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QUESTION A: PHARMACEUTICAL PRODUCTS AND COMPETITION LAW

In the case of pharmaceuticals, in what way should the application of the competition rules be affected by the specific characteristics of those products and markets (including consumer protection rules, the need to promote innovation, the need to protect public budgets, and other public interest considerations)?

INTERNATIONAL REPORT

Stephen Dnes

Lecturer in Law, University of Dundee, Scotland

Senior Consultant, Preiskel & Co LLP, London

s.m.dnes@dundee.ac.uk

A. Introduction and Summary

1. This report summarises responses received from national reporters in several jurisdictions, in response to the question:

> In the case of pharmaceuticals, in what way should the application of the competition rules be affected by the specific characteristics of those products and markets (including consumer protection rules, the need to promote innovation, the need to protect public budgets, and other public interest considerations)

2. A questionnaire exploring this question was prepared and circulated to national rapporteurs. This questionnaire can be found at the end of this report, attached as Annex A. In summary, the report asked questions seeking to determine if common practices exist in the treatment of pharmaceutical products under competition law. These questions were divided into four headings, seeking information on the following points. These are summarised together with the draft recommendations to which they relate.

1. Scope to differentiate pharmaceutical cases as a matter of law

3. These questions sought information on examples of patterns in competition law itself, as applied to pharmaceutical products. Specifically, it sought to identify categorisation rules on evidence, such as the object and effect distinction under EU competition law and the per se / rule of reason distinction seen in U.S. federal antitrust law. It also sought information on special pricing rules, and on the justifications or business defences available to pharmaceutical products.

> ***Recommendation 1:*** **No specific legal differentiation of pharmaceutical products is recommended, as there is no widespread and shared practice suggesting that pharmaceutical products should be distinguished as a matter of basic competition law. However, there may be scope to consider pharmaceutical-specific rules or**

reviews to address market power issues that can arise even in the absence of dominance.

Recommendation 2: **Market definition should operate with due regard to the specifics of the pharmaceutical market, notably the role of insurance and the role of medical professionals in prescribing products. These factors should inform a context-sensitive market definition survey that does not apply the WHO ATC categorisation without further calibration to market context.**

2. Enforcement patterns and consumer protection in pharmaceutical cases

4. These questions raised whether shared practices exist in the application of the law, rather than the law itself, and also looked to explore the relationship between consumer law and competition law in the pharmaceutical sector.

5. These questions considered (i) which types of competition law were or should prove most useful in competition law enforcement in pharmaceutical cases; (ii) the role of sector reviews; (iii) the role of sector-specific guidelines and bodies; (iv) the balance between private and public enforcement; (v) whether a register of patent settlements should be required, and other issues in the enforcement pattern.

Recommendation 3: **Increased private enforcement could be considered in jurisdictions which may have an enforcement gap, reflecting experience that would suggest its having a significant role to play in *complementing* public enforcement efforts.**

Recommendation 4: **Sector-specific joint purchasing guidelines could be considered as a means to address monopoly supply issues in some markets.**

3. Innovation and competition nexus

6. A major aim of the report is to identify areas of consistency in the interplay of competition law and intellectual property law, such as scope of patent tests and similar constructions designed to manage the interplay of originator patent protection and competition law. The focus of the questions here was on how strict the review of a so-called "reverse payment" would be under competition law, where patent protection exists, with a focus on whether a wider market effect on other rivals not party to the agreement was needed for competition law to bite, where the reverse payment happened under the shadow of patent protection. The role of the date of settlements within patent terms was also considered.

7. Related questions also considered the potential role of legislation and other measures to lower barriers to entry for generic products.

Recommendation 5: **Context-sensitive weighing of intellectual property and competition law concerns should take place, without reference to the scope of the underlying intellectual property law under a patent scope test.**

Recommendation 6: **Increased attention to patent settlements with potentially anti-competitive effects might potentially be beneficial to increase the scope to identify and address competition law issues arising from these agreements.**

4. Public finance and other considerations

8. Where public funds are involved, competition law protections might vary to reflect the role of public purchasing bodies, and to protect interventions in the market that might otherwise be eroded by practices such as parallel trade. The questions sought to identify exemptions granted to healthcare bodies, and also situations where public bodies responsible for healthcare decisions were not so exempted. The questions also raised whether the presence of a third party payer, whether public or private, altered analysis, and whether special treatment of otherwise protected parallel trade resulted. The questions also invited comment on any other relevant factor, both within heading (4) on the role of drug financing, and also as a

separate heading (5) inviting any other observations relevant to the interplay of competition law and pharmaceutical products.

