

**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE**

Global Forum on Competition

COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Summary of Discussion --

27-28 February 2014

The attached document is a draft summary of the discussion held during Session III of the 13th meeting of the Global Forum on Competition on 27-28 February 2014.

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SUMMARY OF DISCUSSION

By the Secretariat

1. Introduction by the Chair

1. The Chairman of the OECD Competition Committee, Prof. Frédéric Jenny, introduced the session and gave the floor to the **Chair**, Ms Michelle Cohen, President of Pro-Competencia (Dominican Republic).

2. The Chair pointed out that markets for pharmaceuticals are typically heavily regulated because of their distinctive characteristics. The presence of patents creates a considerable degree of market power on the part of manufacturers. Consumer demand is rather inelastic, because the choice of drug is made by the doctor and the bill is paid by the insurer (public or private). Demand at the level of wholesalers and retailers is rather rigid, because of the must-have nature of many drugs and the lack of alternatives, and because of regulatory requirements on the range and level of the products that must be made available. These features imply that competition cannot be fully relied upon to reach an efficient allocation of resources. In addition, many governments consider that drugs should be affordable and accessible to all citizens regardless of income or geographic location, and competition alone cannot ensure that such equity and fairness concerns are met.

3. Nevertheless, she said, competition could and should play an important role in ensuring that the market work well for consumers in terms of lower prices, higher quality, wider choice and variety, and greater innovation. The session would therefore focus on how competition could support regulation in achieving these objectives, and whether and when it could replace regulation. It would also consider the challenges of assessing mergers and vertical agreements in distribution, and examine what conditions could favour collusion and the creation of cartels.

2. Presentation by Panos Kanavos, Reader in International Health, London School of Economics (UK)

4. **Dr. Kanavos** gave a presentation entitled ‘Competition issues in pharmaceutical distribution’.

5. Dr Kanavos began by characterising the role of distribution in the pharmaceutical supply chain. Typically, manufacturers sold drugs to wholesale distributors, who supplied them to pharmacies, who in turn dispensed them to consumers. However, there were variations. For example, in some cases, doctors dispensed directly, while manufacturers sometimes sold directly to retailers, bypassing the wholesaling channel; this was quite common with generic medicines but increasingly also with specialty drugs. There was also the phenomenon of parallel exports, in which wholesalers sourced pharmaceuticals in lower-priced countries and resold them in higher-priced countries. This was particularly an issue in the European Union because of the principle of original exhaustion of intellectual property rights within the EU.

6. Dr Kanavos presented data showing that wholesaler and retailer markups varied widely across European countries, resulting in significant differences in final prices for drugs even with the same ex-factory price. Markups in distribution were proportionately higher on lower-priced generic drugs. He also

presented data for lower and middle income countries, showing that markups there could be as high as several hundred percent because of weaker regulation and greater fragmentation. The contribution of distribution to total cost was therefore very important.

7. With regard to market structure, in Europe many small or medium-sized countries had significant numbers of wholesalers, many of whom were not ‘full-liners’ but ‘short-liners’, supplying a limited number of products or operating regionally. There was a weak positive correlation between the level of remuneration and the number of competing wholesalers. Community pharmacy numbers in Europe ranged from one per 18,000 people in Denmark to one per 2000 in Spain and one per 1000 in Greece. These differences in density were partly due to differences in historical development, but could have implications for competition.

8. Retail market entry and exit regulations often involved geographical criteria regarding minimum distances between pharmacies, and demographic criteria regarding the minimum population to be served. However, there were no explicit rules requiring an equal distribution of pharmacies in rural and urban areas, and there were often problems in rural areas relating to the number of pharmacies, the geographical area they cover and the range of medicines available to consumers. Ownership regulation determined whether only a pharmacist could own a pharmacy, how many pharmacies a single entity could own, and whether pharmacy licences could be traded.

9. Remuneration to wholesalers and retailers was typically governed by regressive markups, whereby the percentage markup was lower on higher-cost medicines. In addition, where manufacturers were allowed to offer discounts to pharmacies, regulators or insurers sought to claw back a proportion of such discounts from their remuneration of pharmacies, although they did not know the exact level of discount in each case. Competition then focused on the level of discount offered. Dr Kanavos presented data from the UK relating to simvastatin, a widely prescribed generic drug for the management of dyslipidemia. Relative to the reimbursed price, the level of discount was around 79% for the widely used 10mg dose, and 50% for the less frequently prescribed dose of 80mg. Since the discount formed part of the pharmacy’s revenue, it had an incentive to procure from the cheapest source.

10. Dr Kanavos then moved on to issues of horizontal and vertical integration. Horizontal integration among wholesalers in Europe had been allowed in some cases but not in others. There had also been a considerable amount of vertical integration in which pharmacies or pharmacy chains acquired wholesalers or vice versa. In some cases integration was limited by regulations such as limits on the number of pharmacies that could be owned by one entity. In addition, new forms of integrated business model were emerging which had interesting competition implications, such as the direct-to-pharmacy model in which a single wholesaler-manufacturer agreement covers all or part of a manufacturer’s portfolio and the wholesaler becomes a logistics provider, and the reduced wholesaler model in which a manufacturer appoints a selected number of wholesalers to distribute some or all of its products. These models were becoming more frequent at the expense of the traditional model in which products were sold to pharmacies by full-line wholesalers.

11. Finally, competition issues could arise from the fact that pharmacies were increasingly supplying services other than dispensing, such as disposal of waste, blood pressure monitoring and patient advice, which in some cases were paid for by the health insurer.

12. Summarising, Dr Kanavos highlighted the contrast between the high degree of regulation of wholesaling and retailing in Europe and the unclear rules of the game in many lower and middle income countries. Regulation covered remuneration and entry, but structures were fragmented. There was considerable variability in horizontal and vertical integration and in the acceptance of practices such as discounting.

