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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from Senegal

-- Session III --

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Ms Cristiana Vitale, Senior Competition Expert, OECD Competition Division, tel. +33 1 45 24 85 30,
e mail: cristiana.vitale@oecd.org

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Senegal* --

1. It is a truism to state that one of the purposes of manufacturing any goods, items or products is to distribute them, frequently by means of a long distribution chain.
2. However, the manufacture and distribution of pharmaceuticals immediately finds itself in a paradoxical situation due to the particular characteristics of these goods, which can be simultaneously useful, useless and dangerous¹ (for example, Mediator, Vioxx... or drugs to combat the common cold that are harmful to health and have been withdrawn).
3. In addition to their beneficial effects in terms of preventing, curing, treating and sedating, we have to consider their negative or harmful effects (side effects and allergic reactions, for example) and all the risks that drugs may entail, which are difficult to evaluate. These risks are assessed and monitored by the national pharmacovigilance system which needs to be strengthened.
4. In contrast to the drive demonstrated by pharmaceutical industries in the costly field of research and development, despite the fact that the discovery of new molecules is becoming increasingly rare or requires lengthy development, we also need to bear in mind the cases of corruption, of complicity sometimes on the part of supervisory authorities, and the ever-increasing prevalence of contraband and drug counterfeiting activities which adds to the hazardous and ineffectual nature of these goods (in particular by means of Internet sales which are targeted at developing countries in particular).
5. Thus, any pharmaceuticals policy needs to reconcile two imperatives:
 - to supervise the manufacture and distribution to the population of quality drugs using strict controls but without going beyond what is strictly necessary to achieve that major public health objective;
 - to make drugs accessible to all strata of the population, especially to those who are most disadvantaged, wherever they may be and whatever their financial means.
6. Senegal has incorporated these imperatives into its national pharmaceutical policy² which takes its cue from the strategic guidelines for national health policy, and more generally from various government policies or development programmes set up by the State, including the National Strategy for Economic and Social Development (SNDES) and the National Health Development Programme 2009-2018 (NHDP) of the Ministry of Health and Social Action Programme.

* Document submitted by Mouhamadou Diawara, Chairman of the Senegal Competition Committee.

¹ Prof. Even and Prof. Debré "Guide des 4 000 médicaments utiles, inutiles ou dangereux", Cherche Midi 2012.

² National pharmaceutical policy must be reviewed on a regular basis. The last amendment to be made public was in 2006. We have not been able to obtain data for the forthcoming amendment, due to be approved shortly.

7. Further to French Law No. 54-418 of 15 April 1954 extending to the Overseas Territories the provisions of the French Public Health Code and other laws and regulations, Senegal adopted other instruments, after gaining independence, with a view to amending, supplementing, replacing or fleshing out the existing instrument and adjusting it, as necessary, in order to comply with best international rules and practices.

8. Of the numerous texts adopted, some can be repealed, for example: Law No. 65-33 of 19 May 1965 amending the provisions of the public health code concerning the manufacture, sale and advertising of pharmaceuticals, Decree No. 67-008 of 4 January 1967 concerning the certification of pharmaceuticals, Law No. 73-62 of 19 December 1973 establishing the Order of Pharmacists, Law No. 94-57 of 26 June 1994 laying down the definition of drugs, Decree No. 96-395 of 15 May 1996 supplementing Article 68 of Decree No. 81-039 of 2 February 1981 establishing a code of conduct for pharmacists³, Implementing Decree No. 006217 of 22 August 2003, Implementing Decree No. 000188 of 15 January 2003 setting out the method of calculating the retail price of drugs, goods and objects covered by the pharmaceutical monopoly, the regulation No. 06/2010/CM/UEMOA on approval procedures for pharmaceutical products for human use, five WAEMU Decisions relating to cosmetic products, nutritional supplement products, Rules of Good Manufacturing Practices (BPF), Rules of Good Distribution Practices (BPD), the repository of the Pharmaceutical Inspectorate. These WAEMU texts apply since October 2011.

9. From the point of view of the competition authority, it is a matter of whether this set of provisions leaves scope for competition such that its positive effects, which are also a public policy objective, benefit consumers in terms of the quality and innovativeness as well as the financial and geographical accessibility of pharmaceuticals.