Recommendation 7: **In some instances, international comparisons reveal drug price regulation to be broader than necessary in some instances; it could be curtailed in competitive markets while preserving important protections where there is market power.**

Recommendation 8: **Reference pricing could be carefully reviewed for potential competition law issues from price interdependency where benchmarks interact, and for its potential to provide a benchmark for predatory pricing cost measures.**

Recommendation 9: **Retail and wholesale margins, if regulated, should be regulated with reference to costs and not as a percentage of total sales, as a large or fixed retail margin creates a potent disincentive to prescribe generic drugs. Additionally, certain bans on loyalty discounts and other price cuts could be relaxed to enable more retail competition.**

Recommendation 10: **Obligations to supply entire markets should be carefully calibrated to ensure that this does not act as a barrier to entry in the distribution market.**

9. Detailed summaries and analysis of law, practice and experience from the reports received follows in relation to each heading of questions asked. The responses are drawn together to inform draft recommendations at the conclusion of the report.

10. Responses were kindly provided by lawyers in the following jurisdictions. The responses are published on the Ligue's website, www.ligue.org.

Australia

Austria

Belgium

Brazil

Czech Republic

France

Germany

India

Italy

Malta

Netherlands

Switzerland

United Kingdom

Ukraine

B. Summary of questionnaire responses

1. Legal differentiation of pharmaceutical cases in competition law

i. Differences in underlying legal standards

11. No respondent country reported differences in the underlying competition law rules as applied to the pharmaceutical sector, which in many cases derived from Articles 101 and 102 TFEU. In some cases, however, differences in practical application were noted. In this regard, the following response in the Czech report is representative of many jurisdictions:

> There are no specific provisions regarding market definition in pharmaceutical sector compared to other sectors. Of course specificities of this sector (price regulation especially, public health insurance regulation, legal provisions etc.) have been always taken into account in practice when markets within it were defined.

12. The Australian report noted particular difficulties in the design and application of specific legislation designed to guide the balance between intellectual property and competition law through the application of presumptions under section 53(3) of the Competition and Consumer Act, including a proposal for repeal of the relevant IP-specific legislation under the Harper Competition Policy Review conducted in 2015.

13. In the rare cases where some differentiation in the underlying law was noted, this was only as regards the application of certain underlying legal rules, where the unique pharmaceutical context gave exercise to some rarely-seen competition law provisions. The French report, for example, details scope to argue for objective justification on the basis of the underlying economics of parallel imports:

> In another decision related to parallel trade of medicines, the Competition Council considered that the practices of quotas system of laboratories in dominant position could have been accepted "at the condition that the restrictions induced by this regulation would have been limited to what is strictly necessary to a reliable and optimal supplying of the national market."

14. As explored further below, some of the reports suggest that policies to restrict parallel imports might justify otherwise restrictive conduct that is rarely if ever justified in other sectors, but as a matter of interpretation rather than a substantive legal difference.

15. In some cases, specific legislative provisions were flagged as being especially relevant to the pharmaceutical sector. In Brazil, Article 68 of Federal Law No. 9,279/96 provides for automatic mandatory licensing, where there is a finding of abuse by the competition authority or a court.

16. A rare example of pharmaceutical-specific competition law legislation is found in the Netherlands, which lays down a special, and potentially stricter, rule on dominance in the pharmaceutical sector. The Report noted:

> **1.1.1 The Concept of "Significant Market Power" in the Dutch Healthcare Market**
>
> Article 47 et seq. of the Dutch Healthcare Market Regulation Act provides the NZa with the authority to intervene if one or more health care providers or health insurers has significant market power (aanmerkelijke marktmacht). Significant market power is defined as the ability to – alone or conjointly – restrict the development of the actual competition on the Dutch market or a part thereof as a result of the possibility to act independently from (i) its competitors, (ii) health insurers, if it's a health care provider, (iii) health care providers and (iv) consumers. It is important to note that the legal definition of significant market power does not require abuse of this position.
>
> Significant market power is a rebuttal assumption for parties with a market share of 55% or more. The NZa defines the relevant market in accordance with the guidelines of the Commission. If the market share is between 40% and 55% significant market power is deemed plausible and between 25% and 40% it is considered a possibility. Below 25% significant market power is considered implausible.
>
> The mere existence of significant market power is sufficient for the NZa to exercise its powers. The NZa has a wide range of legal powers and can, amongst other things, oblige parties with significant market power to enter into fair and reasonable contracts, require parties to provide information to interested third parties and impose methods for calculating prices.