13. Dr Kanavos suggested that further work should be focused on: better data and understanding about operating and regulatory conditions in lower and middle income countries; market structure and concentration, including at the rural level; the impact of horizontal and vertical integration on the availability of medicines and on service quality; approaches to remuneration and the impact on consumer interests, especially in lower and middle income countries; safety and quality assurance in connection with the rise of e-pharmacies; the appropriate future role of distribution, including whether distributors should act as logistics providers or as wholesalers subject to requirements for levels of service; and whether discounting is competition-enhancing or competition-reducing.

3. Presentation by the Senegal delegation

14. A delegate from **Senegal** made an oral presentation on the challenges and achievements of pharmaceutical policy in Senegal, and whether competition could play a role in improving the distribution of medications.

15. Senegal's national pharmaceutical policy, she said, was supported by several state development programmes, including the National Strategy for Economic and Social Development and the National Health Development Policy for the period 2009-2018. Its goal was to meet the need for quality medications that were affordable and geographically accessible.

16. Quality was addressed by an authorisation process for distribution of all drugs imported into Senegal. Authorisation was granted for a period of five years, after which time it must be renewed. It was based on administrative and technical checks and an evaluation of risks posed by the medication concerned.

17. Policy measures to ensure that medications were affordable and accessible included the promotion of generics through the National Supply Pharmacy (Pharmacie Nationale d'Approvisionnement), which procures essential drugs and supplies them to regional supply pharmacies, which in turn distribute them to public health centres and outlets. Alongside the National Supply Pharmacy were six private wholesalers. Wholesalers procured some drugs from abroad via tender, thus creating a degree of competition. Senegal was also developing local manufacturing. Four multinational manufacturers were present in the country.

18. Prices and margins in Senegal were set by national authorities, with a view to ensuring affordability. Medicines were not subject to tax. Some drugs, such as artemisinin derivatives (used to treat malaria) and drugs against tuberculosis and AIDS, were made available free of charge, while the Sesame Plan made healthcare free to people over 60.

19. Overall, the local supply of drugs was satisfactory, but surveys had shown that prices were very high compared to international benchmarks. This raised the question whether greater competition could improve the situation. Price-based competition was not possible since prices were set by government. Organised competition between private wholesalers and an ability of the National Supply Pharmacy to purchase on the international market were potential solutions. However, it was typically always the same companies who responded to tenders, which suggested a lack of adequate competition.

4. Presentation by Pradeep Mehta Secretary General of Consumer Unity & Trust Society International) (India) sector'

20. **Mr Mehta** gave a presentation entitled 'Competition issues in marketing in the Indian pharmaceutical sector'.

21. Mr Mehta began with a snapshot of the pharmaceuticals sector in India. The Indian pharmaceutical industry was ranked third in the world by volume and 14th by value. It was one of the largest and most advanced among developing countries, growing at 9-10% per annum from a mere USD 0.3 billion in the 1980s to around USD 12.5 billion in 2012. It was highly fragmented, with more than 20,000 firms, but with the top 250 firms accounting for 70% of the market. India was considered the generic capital of the world, with branded generics constituting 75-80% of the market.

22. However, access to medicines by the poor was still a problem. The pharmaceutical sector was governed by a wide array of legislation and regulatory agencies which were poorly co-ordinated. This invited opportunistic behaviour by market players across the entire healthcare sector. A World Bank study in 2011-2012 had shown that medicines accounted for 86% of consumers' out of pocket expenses, one of the highest rates in the world, and significantly higher than in the neighbouring countries of Nepal (49%) and Sri Lanka (44%). It found that healthcare expenditure aggravated poverty in India, resulting in about 39 million people falling into poverty each year.

23. Possible reasons for this situation were the low public expenditure on healthcare (about 1.1% of GDP), inadequate insurance coverage, a high presence of private for-profit hospitals, and the nexus of doctors and pharmaceutical companies raising demand for expensive drugs.

24. In stark contrast to developed countries, less than 15% of India's population was covered by any form of health insurance, which mainly covered expenses on patented medicines. The poor provision of healthcare by the public sector led to a large role for private for-profit healthcare providers, which were associated with unethical and corrupt practices.

25. Collusive practices among the players in the Indian healthcare supply chain were widespread. This included what Mr Mehta referred to as an 'unholy nexus' between drugs manufacturers and doctors, which created incentives for prescribing irrational drug combinations and expensive brands. There was a second 'unholy nexus' between hospital doctors and diagnostic clinics, in which the practice of paying cuts and commissions to referring doctors gave them an incentive to make large numbers of referrals for diagnostic tests.

26. The Indian media had given prominent coverage to cases such as that of GlaxoSmithKline (GSK) in China, which was accused of spending 490 million dollars in bribing doctors, hospitals and government officers, and the 13 billion dollars paid in fines by various leading firms in the past five years for misleading marketing and bribes to doctors. Numerous surveys, interviews and anecdotal media reports indicated that such practices were quite common in the pharmaceutical market in India, yet the Competition Commission of India (CCI) had not taken action because of a lack of documented evidence.

27. CUTS had carried out two audit studies in order to analyse how prescriptions were being made in India. A 1995 survey in six states of India showed that 26% of prescriptions were made without a mandatory diagnosis and about 60% were irrational. There was also a very high occurrence of polypharmacy, i.e. multiple drugs (as many as four or five) being prescribed for the same problem. A second survey, conducted in two states in 2010, found that only 20% of consumers obtained medicines from public hospitals because doctors were prescribing expensive medicines available only in private pharmacies. The incidence of polypharmacy and irrational combinations was about 50% in both states. Incentives on doctors to mis-prescribe were the cause of this behaviour, and of the consumer poverty it created. Pharmaceutical companies were spending more on drug promotion than on research and development because promotion generated profits more easily.

