting prices for procurement from the manufacturers' level, reflecting a greater emphasis in the market on large purchases from a few manufacturers, and also reflecting the shift from independent wholesaling to procurement agency activity discussed further below.

The main users of these data are those professionally involved in procurement. The WHO/HAI comparative survey data appear to have been particularly useful to public and mission sector procurement organisations distributing to countries' facilities, who previously lacked information about other countries' procurement prices, and to medicines regulatory authorities seeking to spot over-payment^{xxvi}:

Most of the evidence we have got, what has resulted from these pricing surveys have been policy changes [at country level] (WHO interviewee)

We are not regulating, we are reporting. (WHO interviewee)

WHO interviewees stressed that the WHO is not a regulatory agency; rather it provides information and sets standards. In elaborating the point, one expert defined regulation as price control, and made the point that the WHO is promoting price transparency, not control:

If transparency can lead to choice ... we are promoting an effective market, we are not regulating the market, we are not regulating the prices.' (WHO interviewee)

The accepted definition of 'regulation' in these debates is thus a narrow one. On the broader economic definition of regulation proposed above, publicising market information has regulatory effects, by influencing firms' behaviour, reducing asymmetric information on prices, and reducing opportunities for exploitation of the final consumer.

The other element requiring regulation is quality, and a number of experienced interviewees worried that there had recently been an over-emphasis on price to the detriment of quality

concerns. The second major WHO role in the medicines markets, in 'pre-qualifying' suppliers and laboratories, is designed to address this, particularly in the area of HIV/AIDS, malaria and TB drugs^{xxvii}. The WHO's mission centrally includes the setting of guidelines and standard for medicines production, including Good Manufacturing Practice (GMP) standards in pharmaceuticals. In recent years they have moved to actively assessing manufacturers and creating lists of medicines from particular suppliers and manufacturing sites that are 'pre-qualified' by WHO to supply quality products.

The WHO prequalification scheme .. to help countries to get into the area of anti-retrovirals and other difficult medicines to source, that was the aim. (WHO interviewee)

WHO inspections work with local inspectors and are also 'useful also for developing countries', since they have an impact in training country assessors in GMP and in improving national regulation of firms.

Pre-qualification is not a new idea; indeed 'the accomplished pharmaceutical procurement organisations always use pre-qualification' (WHO interviewee). As described above, the main wholesalers and large buyers inspect manufacturers and create lists of suppliers and sites they regard as qualified for supplying particular products. The WHO pre-qualification effort has formalised and internationalised the pre-qualification process. It publishes lists of pre-qualified firms, and these lists indicate the main acceptable manufacturers' to be used as sources for procurement by those buying from Global Fund money and by some other major purchasers, notably in the UN. This has meant that the WHO has taken an unprecedented role as manager of a list which plays a gatekeeper role in the market; for example it has asked a firm that had provided misinformation to leave the list voluntarily, as an alternative to removal by WHO:

... that was a complete new shift for WHO, not only to preach guidelines ... also to implement them. (WHO interviewee)

This increase in market information on manufacturers' standards has also created an incentive for collaboration among the big market players. Two non-profit firms which did their own GMP audits gave different answers to the question whether they would inspect for themselves a manufacturer that was pre-qualified by WHO for the relevant item. One said

No, we wouldn't bother if it is WHO or EU pre-qualified, we would accept that.,

- and the other:

Ah that's a good question. At the moment we do it also.... And that's a discussion, like if you took WHO, Global Fund and let's say for example [this company]... The three parties are doing it So actually that's a waste of time and money....and we had a discussion recently, we should work together more in that part.

So there are increasing efforts by the main procurement bodies to share this type of manufacturing audit information, and also results of subsequent batch testing. One informal

group sharing information (among others) includes some UN organisations, the International Red Cross Red Crescent (ICRC), and also *Médicins sans Frontières* (MSF)^{xxviii}.

Co-operation and competition in a political and relational market

You have to be clear, the WHO certification schemes ... have a major impact on the market. (UN procurement expert)

The WHO does not buy medicines, and its standard setting and certification systems have hugely improved market information. However these standards are also, as many interviewees explained, a tool through which the big funders and buyers manage their market activities and reduce political risk. And the current approaches have both benefits and costs for the end users.