17. The Report also provides an example of the potential operation of this relatively unusual legislation. In AstraZeneca, the Dutch Competition Authority (the ACM) investigated a stark price differential charged for the drug Nexium: the hospital price for the product as 90% lower than the pharmacy price. However, analysis under Article 102 TFEU and its national counterpart fell on the dominance hurdle, in particular over disagreement as to whether the endorsement effect of the drug was sufficient to demonstrate independence from market competition as required for a finding of dominance under EU law standards.

18. To the extent that the unusual circumstances of pharmaceutical products may allow exploitative behaviours to occur without the dominance standard being met, legislation such as Article 47 et seq. of the Dutch Healthcare Market Regulation Act based on the concept of significant market power rather than independence from market discipline might be considered a useful addition to enforcement tools.

ii. Market definition

19. Responses on market definition highlighted market definition considerations relating to:
    a) The relative weight given to classification systems vs. other evidence of drug substitution;
    b) Significant market definition differences that can flow from the fact that physicians rather than consumers often choose drugs; and,
    c) The role of insurance and price regulation systems, which can affect product substitution patterns.

a) Classification systems, the SSNIP test, and other substitution evidence

20. Most countries are reported to follow the Anatomical-Theropeutic-Chemical ("ATC") drug classification codes propagated by the World Health Organization, but to varying extents. The central question here for competition law doctrine is how far such a classification system predominates over substantive analysis of competitive effects in the market place, such as evidence from a SSNIP or other market definition test. Practice differs on how far to follow the classification codes, and in what level of detail, rather than to gather additional evidence

of consumer and supplier use and consumption habits. For example, the Swiss reporter suggested that ATC codes were perhaps being relied on to a greater extent than direct evidence of substitutability. The Italian reporter noted a very high level of detail in the application of the codes, to make maximum use of the differentiation they can offer (e.g. distinguishing the injectable drug from other forms).

21. In Germany, a more use-specific approach has been followed, under which the ATC system is used as a starting point for market definition, while preserving scope to define a broader or narrower market definition as appropriate:

> For approved medicines, the third level of the Anatomical Therapeutic Chemical classification system (ATC 3) is generally used as a starting point.8 The ATC classification system divides medicines into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties. The system's third level groups medicines in pharmacological/therapeutic subgroups (e.g., the subgroup of "blood glucose lowering drugs, excluding insulins"). However, the BCA has recognized that, depending on the circumstances, a narrower or broader market definition may be appropriate.
>
> In *Bofar*, for instance, the Competition Prosecutor-General found that "the analysis of the relevant markets, as regards therapeutic use and substitutability from the point of view of the prescribing physician, differs clearly from the analysis of the same markets from the point of view of the distribution system to pharmacies"9. Adding that, in the latter situation, "the commercial freedom of companies to substitute one pharmaceutical product by another is nearly inexistent".

22. The French report similarly emphasises only using the ATC system as a starting point for analysis, and the importance of also considering other evidence relevant to market definition.

b) Physician, pharmacist and consumer choice

23. In many countries, market definition distinguishes consumer drug use from other markets, such as the wholesale supply market to pharmacies, on the basis that prescribing doctors tend to exercise more choice over the relevant product choice than do consumers. The French report notes the statement of the French Competition Authority that:

> The medical sector has […] a specific feature, since the decision of purchase is not taken by the final user but by the prescribing doctor, who is the one to choose the medication to be administered to his patient.

24. English litigation and UK competition law enforcement have also noted the price-insensitivity of prescribing doctors, suggesting that competition tends to occur on factors other than price, making detailed reference to wider market context essential:

> First, for prescription medicines, the ultimate consumer (the patient) is normally not the same person as the primary decision-maker (the doctor). As explained by the Court of Appeal in *Chemistree*, decisions on prescription medicines are made by the doctor, either alone or in consultation with the patient and "*it is that part of the buying chain that will, or will not react, to a SSNIP or other deterioration in the perceived qualities of [the relevant prescription medicine] as compared with other drugs*" (*Chemistree Homecare Ltd v AbbVie Ltd* [2013] EWCA Civ 1338, at [46] ("*Chemistree*")). Consideration of the hypothetical monopolist test (also known as the "*SSNIP*" test) may need to be adjusted, at least for prescription medicines, because the consumer (patient) tends not to be the primary decision-maker (or indeed the payer).
>
> The economic assessment may differ in pharmaceutical cases because demand-side decisions can be less dictated by price than in other industries. At least for certain drugs serving key medical functions, the pre-dominant factor in doctors' decisions will be the therapeutic function of the medicine in question. As noted in the Office of Fair Trading's ("*OFT's*") Reckitt Benckiser decision of 13 April 2011 (CA/98/02/2011), doctors' decisions "*are not typically driven by price consideration*" (paragraph 4.19) (the OFT has now been replaced by the Competition and Markets Authority ("*CMA*")). To take a concrete example, in the Napp decision of 30 March 2011 (CA/98/2/2001), the OFT noted that "*non-morphine drugs would not be considered a demand-side substitute for morphine on the basis of price alone as the decision to use non-morphine substitutes is based on patient needs and not price considerations*" (paragraph 54).