28. Some steps had been taken to address this problem. There had been voluntary actions by pharmaceutical companies: for example, GSK had announced it would stop paying doctors for drug

promotion, while several others had announced voluntary disclosure about their ‘continuing medical education’ programmes for doctors. In India the tax authorities had announced in 2012 that ‘freebies’ would not be allowable as expenditures and that doctors would have to pay tax on them. This had had some impact. The Department of Pharmaceuticals was considering a mandatory code for pharmaceutical marketing practices. CUTS had suggested to the CCI that it take action including a survey, but this had not been done.

29. There were also what Mr Mehta referred to as ‘coercive’ practices in the distribution and supply chain, involving actions by trade associations to restrict or control the supply of products, which affected whether medicines were available at competitive prices. After the government announced new price controls in 2012, there was a shortage of essential drugs on retail shelves as wholesalers and retailers stopped carrying them in favour of medicines with higher margins. In recent years the CCI had considered three significant cases, two against regional pharmacy associations and one against the All India Organisation of Chemists and Druggists (AIOCD), which had 750,000 pharmacies as members. The AIOCD was found to have acted anti-competitively by: making it mandatory for drug manufacturers to appoint only distributors and stockists holding a ‘no-objection certificate’ issued by it; requiring mandatory advertising on launch of new products; demanding high commissions; and boycotting firms who did not comply with these requirements. However, the fine imposed by the CCI was grossly inadequate as it was levied on the association’s turnover rather its members’ turnover.

30. Mr Mehta considered that the problem of unethical drug promotion could be countered to a great extent by the preparation of treatment guidelines, the conduct of periodic prescription audits, and consumer awareness campaigns to reduce information asymmetries. He cited Saudi Arabia, in which merely the announcement by government of the launch of a prescription audit led immediately to a 60% reduction in mis-prescribing. He also suggested that the Indian authorities could learn from the example of the US Food and Drug Administration (FDA) in introducing strict regulations to curb unethical promotions. The CCI’s decision in the AIOCD case was bound to have some impact on the distribution of medicines in India as well as on prices charged to consumers, since drugs manufacturers could now appoint whichever distributor they chose without fear of repercussions from trade associations.

5. Presentation by Ms Valérie Paris, senior health advisor in the OECD Health Division

31. **Valérie Paris** gave a presentation entitled ‘A core set of indicators to characterise and assess the distribution chain in the pharmaceutical sector’.

32. Ms Paris’ presentation was motivated by the realisation that the OECD Health Division’s databases of health policy indicators contained virtually nothing about the distribution of pharmaceuticals. Her presentation considered how this gap might be filled by constructing a core set of qualitative and quantitative indicators describing regulation and characteristics of the distribution of pharmaceuticals and assessing the effectiveness of the distribution chain for different countries.

33. At OECD level, there were a few questions relating to pharmacy in the previous Product Market Regulation survey, while the OECD Health Statistics contained only the number of pharmacists. Outside the OECD, the WHO European Health for All database contained the number of pharmacists and pharmacists graduating, while the WHO country profiles contained more extensive information, but only for a few countries in each region. The Pharmaceutical Health Information System (PHIS) contained data for European countries on the density of medicine dispensaries, price regulation and reference price systems, while the PHIS and Pharmaceutical Pricing and Reimbursement Information (PPRI) country profiles gave information on the regulation of wholesale and retail distributors and markups, but again only for Europe.

34. In relation to wholesale distribution, Ms Paris proposed that regulatory indicators should be gathered regarding: regulation of ownership and licensing; type (if any) of regulation of vertical integration with retailers; public service obligations (i.e. whether wholesalers must provide full-line distribution of all products, or could provide short-line distribution of only some products); the type (if any) of regulation of markups; and the type (if any) of regulation of discounts to pharmacies. Market structure indicators would be the number of wholesalers by type, and a measure of market concentration. As an illustration, Ms Paris showed how indicators of the regulation of wholesale markups could be put together from the PHIS database.

35. In relation to retail distribution, Ms Paris proposed that the regulatory indicators should include: the types of retailers allowed to distribute medicines (prescription and OTC), including dispensing doctors; regulation of ownership for pharmacies (e.g. whether ownership was reserved to pharmacists, and whether one entity could own multiple pharmacies); regulations on the establishment of new pharmacies (such as quotas per population or minimum distances between pharmacies); service obligations for pharmacies (such as regulation of opening hours, and the range of products that must be provided within certain delays); and the system of regulated markups and/or retail prices. Indicators of market characteristics would be the number and density of dispensaries allowed to dispense medicines. Ms Paris showed how indicators of retail price regulation could be constructed from the PHIS database.

36. Ms Paris proposed that the first set of outcome measures would concern distribution costs, and could be expressed as markups on the ex-factory price or as proportions of the retail price. Ms Paris presented published information for some European countries, and noted that some data had been collected from ad hoc surveys by the WHO/Health Action International (HAI) Project on Medicine Prices and Availability for certain middle and low income countries.

37. The second set of outcome measures should relate to the availability of medicines. It would be easy, she said, to collect data on the density of prescription medicine dispensaries for many countries, but probably more difficult for pharmacies selling other types of medication. For some countries there was information on the distance to the nearest pharmacy. In some cases there might be information on the occurrence of shortages, although this was not always attributable to the distribution system but sometimes to the manufacturer. Availability of medicines at outlets would be very difficult to assess; ad hoc surveys were sometimes conducted, notably using the WHO/HAI method, but the information was very local. Quality of supply would also be difficult to measure, but could be proxied by the number of pharmacists or professionals with a certain level of pharmacy training. WHO gathered information on the existence of policies on inspections and controls, but this might not be an appropriate quality measure. Some countries produced data on counterfeit medicines, but this measure could reflect detection rates rather than the true extent of the counterfeit market.

38. In her presentation, Ms Paris acknowledged that she took an OECD perspective but stressed that the OECD was willing to work with other organisations on wider data collection if there was interest. As a health policy specialist, she also invited input from competition economists as to the most appropriate indicators.

6. Presentation by Aidan Hollis, professor of economics at the University of Calgary (Canada)

39. **Prof. Hollis** gave a presentation on ‘Competition Issues in the Distribution of Pharmaceuticals’.