There are two ways in which the use of the standards can reduce competition. First, they may raise barriers to entry into the market. Some funding agencies and buyers buy only from WHO-prequalified firms except in exceptional circumstances; this is true for example of Global Fund-supported purchases of medicines for its key diseases. African pharmaceutical firms find it very hard to reach WHO pre-qualification standard in their developing capacity to produce ARVs, and none outside South Africa yet have^{xxix}. In contrast, wholesalers putting together, for example, kits for primary care for a particular country using other funding sources funds can and do buy some items from local suppliers they have inspected themselves. They may also combine such purchasing with supporting renovation and upgrading. Similarly, early decisions to use only WHO-prequalified suppliers for some items^{xxx} produced some monopoly profits; as new suppliers are pre-qualified, competition can increase. The Global Fund see the restriction to WHO-prequalified suppliers as wholly beneficial, encouraging African firms to reach appropriate standards with Global Fund technical assistance if needed^{xxxi}, and some UN interviewees agreed. African manufacturers frequently feel the objective is too stringent, out of reach^{xxxii}, and their continued development relies on the willingness of local purchasing bodies to buy from them – a matter subject of course to political influence and debate.

A second restriction on competition may arise if the impact of the new funding sources reduces the competitive behaviour and independence of the main players in what is a quite concentrated and close knit wholesale market. The key players are a small number of firms and organisations run by people some of whom have worked collaboratively and in competition, and some of whom have moved between firms, since the 1970s. The Global Fund and PEPFAR financing has been large. One commercial wholesaler said that in 2004, when the Global Fund came in, his firm initially saw a *drop* in market activity of up to 25%, as country-level procurement contracts were put on hold because buyers were adjusting to new funding sources. A period of shaky firms' finances in the market was then followed by a huge rise in market activity, but in a changing market structure. Existing players have found their roles changing and new competitors emerging. New players included, as noted, the UNDP's procurement service, IAPSO^{xxxiii}, and also new players within the US-led Supply Chain Management System set up to work with PEPFAR.

The new players and funding might have increased competition but the effects were characterised by one director of a commercial firm as '*centralisation*', while an experienced UN procurement manager called it '*corporatism*'. Both were referring to the same market phenomenon: a concentration of buying power that is reducing competition in procurement, and an associated development of close relationships between a small set of market players including buyers, sellers and intermediaries, with some organisations playing multiple roles. The impact of the Global Fund has spread outwards from the original concentration on anti-retrovirals and malaria and TB drugs :

What's happening is that the Global Fund is financing more and more of the products which actually were part of the normal CMS [Central Medical Stores] product range (commercial firm manager)

- since it now finances, if countries request it, medicines for opportunistic infections associated with HIV/AIDS. Increasingly the existing wholesalers have become purchasing agents for the big funds and the UN agencies; the reduced autonomy allows businesses to expand but faces them with greater financial volatility, as big contracts are won and lost.

The Global Fund is emphasising large scale buying, and has recently agreed a policy of pooled purchasing^{xxxiv}. There were repeated anxieties expressed in the interviews that this shift to larger scale procurement would not produce further price benefits, but would further reduce competition^{xxxv}. As an organisation, the Global Fund may not yet have put much thought into its impact on market structure. A Global Fund interviewee^{xxxvi} replied, when asked about this, that since the Fund started work, '*I don't see a different landscape in terms of who is procuring or how*'. Procurement experts in other organisations disagreed however, expressing a number of related anxieties about this market restructuring.

One worry was the market implications of a growing pattern of '*monopsony facing oligopoly*': that is, a very heavy concentration of buying power in a few hands buying from a deliberately restricted pool of sellers. One buyer argued that the big funders operating under the '*political gaze*' have the same problems as big public sector purchasers more generally: they operate on known rules and become predictable. As a result they become open to manipulation by a small collusive pool of sellers: examples of market manipulation by manufacturers were cited. One buyer argued that effective purchasing means retaining flexibility, playing suppliers against one another, and that the formalisation and rule setting was reducing scope for that. The Global Fund interviewees countered that they were simply requiring good procurement standards and pushing up quality in the market as a result.

Another widely expressed worry was the longer term implications of reduced competition on prices. Prices for anti-retrovirals have certainly been driven down by effective purchasing. However reduction in competition could undermine this:

The potential risk with the more centralised approach is that while ...year 1, year 2 you may get a better price but then, you have basically killed a market [UN interviewee]

The view was expressed that there is '*not sufficient awareness of the potential pitfalls of these procurement schemes*' in terms of impact on market structure and the scope they offer for big suppliers to shape the terms of supply.

There were some suggestions that the WHO had provided too much support for market centralisation; two procurement experts each called this aspect of the WHO approach 'naïve':

It brings all the parties including the suppliers to the table, and this is all done in the name of partnership but it also brings the opportunity for players to manipulate, it's the classic corporatist model It opens them up for massive influence To have suppliers sitting down at the same table working out how they are going to go about doing things with a major customer ... would never happen in a national jurisdiction because it would be absolutely forbidden under competition law ...