10. It is therefore necessary to examine the pharmaceuticals market in Senegal and identify its structure (I), to examine whether there are barriers to competition in the sale or distribution of drugs or whether competition is implicit (II) and to establish, finally, in a concluding phase (III), whether competition law and its implementation can enable Senegal to achieve its objectives, namely to supply quality drugs to all its citizens at affordable prices.

1. The drug distribution market in Senegal

11. This market comprises manufacturers (1.2), distributors (1.3) and dispensers (1.4). However, it is first necessary to make a few preliminary remarks (1.1).

1.1 Preliminary remarks

12. The manufacture, distribution and sale of drugs in Senegal cannot be undertaken freely. It is primarily a public health issue. An authorisation fee⁴ is applicable to all drugs imported into Senegal. A marketing authorisation (MA) is issued by the Ministry of Health⁵ whose directorates and departments are

³ When defining drugs which may be substituted, Article 1 of that decree states: “however, one drug may be substituted for another if the two drugs are pharmaceutically equivalent and if the former is on a list promulgated by decree of the Minister for Health. Pharmaceutical equivalence means that the two drugs are obtained from the same active principle in the same dosage and are presented in the same pharmaceutical form”.

⁴ Authorisation fees are paid only once and renewed every five years (for half the cost).

⁵ Regulation No. 6/2010/CM/WAEMU relating to approval procedures for pharmaceuticals for human use in WAEMU Member States provides as follows: **Article 4**. “No pharmaceutical product for human use may be marketed free of charge or against payment in a WAEMU Member State unless it has first obtained a Marketing Authorisation”; **Article 5**. “Applications for a Marketing Authorisation for a pharmaceutical product for human use shall be made to the Minister for Health...”

responsible for the administrative and technical control of drugs. These drugs and essential substances are included in a list which is regularly updated.

13. Imported drugs are liable solely to WAEMU⁶ and ECOWAS⁷ community taxes and levies at a combined rate of 2.5%.

14. A total of 90% of drugs are imported. In 2012, the turnover of the pharmaceuticals market excluding the PNA (*Pharmacie Nationale d'Approvisionnement*) was estimated to be 80 billion CFA francs (EUR 121 951 219). The private sector accounts for the majority of this turnover. As a general rule, pharmacists have a monopoly over the manufacture and distribution of drugs in Senegal.

1.2 Domestic production

15. This barely covers 10% of demand. Four pharmaceutical companies produce proprietary and generic drugs, namely:

- Winthrop Pharma, a subsidiary of Sanofi Aventis SA, which manufactures essential drugs (30%) and generics (70%). Around 40 products are branded drugs manufactured under licence, and 90% are generics. Public procurement accounts for 30% of turnover, and 25% of production is exported.
- Pfizer Afrique de l'Ouest, which bought up Park Davis, is treated for customs purposes as a free export undertaking. It exports 80% of its production, which includes 21 proprietary drugs, and has a 15% market share. Pfizer is allowed to manufacture the proprietary drugs of its parent company.
- The Canonne SA (Valdafrique) laboratory. This laboratory manufactures certain proprietary drugs (powders, creams, lozenges) in addition to products for sale in retail pharmacies (PCOs). Exports account for only 25% of its turnover in Africa, either through direct sales or through its partners in France such as Epdis and Planet pharma.
- West Africa Pharma (WAPH), a subsidiary of Sothema Maroc. This company has been operating in Senegal for about three years and manufactures generics for the most common pathologies such as malaria and chronic diarrhoea.

16. We would also mention the Pasteur Institute in Dakar which manufactures vaccine against yellow fever (anti-amaril vaccine for which Senegal is one of the three largest producers in the world).

17. These laboratories, which supply a small proportion of local drug needs, are part of a distribution chain which includes public and private wholesalers and other pharmacies.

1.3 Distribution of drugs in Senegal

18. This task is performed by a huge public wholesaler, the *Pharmacie Nationale d'Approvisionnement* (PNA) and its regional outposts, and by private wholesalers and retailers.

1.3.1 The Pharmacie Nationale d'Approvisionnement

19. This can be said to have taken over from the *Pharmacie Fédérale d'Approvisionnement* (pharmapro) which, in the colonial era, used to supply drugs to the whole of French West Africa⁸.