40. Prof. Hollis explained that the underlying problem was that in markets with insured consumers and no price sensitivity, pharmacies exercised very high market power. With free entry, competition for the consumer would result in excessive numbers of pharmacies, high service levels, small volumes per pharmacy and high unit costs. This outcome was not economically efficient.

41. In response, insurers could use two tools to limit the cost of reimbursements. The first was to set the level of reimbursement of the official markup or dispensing fee. Secondly, they could attempt to limit the reimbursable component of the price of the drug. In the case of patented drugs, the insurer could observe the price of the drug and negotiate over the reimbursable level by reference to cost-effectiveness analysis and price referencing. Reimbursement of generic drugs was more complex, however. Since generics were homogeneous goods, prices should simply reflect their cost of production, leading to very low wholesale prices. However, because of their market power, pharmacies did not have to pass on these low wholesale prices to consumers. Therefore the insurer did not observe the true wholesale price. As a result, even if there was robust competition between manufacturers, insured prices could end up being very high, and the party that benefited from the competition between manufacturers was the pharmacy rather than the insurer or consumer.

42. Various solutions were used to control generic pricing in these circumstances. A strategy favoured by economists was try to make consumers price sensitive by not insuring them fully, thus encouraging them to exert competitive pressure on pharmacy prices. However, this could be bad for patient health and for overall healthcare costs, since low income patients might simply not fill their prescription.

43. A second strategy, used to some extent in the United States, was for the insurer to create competition between pharmacies for preferred status. The selected pharmacies had to offer low prices to the insurer. However, patients must then travel to specific pharmacies to fill their prescriptions, which could worsen access. In addition, if there was a single dominant insurer, it could direct all the business to just one or two pharmacies.

44. A third, and very common, strategy was to make the reimbursable price of generic drugs a fixed ratio (say, 70%) of the price of the corresponding branded drug. This was simple to implement, but the true cost of production of the generic could be very much lower (such as 5%). Manufacturers would compete to get their product into the pharmacy, but the pharmacy rather than the payer obtained the benefit.

45. In another approach, the insurer used tendering to negotiate the price directly with the manufacturer just as with branded products, and the retailer had no opportunity to increase the price beyond the allowed margin. This strategy had been used to great effect in New Zealand but with less success in Canada. Tendering also created a risk of shortages if there was only one supplier.

46. A fifth method was benchmarking or yardstick pricing. Here, the insurer collected all wholesale transaction prices in each period and used them to set a reimbursement price for the next period, which meant that each pharmacy had an incentive to purchase at the lowest price in order to maximise its margins. This was used in England and Australia with varying results. A challenge with this system was that no-one had an incentive to report prices honestly.

47. A final model was a declining price schedule, where the generic price was set as a fraction of the brand price and the fraction declined with every new generic drug that entered the market, in an attempt to mimic a competitive outcome. This approach had been used only in a few relatively small markets and the evidence for its success was weak.

48. Prof. Hollis presented data on the prices of ten common generic drugs across countries with different systems, as compared with prices in Quebec, Canada, which used a fixed price ratio approach. Tendering resulted in prices that were in one case much lower and in another much higher than under the fixed price ratio approach. Benchmarking produced prices that were lower in England but higher in Australia. This suggested that institutional details mattered for outcomes.

49. Prof. Hollis concluded that different strategies for controlling reimbursement prices had different costs and benefits and different effects on the nature of competition. Competition authorities had a legitimate interest in the mechanisms used by insurers, and also possessed special competence to help guide the choice of mechanisms.

7. Presentation by Sabine Vogler, Austrian Health Institute (Austria)

50. **Dr Sabine Vogler** gave a presentation on ‘Liberalisation in the pharmacy sector’.

51. Deregulation or liberalisation in community pharmacy primarily concerned the issue of market entry rather than prices, and in particular the rules governing the establishment of new pharmacies, pharmacy ownership, and non-pharmacy selling of OTC medicines.

52. Many countries had a mixture of criteria governing the establishment of new pharmacies based on minimum distances between pharmacies or the size of population that pharmacies should serve. Under full deregulation, new pharmacies could be set up in any location.

53. Ownership regulation usually stipulated that pharmacies must be owned, or at least majority-owned, by pharmacists, while under deregulation there were no such restrictions. However, some countries still prohibited manufacturers or prescribers from owning pharmacies.

54. Sale of at least some OTC medicines outside pharmacies was permitted in many European countries. However, most European countries still had regulations related to establishment and ownership.

55. Countries that had moved from a highly regulated to a more deregulated system included Iceland in the 1990s, Norway in 2001 and Sweden in 2009. Liberalisation was typically expected to create improvements in accessibility, availability of OTCs, opening hours, product range and service. It was also expected to reduce medicine prices, although opponents of liberalisation argued that the quality of pharmacy services might deteriorate.

56. Because prices of prescription medicines were regulated at the wholesale and retail level, one could only expect to observe improvements in prices of non-reimbursable OTC medicines. Very few studies of the price of OTCs had been made, and none of them could confirm a decrease in OTC medicine prices after liberalisation.

57. With regard to accessibility, liberalisation had increased the number of pharmacies as intended. The number of pharmacies in Sweden increased by 36% in the three years after liberalisation in 2009. The number of pharmacies in Norway had continued to follow an upward trend after liberalisation in 2001. However, the increase tended to be concentrated in urban areas, where there was already good accessibility. For example, figures for Sweden showed that only a very small proportion of new pharmacies and OTC retailers had opened in rural areas. This implied that other incentives and regulations were required to stimulate provision in such areas. There was an indication that opening hours had improved. However, liberalisation had also resulted in vertical integration. For example, in Norway more than 80% of the market had ended up in the hands of three wholesalers, and there was evidence that the product range had contracted and become more restricted to products of the owners.