The speaker agreed that the cooperation this approach elicits also has benefits, but, as the other purchasing expert offering this comment concluded, '*it's not always good to sit around the table*'. Procurement schemes and partnerships are, these interviewees agreed, regulatory structures: methods of influencing the market that need to be analysed as such, with proper attention to sustaining competition and to '*commercial disciplines*'.

In the wider market for essential medicines, there were worries that there had been an over-emphasis on driving down prices of already cheap drugs, such as basic antibiotics sourced in India:

For many of those products we are down to rock bottom prices and there is actually exit from the manufacturers who produce them (UN interviewee)

As a result, buyers were finding the number of reputable suppliers becoming dangerously small, as Indian manufacturers found they could use their production lines more profitably for other items. Large funders may accept bids at unsustainably low prices from players seeking to establish themselves in the market; experienced purchasing agents feel trapped between contradictory pressures that worsen market incentives to cheat:

you can't have wildly diverging things ... someone saying, oh, you've got to get the prices down, and by the way you've got to have this quality standard, the golden standard ... they will try to cut corners

The interviews contain a number of specific stories about tenders accepted on price alone, and producing poor quality as a result, and about UN and government aid bodies 'buying the contract' at unsustainably low prices to establish themselves as a player in this tightly knit market. The number of commercial firms in the market appears to be rising, and there is repeated questioning of the commitment to quality. Such stories reflect the interests of the tellers, but they also pick up well founded anxieties generated by shifting market structures.

Finally, there were worries about sustainability. The system is increasingly oriented around the purchasing of a narrow range of medicines, on the basis of high levels of expenditure that has no guarantee of sustainability, despite the chronic and recurrent nature of the main diseases being treated, especially HIV where continuity is essential.

The international market for essential medicines for developing countries is thus a curious mixture of strong competition and corporate collusiveness. It can be characterised, over the long term, as a *relational* market. That is, working relationships depend strongly on past experience, and repeat contracting with long term suppliers is common. So reputation – of individuals as well as firms – is key to success. The NGOs and international bodies buying for their use were not solely focused on price^{xxxvii}, but paid close attention to delivery capability and experience, and some had formal long term agreements with procurement agents and manufacturers. The market for tenders for large procurement orders is highly competitive and very price sensitive, but at the same time there are also a small number of major players: one experienced buyer called them '*the usual suspects*'. These organisations, which include the major non-profit and socially oriented commercial enterprises, play multiple roles. For example, a large procurement agent may compete with a big wholesaler for a large tender; they may put out a tender on behalf of a government or funding body for which that wholesaler competes with others; they may buy from the wholesaler to make up orders; they may compete for a tender put out by the wholesaler working as a procurement agent also. The buyers know each other, and are tied into each other's plans through long term agreements and established working relationships.

Conclusion: social enterprise and formal regulation in an unstable corporatised market

In this context of complex, cascading and interdependent contractual processes among a relatively few players, further centralisation should be assessed with care. The WHO's standard setting and market information efforts have been influential in encouraging reduced prices and better quality via greatly improved market information. These are market-shaping activities – formal and regulatory on our broader definition of regulation – and key beneficial influences on the market.

What needs thinking through more carefully, it seems from the above analysis, is the pattern of procurement and collaboration that is emerging and is making use of the new information sources. There are widespread expressed worries by market players about the loss of competition and the dangers of collusion, which need to be taken seriously, as do the worries that commitment to quality is slipping under extreme pressure on prices for some basic medicines. A successful regulatory effort in this relational market requires a mixture of good market information and the sustaining of competition. To sustain competition is not only a matter

of pre-qualifying new players; it requires a pattern of contracting – especially by the large funders – that allows a range of competing actors to remain in the market.

This is especially a concern in the longer term. One interviewee from an international organisation was optimistic:

Funding is not the issue any more, there is money as long as you have good proposals ... the issue now is often to support recipients' capacity to procure, manage, store and distribute drugs.

Other interviewees however were much more wary, worried about the funds running out. The centralisation process has viewed the problem as one of *delivery*, a performance focus that has great strengths and can raise efficiency. To this, however, needs adding a concern to sustain a competitive market process, not only for the big funds but also for the broader market for essential medicines.