⁶ West-African Economic and Monetary Union (WAEMU).

⁷ Economic Community of West African States (ECOWAS).

20. It is the wholesale distributor for the public and para-public sector. It is a public health entity⁹ which supplies the regional supply pharmacies (11 out of 14 regions) which, in their turn, “provision” the health districts which, for their part, supply the health centres and posts scattered around the country.

21. The mobile PNA is the outcome of the government’s intention to make drugs available and accessible everywhere. This is also the intention underlying the PNA’s purchasing system which relies on international invitations to tender in INNs (International Non-proprietary Names) based on a national list of essential drugs.

22. The PNA basically obtains supplies of generic drugs. It is not allowed to sell to private pharmacies. However, it may, subject to ministerial authorisation, sell a certain number of molecules from an exhaustive list to private wholesale distributors. These are basic drugs to treat the most common pathologies. Hence, out of 2 500 listed drugs, 50 to 70 molecules may be sold by the PNA to private wholesale distributors.

1.3.2 *Private wholesale distributors*

23. These distributors basically import proprietary or branded generic drugs, and six of them share a market which, in 2012, amounted to 80 billion CFA francs. In order of importance, they are:

- Laborex, a subsidiary of the Eurapharma group. It has a 48% market share and six agencies in the principal cities.
- Cophase (Coopération pharmaceutique sénégalaise), a subsidiary of the Planet Pharma group. It has a 33% market share and also has agencies in the most important regions.
- Sodipharm, bought 5 years ago by the CERP Laboratories group, has a market share of around 11%.
- Sogen, Duopharm and Ecopharm share the remaining 8% of the market.

1.3.3 *Pharmacies*

24. By mid-2013, there were 963 private pharmacies in Senegal, 62% of which were in the region of Dakar alone. This finding is indicative of a very unequal spread over national territory and conflicts with the WHO recommendation of one pharmacy per 5 000 inhabitants. The hypertrophied capital accounts for 55% of GDP and 90% of manufacturing output, which explains why there are so many pharmacies, even though a *numerus clausus* requires a distance of 300 m as the crow flies between pharmacies. As a result, nearly 40% of pharmacies have low turnover and experience difficulties given that the minimum set-up cost for a pharmacy is FCFA 3 million.

25. Pharmacies enjoy rebates, discounts and bonuses from their wholesaler based on turnover: it is unlikely that any of these are passed on to customers.

26. The average turnover of a pharmacy varies depending on location and proximity to the catchment area: it ranges between 200 000 and 300 000 CFA francs per day for the smaller pharmacies to between 1 and 2 million CFA francs per day for the larger ones. One of the largest pharmacies can take over 10 million CFA francs per day.

⁸ French West Africa included the following States: Senegal, French Sudan (now Mali), Ivory Coast, Mauritania, French Guinea, Dahomey (now Benin), French Togoland and Niger.

⁹ The idea of making the PNA a nationally owned company or a public limited company no longer seems to have any currency.

1.4 Other entities dispensing or supplying drugs in Senegal

27. These include private depots in a few rural villages or communities (pharmacy subsidiaries for example) in areas where, in principle, there is no good reason for a pharmacy to become permanently established. There are also private donors (NGOs and others for drugs that are not to be included on the official list, such as narcotics and psychotropic substances), denominational health entities (supplied by the PNA but, when supply is interrupted, able to obtain dispensation to obtain supplies from private wholesalers) and development partners (principally the Global Fund, UNFPA, UNICEF, US-AID).

28. It is also worth noting that, in the drug distribution field, there are around 40 medical delegations representing large and small laboratories which specialise in generic drugs. Medical representatives are responsible for proposing their products to prescribers and, due to the guidance that they are able to offer, they play a not insignificant role in terms of drug distribution. However, does this distribution system leave any scope for competition?

2. Competition in the field of drug distribution in Senegal

29. In the absence of a sector-wide survey and complaints or decisions on the part of the competition authority, there can be no valid reason for stating that abuse of a dominant position, collusion or unilateral practices exist. Likewise, it is not possible to state definitively that there are vertical agreements between wholesalers and manufacturers¹⁰. However, scrutiny of the various texts and of certain practices indicates that there are some pro-competitive provisions and practices (2.1) but that there is also, and more particularly, a genuine lack of competition on retail prices in respect of drugs (2.2) meaning that, for stakeholders, competition can exist only at other levels (2.3).