58. Dr Vogler concluded that liberalisation in the community pharmacy sector did not always fully meet expectations. There was no evidence of increased price competition on non-regulated, non-reimbursed OTC medicines in the surveyed countries of Europe. Accessibility in terms of the number of pharmacies nationally had improved but there had been adverse effects in relation to equality of access in remote areas. Findings such as a distortion of competition due to unbalanced market power or uneven accessibility might well be relevant to countries with a less regulated pharmacy sector.

8. Presentation by the UK delegation

59. The **UK delegation** gave a presentation on ‘Competition issues in the market for anti-malaria drugs in Burma’.

60. Malaria was endemic in parts of Burma and was developing resistance to the standard treatment (anti-malaria monotherapy treatment or AMT) that could potentially spread around the world. The UK’s Department for International Development (DfID) backed a project led by PSI, an international charity, to help subsidise a switch to a new treatment (anti-malaria combined treatment or ACT) that was less susceptible to resistance.

61. The usual approach would have been to offer the subsidised product to any wholesale distributor willing to supply it. However, this was not possible because of political considerations. Instead, PSI offered a single company, AA, a temporary licence to distribute it in Burma under a retail price control, with PSI as the brand holder providing significant advertising.

62. There were concerns over whether giving a single firm such a competitive advantage would create risks for competition. Currently Burma does not have a competition law. In addition to meeting the health objectives, the scheme co-ordinators were keen to minimise damage to competition. DfID engaged the OFT to provide technical assistance to PSI in May 2013, by which time the scheme had been running for a year.

63. The primary theory of harm was that the subsidy would allow AA to build up a dominant position that it would be able to exploit after the price control ended. AA could potentially accumulate market power in two ways. One was through brand value: at the time there was no public sector involvement in the distribution of drugs to pharmacies, with the result that brand was important to consumers. The second was through foreclosure of the market: AA’s main competitor, BB, also supplied the treatment but might be forced out of the market without access to the subsidy.

64. This theory of harm would only be relevant if the project was successful. Since consumers could not afford unsubsidised ACT even at the current wholesale cost, no ACT would be sold irrespective of any retail monopoly mark-up. AA would only have an incentive to exploit a monopoly position if the unsubsidised wholesale cost fell to viable levels.

65. Three potential sources of mitigation of these potential competitive harms were identified. The first related to the brand effect. PSI advertised a government-approved quality seal rather than the AA brand. This reduced the branding advantage to AA and removed a barrier to entry (or re-entry) by BB, which would also be able to carry the seal. It was difficult to assess how successful this mitigation would be since the advertising was only just beginning and as yet only AA had access to the seal.

66. The second possibility concerned extending the subsidy to BB. This would remove the brand effect and foreclosure concerns, and potentially also concerns about fairness. However, there were also certain costs involved, such as the costs of negotiation with BB and additional advertising costs, and it was not clear that BB provided additional geographic scope. There was also a risk that the political objective would not necessarily be met.

67. The third source of mitigation was the fact that under the contract between PSI and AA, PSI retained all the IP rights to the brand, which it licensed to AA. If AA wished to continue to supply the product after the end of subsidy, PSI would be able to continue to impose a price control.

68. The OFT’s review concluded that there was relatively limited risk to competition if the scheme was successful, particularly since it took time to build up a brand and the subsidy was for only two years.

Of the three mitigations, the quality seal was the most uncertain, while extending the subsidy was the most costly. It was left to PSI to decide on an appropriate mitigation strategy.

69. Finally, the case of the ACT subsidy in Burma showed how competition objectives sometimes had to interact with other objectives, such as health policy-related and political ones. It also highlighted a reliance on the private sector in delivering healthcare in developing countries.

9. Presentation by Farasat Bokhari, Lecturer in Economics, University of East Anglia (UK)

70. **Dr Bokhari** gave a presentation on ‘Evaluating wholesale and retail mergers in pharmaceutical markets’.

71. Dr Bokhari began by pointing out that in obtaining drugs from manufacturers and passing them downstream, wholesalers and retailers add several differentiating services to what would otherwise be similar products. For example, wholesalers differ in the number and location of warehouses, storage capacity, and delivery frequency to pharmacies. Similarly, pharmacies provide different types of quality in terms of location of stores, hours of operation, queuing time, advice from a trained pharmacist, and other aspects of service. Thus, there is vertical and horizontal differentiation even in the distribution of one and the same drug, which means that it cannot be considered a homogeneous product. In turn, this implies that relying on measures of market shares, such as concentration ratios or Herfindahl indexes, can be misleading when predicting a merger’s consequences for market power.

72. Dr Bokhari then presented a model that permitted estimates of pre- and post-merger prices and market power (defined by price-cost margins), and of changes in consumer welfare due to a merger at the wholesale or retail level. In outline, the model involved a manufacturer selling a drug to wholesalers, who in turn supplied it to pharmacies. The wholesalers were permitted a maximum markup on the ex-manufacturer price and could choose the level of discount in selling to pharmacies. Pharmacies chose the quantity they wished to purchase from the wholesalers and the price and quality they offered consumers. Consumers then chose which pharmacy to visit based on the price, quality and location of stores.

73. The model predicted that a horizontal merger at the wholesale level would lead to lower wholesale discounts to pharmacies, and higher pharmacy retail prices. Typically, however, the increase in the retail price would be less than the decrease in the discount. In this case, the quality of services provided by pharmacies would decrease. A merger of pharmacies, on the other hand, would unambiguously increase retail prices and reduce service quality. In both cases, the extent of the change in quality and prices at the pharmacy level was an empirical issue depending on, among other things, consumer demand for pharmacy services.

74. The empirical challenge was to estimate this model on data from pharmacy sales of many thousands of different products. Mergers among manufacturers, by contrast, usually involved only one or two products. Dr Bokhari’s approach was to convert the sales of individual drugs into standard units, and then to aggregate the quantity and price of these standard units for each pharmacy chain or geographical market. Data could also be gathered on the observable quality characteristics of pharmacy chains in each market (such as the number of stores, trained pharmacists, and average opening hours). One could then write the quantity of demand at each pharmacy as a function of the price and quality of the pharmacy itself and of its competitors, using one of several standard demand models which today were easy to program.