25. The shared experience across many jurisdictions suggests that this context is extremely relevant in determining product substitution patterns.

c) Insurance and price regulation

26. The role of insurance and reimbursement systems also affects market definition. In the Dutch AstraZeneca case mentioned above, the market for Nexium turned not only on whether it was in the same market as generics, but also on the purchasing and insurance elements of supply and demand which turned on insurance and reimbursement aspects of substitutability.

2. Enforcement patterns, specialist bodies and reviews, and consumer protection interplays

i. Enforcement patterns

27. No general trend was reported to suggest that the ban on restrictive agreements, the ban on dominance, or merger review law tends to predominate, and several reports noted activities in all three areas. For example, the Czech report notes no significant differentiation on this point.

28. The role of price caps seems to have limited the scope for excessive pricing cases, perhaps suggesting that exploitative abuses such as excessive pricing have, in practice, proved less important than exclusionary abuses such as predatory pricing or conduct intended to raise barriers to entry such as "product-hopping".

29. The role of direct price regulation and its impact on competition law analysis is explored further in section (4) below. In terms of the enforcement pattern, we can note that the jurisprudence on exploitative abuse may be limited because of the prevalence of price caps. Where these are successful, they would appear to have been potent means to prevent exploitative abuse, although this may arguably have come at the expense of dynamic innovation benefits as explored further in the discussion under (4) below. The UK and Dutch reports noted a preference for the pursuit of cases under dominance law where possible.

30. The UK report emphasised difficulties in bringing excessive pricing cases against exploitative abuses:

> In 2012, Pfizer transferred the marketing of Epanutin to Flynn Pharma. Flynn de-branded (or genericised) the medicine, and renamed it as "*Phenytoin Sodium Flynn Hard Capsules*". According to the CMA, Pfizer continued to manufacture the drug, which it sold to Flynn at prices that were significantly higher than those at which it had previously sold Epanutin in the UK – between 8 and 17 times Pfizer's historic prices. Flynn then sold the drug on to customers at prices which were between 25 and 27 times higher than those historically charged by Pfizer. This case is potentially interesting from a price regulation perspective. It might be argued by the CMA that Pfizer and Flynn have sought to take advantage of gaps in the UK's price regulation in order to hike up the price of Epanutin.

That said, it is hard to see that there is anything wrong per se with genericising a medicine which might normally be seen as an invitation to more competition on the market and the CMA bears the difficult burden of proof of showing that there was excessive pricing.

31. This comparative difficulty in bringing an exploitative case seems to be widely shared, although some examples of exploitative cases do exist, such as the UK Napp case discussed below. Where enforcement has happened under monopolization or abuse of dominance standards, this has more commonly followed alleged predatory pricing or discounting schemes (see e.g. the Ely Lily case referred to in the Belgian report and discussed further below in relation to reference pricing). In these cases, courts appear to have struggled to weigh the potential for anti-competitive foreclosure from predatory prices against short-term consumer benefits from decreased prices. (This complexity may reflect issues with relatively low variable costs in creating additional pharmaceutical products, and seems to be an especially severe instance of the potential for low average costs enjoyed by incumbents potentially to foreclose rivals in the short to medium term.)

32. Reports made only passing reference to merger clearance law, e.g. the Swedish report which reports only 30 merger cases since 1993, a seemingly low number. This suggests that more attention could possibly be paid to this area of law: Although many drug mergers will trigger EU jurisdiction, there may be scope to increase scrutiny in distribution mergers, especially in markets where distribution appears to have encountered competition issues.

ii. Public enforcement and fines

33. Significant fines have been levied across many jurisdictions. In most reports, fines predominate and disgorgement remedies are not prominent.

34. The preponderance of fines have followed findings of anticompetitive unilateral conduct, although some conduct has also encompassed distribution restraints. Examples of recent enforcement activities resulting in fines include significant fines in Brazil, France, Germany, Italy, and the UK:

Brazil

35. In recent cases, the Brazilian competition regulator CADE has imposed significant fines, including a $10 million fine where a pharmaceutical producer held a drug patent for the purpose of sham litigation in several jurisdictions. In August 2014, a laboratory was fined $1.5 million for a cartel designed to prevent generic sales.