2.1 Pro-competitive provisions and practices in the field of drug distribution in Senegal

30. The relevant provisions are those of Decree No. 81-039 of 2 February 1981 establishing a code of conduct for pharmacists, and those of the PNA's drug supply system, notwithstanding certain limits, and of the system applicable to private wholesale distributors.

2.1.1 Pro-competitive provisions of the Decree establishing a code of conduct for pharmacists¹¹

31. In addition to prohibiting certain customer research procedures, in order to guarantee freedom of choice of pharmacy for patients, and the use of elected positions or administrative posts in order to boost clientele, the following are prohibited: "all payments and acceptances, solicitations, offers to share proceeds between pharmacists or between pharmacists and members of the medical corps and other health professionals (...) all unlawful rebates in cash or in kind on the price of a service or product (...) all **collusion** between pharmacists and doctors, other health professionals or any other persons".

2.1.2 Supply system of the PNA

32. This section can be broken down into the following three points.

- The PNA is subject to the Public Procurement Code. It is also required to issue international invitations to tender for the essential (generic) drugs that it imports. This should guarantee a degree of transparency in the awarding of contracts and place laboratories and drug

¹⁰ The existence of such practices or agreements is denied by one manufacturer, several pharmacists and two former employees of the national pharmacy directorate.

¹¹ The examples given are purely indicative.

manufacturers on a competitive footing. This call for competition should have a knock-on effect on prices and product quality.

- The opening up of competition appears to be closely monitored by the authority responsible for regulating public procurement (ARMP). Its dispute settlement committee, in a decision regarding a complaint against the provisional award of a contract to an undertaking which had “no specialist personnel or any experience akin to that to which the contract relates”, decided that:

*“X has failed to satisfy the requirement of experience akin to that to which the contract relates; that failure to satisfy the criterion does not undermine the proper performance of the contract; the award of the contract to X makes it possible to **remove a barrier to entry for a competitive award of this type of contract**»*

- This international invitation to tender requirement is not absolute. The PNA increasingly resorts to direct agreements which are apparently justified by breaks in drug supply¹² and a lack of emergency procedures for awarding public contracts.

33. However, the fairly frequent recourse to direct agreements has put a fly in the ointment and is heavily frowned upon by the regulatory authority.

2.1.3 *Supplying the wholesale distributors*

34. It should be remembered that the PNA can supply a few molecules to private wholesale distributors. For products that they import, the latter obtain supplies on the international market or from their parent companies. They can therefore issue international invitations to tender.

35. Irrespective of their drug purchasing procedure, the fixing of prices by obtaining official approval leaves no scope for competition on prices.

2.2 *Lack of competition in the fixing of drug prices in Senegal*

36. Senegal has always been concerned by the price of drugs. It is a signatory to the Bamako Initiative (BI) which seeks to promote a public essential medicines policy for grassroots communities, in order to reduce the cost of drugs, especially those used in primary health care, some of which are too expensive for such people to afford.

37. At the present time, Senegal’s pricing policy is geared towards providing some drugs free of charge (2.2.1) and administering the supply of others (2.2.2).

2.2.1 *Free provision of certain drugs*

38. In this context, competition can operate only in regard to the method of supplying such products. These drugs are backed by donors and state subsidies.

39. In the public sector, all drugs derived from artemisinin (ACT drugs to combat malaria) are free. Drugs used to combat tuberculosis and AIDS (ARVs) as well as tests and analyses for detecting and following-up the evolution of those diseases are also free.

¹² In a current dispute, “the PNA referred to the level of stocks and the threat to public health as a result of a scheduled break in [the supply of] drugs”.

40. With the introduction of universal sickness cover (CMU) at the end of 2013, some drugs are now free up to the age of five.

41. Under the “Sesame” plan, senior citizens (over 60) are entitled to free drugs obtained at health centres and elsewhere.