75. Having estimated this model econometrically, it was then possible to estimate the firms’ marginal costs mathematically using the assumption of profit maximisation, even without direct data on those costs. This information could then be used to simulate the effects of a merger on prices and markups, on measures of quality (such as the number of new pharmacies), and hence ultimately on consumer welfare.

For example, one could analyse what level of monetary compensation would have to be given to a representative consumer or third-party payer in order to leave them as well off as they were before the merger. This analysis could then be used in assessing whether or not a proposed merger should be permitted.

76. Dr Bokhari emphasised that the theory, tools and data for such analysis were now well developed and widely available, and suggested that applied practitioners should incorporate it more routinely into their work.

10. Presentation by Mr Adrian Majumdar, RBB Economics (UK)

77. **Dr Majumdar** gave a presentation entitled ‘Competition issues in the distribution of pharmaceuticals: a UK retail perspective’.

78. Dr Majumdar’s presentation considered the theories of harm that were examined by the Office of Fair Trading (OFT), UK’s competition authority responsible for phase one merger investigations, in a relatively recent merger among two retail pharmacy chains.

79. Dr Majumdar explained that in reviewing such a merger, the OFT would look at three products: prescription medicines, pharmacy-only medicines that did not require a prescription but must be sold in the presence of a pharmacist, and general sales list (GSL) medicines such as headache tablets that can be sold by non-pharmacy retailers.

80. The OFT concluded that it was not concerned about GSL medicines because they are sold very widely and are subject to competition. It also considered that a merger among pharmacy chains at the retail level would be unlikely to cause substantial consumer harm in relation to prescription medicines because there was no price competition (prices are regulated) and only limited non-price competition on dimensions such as location, range, opening hours and quality of service, which were also regulated.

81. With regard to pharmacy-only medicines, the OFT considered that there was some scope for price competition, and therefore for potential harms from a merger. However, there was some competitive pressure from substitutability with GSL medicines, as many pharmacy-only medicines are stronger versions of GSL medicines. It did not expect negative effects of a merger on non-price competition, since non-price factors are regulated.

82. Because of the limited possibility for harm to competition, the OFT concluded that it should apply relatively generous screens for assessing proposed mergers. It found that over 75% of consumers travelled less than one mile (1.6 km) to collect a prescription medicine, and therefore adopted a rule that a merger would be considered problematic if it reduced the number of fascia (pharmacy owners) operating within a one-mile radius from three to two or two to one. This provided a simple screening rule to deal quickly with mergers where there are many overlaps in terms of the local markets.

83. However, certain subtleties had to be considered when applying this rule. For example, a four-to-three local concentration could still present competition concerns if the two merging pharmacies were close together. Secondly, the conclusion could differ according to whether the geographic market was defined as a one-mile radius around a pharmacy or around a source of demand such as a GP surgery. Thirdly, if the merging chains owned several pharmacies between them in a local market, the merged entity could end up with a very high market share even if the reduction in fascias was from four to three.

84. Dr Majumdar turned finally to the issue of input foreclosure when one of the parties in a retail pharmacy merger was also a wholesaler. Here, the first question considered by the OFT was whether the integrated wholesaler could increase prices in a way that would harm rival pharmacies. This was possible if

the integrated wholesaler had upstream market power. The second question was whether it would have an incentive to do so. The concern was that the integrated firm might wish to charge higher prices to rival pharmacies, thus increasing their prices to consumers, who would switch to the integrated pharmacy. However, this incentive to raise rivals' prices did not exist if the rival firms had low rates of pass-through to prices, or if the diversion from rival pharmacies to the integrated pharmacy was small. Finally, the vertical merger assessment would take account of potential efficiencies. For example, the integrated wholesaler might supply the integrated pharmacy at cost or gain logistical savings, putting downward pressure on prices. The overall merger assessment would take account of all of these factors.

11. Presentation by the Mexican delegation

85. A delegate from **Mexico** gave an oral presentation on trends in the pharmaceuticals market in Mexico and recent a vertical merger case.

86. There were 116 producers of pharmaceuticals and raw materials in Mexico in 2012, some of whom had their own distribution division. Wholesale distributors were divided into private sector enterprises, including private hospitals, insurance companies and integrated pharmacy chains, and the public sector, including social security institutions and the federal and state governments. Retailers consisted of both independent pharmacies and pharmacy chains, with the latter being of either a traditional format or, increasingly, a convenience format, including supermarket pharmacies. The only regulatory barrier to entry in retail pharmacy was the requirement for staffing by qualified pharmacists. Some supermarkets and chain pharmacies had their own distribution division.

87. Four distributors accounted for 58% of private distribution in 2012, as compared with 81% in 2009. The decline was due to an increase in the market share of regional competitors and in direct sourcing from manufacturers by supermarkets and large chains. Pharmacies often purchased from more than one distributor. Private demand represented 82% of sales and government demand 18%.

88. Sales of generic drugs were increasing thanks to the adoption of regulatory rules that clarified equivalence issues and a regulatory change that allowed an increase in imports by eliminating the requirement for the installation of plant in Mexico. Generics accounted for 73% of demand by units and were significantly cheaper than branded products. This had produced savings for consumers of more than 1.5 billion dollars in a period of four years. The Mexican government had also adopted OECD recommendations in the public procurement of pharmaceuticals.

89. In 2010 the Mexican Federal Competition Commission (CFC) examined the acquisition of Farmacias Ahumada, a pharmacy chain with more than 700 stores, by Casa Saba, a national distributor that also owned a small pharmacy chain. Its analysis of horizontal effects found that a small overlap in some regions was not enough to alter unilateral market power or the conditions for co-ordinated behaviour aimed at increasing retail prices. It also analysed the possibility of upstream abuse of dominance against pharmaceuticals producers and downstream exclusionary behaviour against independent pharmacies or pharmacy chains. Its conclusion was that Casa Saba did not have or did not obtain substantial market power as a result of the merger.