The market structure furthermore will benefit from sustaining the mix described of competition between commercial and non-profit actors many of whom have the characteristics of social enterprise. One effect of the big funding bodies may have been the entry into the market segment procuring AIDS drugs, ACTs and TB drugs, of more formal commercial actors, and more reliance on formal quality assurance via pre-qualification of manufacturers. This specific and well funded market segment interacts with a broader international market for essential medicines in ways that are not currently being carefully considered, it seems, in the market strategy and policy of the major funders and inter-governmental organisations.

The social enterprises - defined above as firms with a social purpose operating in markets – are an important market safeguard, above all for the less informed buyers and those buying for emergencies. We asked all the firms interviewed what difference non-profit vs. commercial status made to their competitive position. The largely unanimous view was that it made a political difference – since the non-profit firms and charities had a closer relation with governments – but little market difference among the group of '*usual suspects*'. It is not commercial or non-profit status so much as perceived behaviour in this close knit wholesale market that influenced the attitudes of suppliers and customers.

Thus the established commercial firms all said that they were regarded as equal suppliers with non-profit firms by the UN agencies, and did not report any questioning of their ownership status by the big buyers^{xxxviii}. Some said only insiders were aware that some firms were and some were not non-profits. A purchasing manager of a non-profit firm taken over by a commercial company said that at first they had lost their discounts previously provided to a charity by suppliers, but that as their division's exclusive focus on the charitable market, and associated low prices, have become clear to suppliers this has become easier. Again, it is behaviour and market focus that is the defining issue, and this operation has been deliberately isolated from the commercially aggressive behaviour of the rest of the company. In return, the charitable business has '*put [the commercial firm] on the map*' because of the scale of the charitable

business and its visibility and standing. The non-profits accept that many of their main competitors are private for-profit firms, and see themselves as having a greater ethical commitment to quality – a claim strongly disputed by the private firms themselves.

I have argued that the social enterprises – including the socially oriented commercial firms - have historically played a regulatory role in this market in several senses. The early players – and most notably IDA – were closely tied into campaigning groups around the supply of essential medicines in low income markets, and they helped establish the supply of medicines through a key role as ethical traders. Social enterprises in wholesaling have played the role of beneficial market traders by competing as reliable suppliers of quality medicines at affordable prices, and the competitive process as Indian manufacturers have become key suppliers has seen them moving to Indian suppliers and India-based wholesaling to sustain price competitiveness. In a rapidly shifting market without reliable national regulation in India, they have substituted for formal regulation by accrediting their own suppliers.

Now, formal regulation is increasing in this market, though still not from the key national authority – that of India. Instead, it is coming from two other directions. First some African authorities are successfully increasing their own registration requirements and enforcement procedures^{xxxix}. Second, international agencies are greatly increasing their role in ‘pre-qualification’ of manufacturers. The established supplier relationships which have long supported supplier-buyer working in this market are now being formalised into long term agreements with procurement agents for the big international funding bodies. The benchmark role of IDA now appears to be weakening.

Two policy issues arise from these observed processes. One is to locate the pre-qualification process as an important intervention in raising quality, but one which does not substitute for reliable competitively managed supply chains. Many buyers using these suppliers do not reinspect, while others emphasise the continuing scope for cheating (e.g. substituting medicines from uninspected plants) and the need for constant checking along the supply chain^{xl}. It may be in the interests of manufacturing firms to formalise these processes as much as possible; it is likely to be in buyers’ and users’ interests to have an element of competition and unpredictability in the inspection regime in a complex and dangerous market.

The second policy issue is the consequences for market structure, safety and competition over the longer run of the weakening of the independence of the social enterprises in this market, and their relative lack of linkage to NGO campaigning. The current market structure is semi-monopolised, and is becoming more so, and the independent wholesaling firms are moving more towards the status of agents for big buyers, at least in the most profitable market segment. The move is incomplete, but the centralisation or ‘corporatisation’ is well attested. Is this a desirable situation in the longer term? In a market where formal regulation works, social enterprise as a major market regulator is not needed, or much less so, as in rich country markets where regulation is much stronger. Where it is weaker, the case for retaining

competition involving 'social' firms seems strong. At present, the international policies have little to say on market structure, yet the international institutions, strongly encouraged by some manufacturing forms, are pressing towards a less competitive structure. Policy should address this issue more explicitly.

Finally, we should reflect on these social enterprises in the light of the movements for 'fair trade'. There has been a lot of publicity and campaigning, very effectively, for access to medicines for HIV/AIDS, yet the firms trading in essential medicines have only weak links with campaigning groups, and the big campaigning NGOs have focused rather little on the broader market for essential medicines, a few determined individuals excepted. Ensuring a safe sustainable supply of basic medicines to low income consumers has been left as a problem to poorly funded regulatory authorities in Africa plus the international bodies now playing such a large role; absent are Indian authorities, Indian NGOs (again with some small and dedicated exceptions^{xli}), and in general the big international development NGOs. Is there scope for better alliances to ensure a sustainable process of fair trade over the long haul?