France

36. The French report details a EUR 15.3 million fine for Schering-Plough for abuse of dominance preventing generic entry made by generic manufacturer Arrow. Here, there was evidence of an abuse of dominance by the patent holder, and also of anti-competitive agreements between the patent holder, a retailer, and an upstream supplier.

Germany

37. The Bundeskartellamt has sanctioned a number of price agreements and resale price recommendations in recent years, especially in relation to distribution:

- In 2007, the Bundeskartellamt imposed fines amounting to a total of EUR 150,000 on eight pharmacists due to price agreements on non-prescription medicines.

- In 2008, the Bundeskartellamt imposed fines amounting to a total of EUR 465,000 on pharmaceutical and pharmacist associations, as well as pharmaceutical companies, due to calls to pharmacists to adhere to the price recommendations of pharmaceutical companies.

- In 2008, the Bundeskartellamt imposed a fine amounting to EUR 10.34 million on a German pharmaceutical company for influencing resale prices of non-prescription medicines in pharmacies in an anticompetitive manner.

- In 2009, the Bundeskartellamt imposed fines amounting to a total of approximately EUR 1.2 million on pharmacist associations and private individuals due to a call to boycott a pharmaceutical wholesaler.

Italy

38. The national report for Italy details a EUR 10.6m fine for abuse of a dominant position in fraudulent extensions to patent protection:

> Recently, in the *Pfizer* case, the IAA found that the company had abused its dominant position in delaying the entry onto the market of glaucoma treatments based on Latanoprost (marketed by Pfizer as Xalatan). Pfizer was found by the IAA to have implemented a complex strategy of fraudulently seeking to extend the patent coverage for Latanoprost by making a divisional patent application and requesting a supplementary protection certificate (SPC) to extend patent protection until 2011, and to have started a number of legal and administrative actions against generics producers. The company, however, argued that it had lodged its application in full compliance with intellectual property law in order to protect its investments in research and development, and was merely defending itself in litigation brought by generics.
>
> The €10.6m fine imposed by the IAA was at first instance annulled by the Court, which fully accepted the Pfizer's defiance based on compliance with IP law. However, the Italian Council of State (the Administrative Supreme Court), overturned the first instance judgment in January 2014 and reaffirmed the IAA.

UK

39. Significant fines have been levied by the UK competition authorities, including:

- A £3.21 million fine on Napp Pharmaceuticals;
- A £3 million fine on Genzyme;
- A £10 million fine on Reckitt Benckiser;
- Most recently, a £45 million fine on a number of pharmaceutical companies following allegedly anti-competitive patent settlement agreements.

40. In summary, there appears to be robust public enforcement of competition law through fines, across a range of jurisdictions.

iii. Private enforcement

41. In contrast with the very active public enforcement efforts summarised above, relatively few national reports disclose a significant level of private enforcement of competition law in the pharmaceutical sector. This stands in contrast with other industrial sectors, where private litigation is increasingly active.

42. Here, the UK national report is worth detailed review as an instance of a very high level of private enforcement, especially by public bodies, complementing the public enforcement seen elsewhere.

43. Total litigation may be understated, owing to confidentiality provisions in settlement agreements. Nonetheless, the report discloses a highly active private litigation pattern. This is especially significant because it complements the large public fines noted above, strongly suggesting that the availability of private damages claims has, at the margin, increased recovery by bodies affected by anti-competitive conduct.

44. Provided that the underlying harm is correctly identified, this should increase economic efficiency by drawing extra resources into enforcement at the margin. The relevant section of the UK report contains significant details and is reproduced in full below:

> There have also been a number of damages actions, some taken by competitors (see (i) and (iv) below) and others taken by the health authorities (see (ii) and (iii) below). These notably include the following:
>
> (i) Healthcare at Home initiated an action against Genzyme following on the OFT's 2003 decision. Genzyme produced Cerezyme which, as explained above, was used to treat Gaucher's disease. Genzyme delivered that medicine to patients' homes. Healthcare at Home provided the same service. Genzyme abused its dominant position by squeezing the margin available to Healthcare at Home (the price it charged Healthcare at Home was the same as the NHS list price). The damages

case settled in 2006 but an interim payment of £2 million in favour of Healthcare at Home was ordered by the CAT.

(ii) In 2002 and 2003 the Secretary of State for Health issued damages proceedings against a number of pharmaceutical companies (including Norton Healthcare, Ranbaxy, Generics UK Limited, and Goldshield Group) arising out of an alleged price-fixing cartel to fix the prices of generic medicines. These cases subsequently settled.