2.2.2 *Administration of drug prices*

42. Article 1 of the Interministerial Decree¹³ of 15 January 2003 provides as follows: “the retail price, in pharmacies and private drug dispensaries, of imported products and items covered by the pharmaceutical monopoly shall be obtained by adding to the wholesale price without tax a delivery CIF cost of 10%, a local transport cost of 1.5% of the CIF value, the cost of the customs stamp at the official rate in force and the wholesale and pharmacy margins”.

43. Further to that article, the following have been fixed:

- the various margins of wholesale distributors and pharmacists depending on the drugs, products and corporate purposes, as appropriate, bulk items (CH products: products packaged for hospital use);
- the retail prices of drugs, products and items sold by the PNA and mark-ups in the public and private sectors.
- Article 5 of the decree provides, on the one hand, that for drugs other than those sold by the PNA a national pharmaceutical tariff is to be set by the pharmacists’ trade union and forwarded to the Directorate for Pharmacies and Drugs and, on the other hand, that the PNA is to draw up, for the drugs that it sells, a catalogue of prices which is to be forwarded to the Directorate for Pharmacies and Drugs, the pharmacists’ trade union and all public health care entities. It must be noted that the ministerial decree does not set the margin of the PNA.

2.3 *Potential competition other than on price*

44. This is an idea supported by certain pharmacists and/or pharmaceutical authorities. They maintain that there can be competition only in other areas, such as drug packaging and counselling.

45. The idea that emerges from the foregoing, or the basic objective, is to introduce some uniformity into the retail pricing of drugs, but has this policy enabled Senegal to achieve its aims of making high-quality drugs available to the most vulnerable sections of the population at affordable prices throughout national territory?

3. **Conclusion. Review of the drug distribution system in Senegal and the possible foci of a competition policy**

46. The drug distribution system in Senegal, which has such a satisfactory structure, is nonetheless subject to certain constraints or barriers (3.1.). However, there are potential solutions (3.2.).

3.1 *Barriers to the distribution of drugs*

47. These are:

¹³ A decree issued by the Minister for the Economy and Finance, the Minister for Health, Prevention and Public Hygiene, and the Minister for SMEs and Trade. This decree is due to be amended.

- **The lack of drug availability** or, in the words of a survey (conducted in the four regions of Senegal) by SOFAGIP¹⁴ for the Ministry of Health: “the distribution of drugs is far from perfect in the public sector”. That survey, which was conducted in 2005, is fairly representative of the current situation. This lack of availability is corroborated by the supply outages experienced by the PNA and other health entities. In its general public report for 2010, the Court of Auditors noted the frequency of stock outages at pharmacy level which had hampered the operation of a regional hospital.
- **The high price of drugs.**¹⁵ Despite the fixing of drug prices by means of the interministerial decree mentioned above, various documents, including those of the Directorate for Pharmacies and Laboratories and SOFAGIP, draw attention to the high price of drugs in Senegal. The margins set by the interministerial decree are not even adhered to within the public sector. There are price infringements and misappropriations of monies received. As a result, a large number of people, finding themselves unable to access certain essential drugs, turn to traditional remedies and the illegal drug market.
- **The illegal sale of drugs.** Illegal drugs may be the result of thefts from pharmacies and health centres or they may be brought into Senegal unlawfully. However, this type of market is sharply characterised by the fact that is, to some extent, a counterfeit pharmaceuticals “fair”. Until recently, the place known as “Keur Serigne Bi”¹⁶ (the Marabout’s house) was doing a good trade. It was possible to find much cheaper proprietary and generic drugs there than those sold in pharmacies, and they were sold by non-pharmacists. Instances of counterfeiting were rife. The Order of Pharmacists and their trade unions have complained about this illegal parallel market on several occasions, but to no avail. Union leaders estimate that the turnover for “street drugs” is 12 billion CFA francs per year¹⁷.

48. This short summary reveals that there is problem with availability of low-cost drugs. This lack of availability is also spatial. It is necessary to remedy these shortcomings by obtaining quality supplies in sufficient quantities and by meeting the cost of patients’ needs. We will outline below some solutions to this problem.

3.2 Possible solutions to the distribution of drugs in Senegal: the competition issue

49. The solutions proposed are far from exhaustive and, in addition to the physical, technical, financial and human resources needed, coupled with effective and pro-active pharmaceutical oversight, they require the engagement of all players (from manufacturers to prescribers). Consumer education is also vital.