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Endnotes

ⁱ The most important partial exception is the United States, which has strong licensing but lacks unified third party payment and strong price control.

ⁱⁱ Genuine improvements are occurring in Tanzania, for example. Source: continuing research for this project led P. Mujinja.

ⁱⁱⁱ There is a small economics literature on these market 'spillovers' from non-profit competition, for example Grabowski and Hirth (2003).

^{iv} This will be the subject of a further working paper.

^v Source: searches on the words 'fair trade' or 'ethical trading' with medicines, essential medicines, or pharmaceuticals produced no hits. The literature on social enterprise and health is large, but we found no articles on essential medicines. The NGO literature on essential medicines and rational use of drugs is quite extensive, but discusses trading issues largely in the context of prices of on-patent medicines.

^{vi} www.haiweb.org; www.tac.org.za/community/ both accessed 25 02.08

^{vii} Current research by Meri Koivusalo for this project is exploring concepts of North/South common interests in international campaigning around access and rational use of medicines.

^{viii} We received only one refusal to be interviewed, from one of the commercial organisations approached.

^{ix} All quotations are from the interviews.

^x The literature on non-profits in medicines is very thin, though growing; an example is Hale (2007).

^{xi} Source: interview with an essential medicines expert, plus interviews with company managers about firms' histories.

^{xii} Source: interview at IDA, and IDA Annual Reports.

^{xiii} That is, a non-profit enterprise.

^{xiv} 'Pre-qualification' is explained and discussed further below.

^{xv} Procurement agency and long term agreements are also discussed further below.

^{xvi} Rough estimate from interviewees of their buying; Tanzanian research for this project supports this order of magnitude of Indian trans-continental export dominance in pharmaceuticals for Africa.

^{xvii} PEPFAR is the United States' President's Emergency Plan for Aids Relief.

^{xviii} This concept of governance within specific markets in developed in Frydman et al (1996) and in a number of the papers in Deakin and Michie (1997); Mackintosh (1999) and Mackintosh and Tiandebage (2002) apply the informal regulation concept to health services.

^{xix} The study as a whole used a set of 31 essential medicines as 'tracers' rights across the supply chain; they were selected in collaboration with the Tanzania Food and Drug Authority, and included paediatric medicines and a range of adult essential medicines including two combination ARVs.

^{xx} All WHO interviewees are speaking in a personal capacity.

^{xxi} 2003 figure www.who.int/medicines/services/essmedicines_def/en/index.html accessed 15.01.08

^{xxii} See Figure 1 and MSH/WHO (2006) reference.

^{xxiii} <http://www.haiweb.org/medicineprices> accessed 5/1/08

^{xxiv} www.who.int/hiv/amds/gprm/en/index.html accessed 15/01/08

^{xxv} Source: WHO and Global Fund interviewees.

^{xxvi} Source: WHO interviewees.

^{xxvii} <http://www.mednet.who.int/prequal> accessed 5/1/08

^{xxviii} Source: UN agency interview.

^{xxix} Source: interviews with Tanzanian manufacturers, and European interviews.

^{xxx} The most frequently cited item in the interviews was long lasting insecticide-impregnated bed nets.

^{xxxi} Source: Global Fund interviewees

^{xxxii} Source: interview with Tanzanian manufacturing firms, with P. Mujinja.

^{xxxiii} Source: UNDP interview

^{xxxiv} Source: interviews and Global Fund Board papers (The Global Fund 2006, 2007)

^{xxxv} There is emerging evidence that beyond a reasonable size of contract, further increases in scale of orders does not result in lower prices in this market: [SSM paper] and personal communication from Brenda Waning.

^{xxxvi} The Global Fund interviewees were speaking in a personal capacity.

^{xxxvii} This was the view of the wholesalers as well as the organisations in question.

^{xxxviii} There was some confusion in the interviews as to whether ECHO, the European Union procurement organisation, planned to restrict its suppliers to non-profits or not.

^{xxxix} This will be the subject of a separate project working paper.

^{xl} A less than ruthless inspection regime is subject to the kind of danger recounted by one inspector: returning a day later to an Indian plant for some forgotten item, he found the plant with a different name on the gate: it had been hired out to a different company that day for inspection purposes!

^{xli} This will be the subject of another working paper.