(iii) The devolved UK health authorities have sought damages from Servier for anticompetitive conduct. These cases were filed in 2012. When the Commission took its Servier decision in July 2014, arrangements were made for disclosure of that decision into a confidentiality ring, on terms acceptable to the Commission. The Claimants subsequently amended their claims in light of the Commission's decision. The claims go beyond follow-on actions in the sense that the claimants also allege that Servier made misleading representations to the EPO and the English courts in respect of the '947 patent which was one of the patents on perindopril (i.e. akin to the first abuse in the *AstraZeneca* case). The Servier damages cases are ongoing; and

(iv) A number of companies (including Teva and Norton Healthcare Limited) and public authorities (including the Secretary of State for Health) claimed damages from Reckitt Benckiser following the OFT's Gaviscon decision. The actions taken by the public authorities settled in 2014.

In addition to the above, other cases have resulted in the payment of damages without any claim being initiated in court.

45. The report notes that the litigation is driven to a considerable extent by the presence of large, public sector claimants, which differentiates private litigation in the pharmaceutical context and suggests that private litigation may have a particularly important role to play in the pharmaceutical sector:

As shown above, a number of the private damages actions have been taken by public health authorities where they consider that they have suffered loss as a result of anti-competitive behaviour by pharmaceutical companies. This is a differentiating feature of damages actions in this field of competition law.

46. Indeed, issues that might otherwise raise questions about the efficiency of private litigation such as passing on, are perhaps less keenly felt where there is a single, well-placed litigant such as a single payer healthcare provider, a social fund, or a large public insurer.

47. This growing litigation pattern in England and Wales, however, does not appear to extend to injunctive relief. For example, in AAH Pharmaceuticals Ltd & Others v Pfizer Ltd [2007] EWHC 565, the High Court rejected an application for interim relief on the basis that damages would suffice to repair competitive harm.

48. This pattern of active private enforcement is, however, relatively rare. The French report, for example, discloses large public fines, but not private enforcement to match these fines. Recent attempts to increase the scope for collective redress appear to have been limited by restrictions on the scope of claims to cases of physical injury, rather than financial harm (an arbitrary distinction from an economic, if not from a legal, perspective):

> This type of litigation might increase with the introduction in French law of the class actions with the Consumer Affair Act n°2014-344 of the 17th March 2014 also called "*Loi Hamon*".
>
> The class action was originally opened only for procedures regarding consumers and competition. Recently, a reform of the Act enabled user's associations that wish to obtain compensation for the prejudice suffered in the medical field45 to resort to the aforesaid class action. However, the latter can only concern the compensation of the prejudice resulting from a physical injury suffered by users of health system.

49. Although the context and appetite for private litigation might reasonably vary between jurisdictions, the UK experience in bringing significant numbers of claims on behalf of health funders, to complement private litigation, perhaps suggests a greater role for similar cases in other jurisdictions seeking to close an enforcement gap, if one is perceived.

iv. Sector specific measures and reviews

50. Practice on sector-specific competition law reviews is mixed. Some countries (e.g. Belgium) have not instituted such reviews, perhaps seeking to rely instead on EU-level reviews.

51. Where there have been sector-specific reviews, experience has been mixed. In Italy, a lengthy sector inquiry lasting from 1994 to 1998 led to some reform efforts, but a number of these were reversed in subsequent years.

52. A salutary episode can be seen in Australia, where a detailed report, the Pharmaceutical Patents Review 2012-2013, was shelved following a change of government with the Delphic comment that the review was "one of a number of reviews of the pharmaceutical system conducted during the term of the previous government," to which the new government had "no plans to respond" concluding that the report would possibly be considered in future policy.

53. Other sector-specific reviews have been more significant. For example, significant changes to Dutch practices on new drug adoption appear to have followed shortly after a February 2015 report on the current state of pharmaceutical markets, as explored further below in section (4).

54. A highly significant report was also seen in France, where reforms to commercial denigration law, which protects generic entrants against unfounded reputational slights that might otherwise discourage use of generic products, followed from the December 2013 publication of opinion 13-A-24.

55. In the UK, two detailed inquiries instated under the Enterprise Act powers to carry out market-wide studies appear to have identified significant issues: a 2007 study of NHS purchasing of branded drugs under the "PPRS system" concluded that it did not offer value for money. A report on direct sales of drugs by manufacturers to end consumers, i.e. bypassing wholesalers, identified potential cost increases flowing from a reduction in the service level provided to pharmacies and patients.