¹⁴ The SOFAGIP document was drafted by a doctor, Mamadou Cissé.

¹⁵ In order to counter this phenomenon, and alongside the private mutual health insurance companies, there is a mutual health insurance company for civil servants which reimburses up to 65% of the cost of generic drugs and up to 50% of the cost of proprietary drugs.

¹⁶ It apparently still exists.

¹⁷ There are two trade unions for pharmacists in Senegal which are responsible for protecting the material and moral interests of the profession.

50. Local drug manufacturing¹⁸ must be encouraged in order to be able to satisfy at least 80% of requirements and benefit from the know-how of foreign partners. (This appears to have happened in Morocco).

51. However, fostering the development of pharmaceutical industries in Senegal should lead to the modification of certain provisions of the law on the pharmaceutical industry so as not to have over 51% of shareholders which are pharmacists. Wouldn't one responsible pharmacist be enough?

52. The constant search for transparency in the distribution of drugs needs to be accompanied by the following measures:

- Proper stock management and mastery of stock management tools in addition to proper programming of orders.
- Preference should be given, when prescribing, to International Nonproprietary Name (INN) rather than branded ones, as is increasingly the case in Europe, in order to reduce the cost of drugs. Prescription of generic drugs should be encouraged.
- Review or adjustment of high margins.
- Penalties for misappropriation.

53. When considered closely, Senegal, like most developing countries, needs, as a first step, to tidy up its pharmaceuticals market and to address the causes of breaks in supply.

54. However, as part of the policy to improve the distribution of drugs, there must, despite the misgivings¹⁹, be room for a sound competition policy.

55. Surely the source of high drug prices must lie in anti-competitive practices?

56. The SOFAGIP report highlighted the fact that “in the public sector, purchase prices are double those of the MSH (Management Sciences for Health 2004) and that such a large discrepancy cannot be justified solely by the difference between the FOB price and the Senegal purchase price times the FOB price”.

57. In this connection, one might ask whether the invitation to compete operates effectively in the context of the PNA's international invitations to tender. In particular, one PNA report on the contracts awarded by the latter refers to: “the impression that it is always the same applicants applying at national and international level”.

58. Is Senegal the victim of a market sharing operation which is distorting competition and making drug prices even higher?

59. Likewise, is it certain or likely that wholesale distributors give their pharmacy customers rebates, discounts or other bonuses based on turnover?

¹⁸ Protection of local production, which is facing fierce competition from abroad due to high domestic production costs, is being advocated by manufacturers and pharmaceutical authorities. Certain forms of relief are also being sought, such as a single trained pharmacist being sufficient to set up a drug manufacturing business in Senegal.

¹⁹ Certain officials and even some pharmacy academics believe that competition would entail the disappearance of a large number of pharmacies, especially some of the smaller ones.

60. Moreover, some wholesalers organise holidays for groups of pharmacists with the gains from accumulated dividends.

61. In our opinion, competition between generic drugs, between generics and branded generics, and between generics and originator drugs must be possible. Genuine competition between private wholesale distributors and between pharmacies must be allowed to exist in the interest of consumers²⁰.

62. Direct agreement distorts competition. A means of rectifying this situation needs to be found. The independent review of contracts awarded by the PNA in 2011 (April 2013) indicates that the number and value of contracts awarded by direct agreement are relatively high in relation to those awarded in 2011 as a whole (47% and 40% respectively).

63. It follows from all the arguments put forward and the questions raised that there is ample scope for competition. As indicated above, a properly implemented competition policy encourages transparency which, in turn, reflects on the cost and quality of products. However, as Bruno Lasserre, Head of the French Competition Authority, says, it is necessary to convince stakeholders that, owing to the sensitivity of the pharmacy sub-sector, competition must be controlled.

64. Therefore, the primary task will be to lay the foundations of a preventive and transparent competition policy in order to improve the organisation of the drug distribution market, a task that will require synergy between the national competition authority, the National Order of Pharmacists and the various departments of the Ministry of Health, especially those responsible for preparing and implementing national pharmaceutical policy.

²⁰ Certain private wholesale distributors in one of the WAEMU Member States had asked that they be allowed to supply the public hospital sector and compete with the public wholesaler.