12. Presentation by the French delegation

90. **France** gave a presentation of a sectoral enquiry into the distribution of non-hospital medicines, undertaken by the Autorité de la Concurrence in 2013. The Authority's report had examined competition throughout the supply chain from manufacturing, through distribution, to retail, and set out areas where it was empowered to intervene.

91. The delegates explained that the price of drugs in France is regulated under an agreement signed between the government and individual pharmaceutical manufacturers. The marketing of drugs is also regulated through the issue of marketing authorisations.

92. In its report, the Authority highlighted recommendations for good practice on the part of manufacturers and set out areas where it could exercise its powers in the event of anti-competitive behaviour. At the same time as it issued its report, the Authority fined two manufacturers, Sanofi-Aventis and Schering Plough, for abusive practices that hindered the entry of generic equivalents of certain of their products.

93. The Authority found that discounts offered by pharmaceuticals manufacturers for generic drugs frequently exceeded the legal maximum. The maximum level of discount was recently increased in response to the Authority's concerns. The Authority also recommended that reimbursements for originators and generics should be differentiated in order to favour generics and thus increase their adoption.

94. The Authority considered that the list of reimbursable generic medicines was narrow, particularly when compared to Germany and the UK, and that it should be expanded. Branded paracetamol, for example, was still not substitutable.

95. The Authority also looked at intellectual property rights. While emphasising the importance of patent enforcement for innovation, it drew attention to potential anti-competitive practices in relation to patents nearing expiry. These included pay-for-delay agreements under which the manufacturer of an original drug paid manufacturers of generics to delay introducing equivalents, and the bringing of multiple proceedings for patent infringement solely with a view to creating an entry-deterrent cost for generic manufacturers. The Authority warned that it had powers to take action against such practices.

96. The delegates explained that various kinds of entity were involved in the distribution of drugs to pharmacies in France. These included not only traditional wholesalers, but also buying associations of pharmacies who negotiated directly with manufacturers in order to achieve better discounts, especially on non-reimbursable OTC drugs.

97. The Authority noted that wholesale distributors were subject to public service obligations to which other entities involved in distribution were not subject. This represented a higher fixed cost for wholesale distributors and could disadvantage them in competing for sales to pharmacies, particularly in relation to non-reimbursable OTCs.

98. It also found that manufacturers offered higher discounts when selling direct to pharmacies than when selling to wholesale distributors and other intermediaries such as buying associations, despite the much the larger volumes ordered by the latter. This indicated a lack of countervailing buyer power, and resulted in some pharmacies, especially smaller ones, being unable to offer low prices to consumers. The Authority formulated various recommendations aiming at strengthening intermediaries' buyer power.

99. The Authority also reiterated its stance on the pro-competitive effect of parallel trade in medicines, particularly in the case of patent-protected drugs. It drew attention to rulings by the European Court of Justice on manufacturers who had attempted to limit parallel trade in their products, and stated that it had powers to take action against manufacturers who set up artificial barriers to parallel exports from France to foreign countries.

100. With regard to retail, the delegates explained that in France drugs may only be sold by pharmacies, which must be owned by registered pharmacists and which are subject to restrictions on their location according to population quotas.

101. A number of innovations were occurring in the role of pharmacists, such as new sources of remuneration for providing additional services. In this context the Authority recommended that the sale of OTCs should be opened up to non-pharmacy retailers. The Authority had looked at the liberalisation of OTC sales in Italy, where OTC prices had fallen by 25% without harming the sustainability of the dispensing pharmacy network. A French consumer association estimated that prices in France would fall by 15% while the number of outlets would increase by 10%. However, the Authority recommended that such sales must take place in a dedicated sales area under the supervision of a qualified pharmacist, and be subject to rules on traceability.

102. Finally, the Authority recommended that rules on the use of price information in advertisements should be relaxed in order to ensure that consumers were better informed about prices of OTCs and to encourage price competition. Spot checks by the Authority had revealed very wide differences in OTC prices.

13. Presentation by the Business and Industry Advisory Committee to the OECD (BIAC)

103. **BIAC** delegates were invited to speak on the role of competition and regulation in ensuring affordable access to medicines in high, medium and lower income countries.

104. BIAC believed there was a very important advocacy role for competition authorities to play in identifying unnecessary state-imposed restrictions on competition and finding ways to eliminate or reduce them. This was no easy task and required additional investment of resources by competition authorities, which BIAC felt was justified by the importance of this sector in the economy. It was not an easy task for businesses to operate efficiently across diverse and differently regulated markets.

105. The delegate said that although there was no global estimate, figures for Europe suggested there were substantial efficiencies to be had from improvement in the supply chain. In 2007 the European Commission pharmaceutical sector enquiry found that there was a gap of 76 billion euros between ex-factory and retail prices of pharmaceuticals in Europe. More recently the European Federation of Pharmaceutical Industries and Association (EFPIA) had estimated that the total EU pharmaceutical market was worth 163 billion euros at ex-factory prices and 238 billion at retail prices, so that 75 billion euros were still caught up in the supply chain.

106. While pharmaceutical wholesalers and pharmacies that had public service obligations were entitled to earn a reasonable profit, EFPIA believed it was imperative to ensure greater transparency in the supply chain and proper enforcement of existing regulatory obligations. If verification of stakeholders' compliance with their respective regulatory obligations to supply were based on more accurate supply and demand data, authorities would be better able to anticipate and identify potential shortages before patients' access was threatened.