56. Although some sector-specific enquiries appear to have been useful, there seems to be little shared practice on the point, and certainly no inquiry with the seismic effect of the EU review that precipitated Lundbeck.

v. Sector-specific guidelines

57. Very few countries operate sector-specific guidelines on the application of competition law in the pharmaceutical sector, beyond the application of general instruments relevant to pharmaceutical cases such as the relevant Block Exemptions (e.g. Sweden, where the Technology Transfer Block Exemption was flagged for particular relevance).

58. In a rare case of sector-specific guidelines, the Dutch ACM has adopted guidelines on joint purchasing of pharmaceutical products by hospitals. This is potentially significant, as the guidelines provide a safe harbour for joint purchasing activities that might otherwise raise sufficient concern that they would not be pursued, even if arguably pro-competitive and thus legal under general competition law principles.

59. The Dutch report summarises the Guidelines as follows:

> Following its report, the ACM recently published its Guidelines on the joint purchase of pharmaceuticals for hospital care. The purpose of the guideline is to offer a safe haven for certain forms of joint purchase and describe the way the ACM assesses these types of agreements. Although in the past the ACM had provided some guidance on this matter, this safe haven for certain joint purchasing agreements is a new policy. The guideline applies to the joint purchase of pharmaceuticals by hospitals and one or more health insurers. The guideline focuses on these parties but leaves the option open for other parties to participate in the joint purchase, such as scientific associations.
>
> **1.** The total costs of the jointly purchased pharmaceuticals are limited to 15% of the turnover of each hospital and 5% of the turnover for each health insurer involved.
>
> **2.** The joint purchasing organisation must be sufficiently accessible for other participants based on transparent, objective and non-discriminatory terms in order to prevent

foreclosure. These terms can provide for a certain (quality) standard, for instance a minimum volume, as long as this is fair and reasonable.

3. There may be no unnecessary restrictions (legal or factual) for participants, for instance concerning the duration of the participation, purchasing obligations, restrictions on the purchase of pharmaceuticals outside of the organisation and leaving of the organisation.

The ACM stresses that any information exchange will only be acceptable if it is indispensable for the adequate functioning of the purchase organisation and that measures should be in place to prevent the exchange of commercially sensitive information. Also, the purchase organisation should – of course – not have the object of limiting competition, for instance if the hospitals should (also) agree on how to best negotiate with health insurers on the reimbursement of pharmaceuticals.

60. These Guidelines aim squarely at efficiency savings that can be achieved where the purchasing power of insurers and hospitals is combined in order to offset potential seller market power (an instance of an efficiency benefit from vertical integration of purchasing). In doing so, the guidance addresses an unusual and differentiating feature of pharmaceutical products, driven by originator patent protection. Offering a safe harbour where combined market shares are low shows a sensible role for tailored guidance to ameliorate potential market power issues on the seller side, which might be helpfully considered in other jurisdictions.

vi. Patent settlement register

61. No respondent flagged a national patent register as being especially important. Germany and the UK both stated that they prefer to rely on the EU-level register. Despite the absence of a formal register, the German report emphasised that the authorities watch patent settlements closely. The French report noted that there was little experience with patent settlements in France.

vii. Interaction of competition law and consumer protection law

62. The interaction of competition law and consumer protection law does not seem to pose unusually major issues in the pharmaceutical sector. The approach to the interaction of the two bodies of law appears to vary: for example, the Swiss report notes the potential for areas premised on other aims, such as social security law, to displace competition law analysis in certain situations.

63. The UK report refers to an unusual example of an argument that regulated pricing by specialist bodies should inform competition law analysis of related conduct: the Napp case rejected an argument that rate-of-return regulation under the PPRS pricing system should carry over to provide a shield to pricing which appeared to be excessive. Interestingly, although the PPRS pricing did not provide a defence, it may have played a role in lowering Napp's fine.

> The OFT held that Napp behaved abusively because *inter alia* it charged excessive prices for its sustained release morphine medicine. Napp sold the product separately to: (a) hospitals for heavily discounted prices because of the presence of competition; and (b) patients in the community where its prices were more than 10 times higher than to hospitals. Napp argued that the pricing of its sustained-release morphine product could not be deemed excessive because it was subject to regulation under the PPRS. The OFT found that it was not a defence to a charge of excessive pricing that Napp did not exceed the limit on return of capital ("*ROC*") allowable under the PPRS.
>
> This was upheld by the Competition Appeal Tribunal on appeal ([2002] CAT 1, at [406]-[427]). The CAT noted that the fact that an undertaking does not exceed ROC allowable under PPRS across the range of its products could not constitute a defence to excessive pricing on one specific product (see, e.g., [408] and [412]). However, the CAT did lower Napp's fine from £3.2 million to £2.2 million for various reasons. One of the mitigating factors it referred to was that, even though the existence of the PPRS could not be a defence, it may have been "*difficult for Napp to come to terms with the fact*" that the Chapter II prohibition on abuse of dominance imposed restraints on Napp's pricing behaviour in addition to those applied under the PPRS. The CAT's generosity in that regard may be linked to the fact that this was the OFT's first decision under the Chapter II prohibition.