107. EFPIA was in favour of swift entry of generics after an innovator's loss of exclusivity and considered that competitive generic pricing was capable of generating substantial healthcare savings. However, it felt that regulatory incentives to encourage generic entry were often designed to achieve short-term cost savings rather than create dynamic competition in the off-patent market. Regulations mandating the level of price differentiation between originator and generic medicines tended to diminish incentives to compete on price and could therefore lead to higher prices than would be expected from a system of market-based pricing. EFPIA also believed that demand-side incentives to encourage generic penetration should not discriminate between generics and off-patent originals.

108. The delegate then turned to what EFPIA considered were distortions caused by certain pricing policies. It was necessary to ensure that pricing provided an adequate return to fund future R&D

investments. For every ten thousand substances synthesised in laboratories only one or two actually made it on to the market, on average after 12 to 13 years of investment in R&D. Adapting medicines' prices on the principle of differentiated Ramsey pricing to reflect the ability to pay in different geographic markets or even in socioeconomic segments could optimise patients' access. This implied that wealthier nations should pay a price reflecting the value of innovative medicines and resist the short-term static gains to be earned from arbitrage or referencing low-price markets. Differentiated pricing could give healthcare systems in poorer countries access to medicines specifically priced for patient groups who would otherwise not be able to afford them, but low-priced medicines specifically provided for such markets should not then be diverted to more affluent populations for which they were not intended.

109. EFPIA considered that many pricing and reimbursement practices had the effect of discouraging price differentiation. According to the 2008 OECD report on pharmaceutical pricing, free trade and external reference pricing "may well result in problems in the availability and affordability of some medicines in some countries within and particularly outside the OECD and that will happen unless policy makers change pricing and reimbursement policies to adapt to the new market dynamic". A report by CRA in 2012 had demonstrated that international reference pricing and parallel trade did indeed have a negative effect on social welfare. EFPIA believed that low-price, low-income countries faced higher prices and reduced access to medicines as a result of current policies.

110. The delegate said that bolder steps to prevent national pricing policies from having significant adverse knock-on effects in other markets would therefore be welfare-enhancing. There were precedents for this in the industry supplying HIV and malaria drugs in Africa. The 2010 OECD report on value for money on health spending recognized that there was a consensus among economists and policy makers that "'cross-country price discrimination for patented pharmaceuticals is a win-win situation in which companies earn the revenues they need to invest in R&D while people in lower-income countries access the medicines they would not access at a high price". The delegate concluded by saying that EFPIA supported a broader debate amongst stakeholders on how best to use differentiated pricing in order to ensure affordability and accessibility of patented medicines to patients.

14. Moderators' summaries of breakout sessions

111. Delegates participated in three afternoon breakout sessions, which the respective moderators summarised briefly at the conclusion of the plenary session.

14.1 Breakout session 1 on Regulation of the retail distribution of pharmaceuticals

112. **Ms Shila Dorai Raj** (CEO, Malaysia Competition Commission), who chaired Breakout Session 1, summarised the discussion. The session had opened with Dr Vogler providing her views on the effect of liberalisation in retail pharmacy services. Countries had then shared their experiences with the removal of regulatory restrictions or the lack of regulation (as in the US), which had brought about increased entry and competition in the market for retail pharmacy services. A common theme in the session was a concern about the accessibility of medicines in rural areas, which, it was considered, justified regulatory intervention.

113. Overall, experiences with deregulation were diverse and the general conclusion was that policy changes needed to be based on an analysis of a country's specific circumstances.

14.2 Breakout session 2 on Roles of competition and regulation in the pricing of prescription pharmaceuticals

114. **Mr Abdelali Benamour** (President, Competition Council in Morocco), who chaired Breakout Session 2, summarised the discussion. The session had consisted of contributions a number of developed

and developing jurisdictions. A number of speakers challenged whether regulating the retail prices of drugs was always appropriate. For example, Peru considered that price regulation could create barriers to entry for generics, while in Russia, regulation of the prices of essential drugs had created shortages and had led to higher prices for unregulated drugs. The experience of Morocco showed that regulation did not always prevent price hikes, which were perhaps the result of increasing concentration and stronger bargaining power, the setting of high reference prices, and possibly bid rigging. Turkey and Spain both considered that reference prices for generics were sometimes set at too low a level.

115. The role of cheaper generics in constraining prices was also discussed. In general delegates were in favour of substitution by pharmacists. However in some countries, like Indonesia, this was not possible and the decision about whether to demand a branded or a generic drug remained with the doctor.

116. Finally, the participants had discussed agreements between industry operators. In Germany, Indonesia, Kazakhstan and Morocco, for example, there were cases of agreements between manufacturers and doctors that reduced competition and harmed consumers.

14.3 Breakout session 3 on competition issues in vertical and horizontal relationships in the distribution chain

117. **Mr Andrey Tsyganov** (Deputy Head, Federal Antimonopoly Service of Russia), who chaired Breakout Session 3, summarised the discussion. The session had begun with an assessment of the Chinese and Romanian experience. China explained the wide range of distribution arrangements that were used in the country. In Romania, an assessment by the competition authority suggested that new distribution practices by manufacturers had led to a reduction in competition. The role of regulation was also discussed. In Norway, for example, the legal obligation on wholesalers to distribute the full line of medicines across the whole country had been challenged by the competition authority on the grounds that it created a barrier to entry and it has advocated that the full assortment requirement is not necessary to ensure that all requested pharmaceuticals are available all over the country. In Bulgaria, vertical integration along the chain manufacturer – wholesaler – retailer is prohibited and the competition agency agreed with this restriction. Their argument was that the risk that vertical mergers could lead to the creation or the strengthening of a dominant position would outweigh any efficiency that may derive from this integration.

118. Issues of horizontal integration were discussed in relation to Chile, where a major cartel case concerned the pharmaceutical retail market. The presentation by Chile concluded that high concentration on the wholesale market favoured collusion at the retail level. A cartel case in Japan concerned suppliers to hospitals and reflected the latter's bargaining position. Finally, the case of India showed how trade associations could create anti-competitive outcomes through practices such as resale price maintenance and requirements for permission for retailers to operate in local markets.