3. Innovation and competition nexus

i. Scope of the patent test

64. No jurisdiction reported the application of a scope of the patent test, or similar shield to reflect intellectual property rights, as seen in some circuit court litigation in the United States. Instead, all respondents emphasised that a context-specific assessment and weighing of competition law and intellectual property law would take place. This rejection of the scope of the patent test is significant, because in principle it can both deny protection to activity that would be shielded by a scope of the patent test ("in-patent restrictions"), but also can lead to greater leniency where ancillary restraints fall outside of the patent doctrine. In the latter case ("out-of-patent restrictions"), a scope of the patent approach might perhaps suggest a stricter approach than would a balancing test.

65. This point is especially clear in the Swedish report, which refers to two KKV decisions on the point:

- *Nobel Biocare* (dnr 645/96) In a case on a licensing agreement, the KKV acknowledged that IPRs are restrictive of competition (because of their exclusivity) but also that they give incentives for competitive behavior. The KKV also expressly stated that the IPR holder could legitimately protects its interest defined by the IPR as well as the interest of the licensee.

- *Marabou* (dnr 1338/93) similarly rejected a formalistic approach of the patent, and expressly acknowledged that restraints could legitimately exceed patent scope in some circumstances.

66. This balancing approach was elegantly summarised in the Austrian report:

> The mere presence of intellectual property does not trigger an absolute bar to competition law enforcement. As a rule of thumb, it can be stated, that enforcing IP can never be considered abusive, settlements and other agreements however can and have to be measured on the scope of the respective IP right.

67. In other words, the court will look to the presence of a patent, but it will not predominate under a mechanical test.

68. The scope of the patent test is also reported to have been rejected in the UK, where the Paroxetine decision is reported to have concerned threats to litigation within the scope of the relevant patent. This appears to have been no bar to enforcement activity. Instead, conventional competition law analysis with no starting presumption appears to have been applied; significantly, a distinction was therefore drawn between vertical and horizontal restraints, leading to a "no grounds for action" decision in the case of one company subject to the investigation.

ii. Assessment of settlements

69. As with the scope of the patent doctrine, there is limited practice on the assessment of the competitive assessment of settlements. The French report, for example, notes very limited experience with patent settlements.

70. If there is to be guidance here, it appears that it will come from the EU Commission's Lundbeck decision. The UK report specifically flags this. The report notes concerns that a rule making it harder for patent holders to obtain an injunction against entrants where the entrants first "clear the way" with a prior warning of planned entry, at which point the patent holder would be expected to seek an injunction, on pain of an injunction being harder to obtain later on. The report flags concerns raised by the EU Commission that this approach could give rise to stronger incentives to settle at the "clear the way" stage, and thus to discourage entry.

71. This reference to Lundbeck suggests that national practice on patent settlements under competition law will closely mirror the EU level decision. However, the dearth of practice on the point may suggest a significant national-level enforcement gap, in that patent settlements have clearly been identified at the EU level, and also by authorities in other advanced economies, but may not currently be detected in all cases at the national level. To put the point another way, given that these settlements appear to be taking place on the basis of the

enforcement that is seen, there is no reason in principle to think that the settlements may not be significantly more widespread and that there may be scope to increase national level enforcement in relation to patent settlements at the margin.

4. The role of public finance, insurance, and the promotion of generic entry

i. Insurers and other protected bodies

72. Some jurisdictions report that funding bodies such as insurers and social welfare funds fall outside of the scope of the EU law concept of an "undertaking" for competition law purposes, and are thus exempt at least for some of their activities.

73. For example, in Germany many large public insurance companies known as AOKs are not fully subjected to competition law, because they are not considered to be relevant undertakings engaged in economic activity. The German report raises some concerns that this may shield rebate practices that would otherwise raise competition law concerns ("there is no meaningful enforcement towards certain payers."). The report does, however, note that public tendering law may mitigate some of the potential adverse effects.

74. The French report also notes that some undertakings are exempted from competition law analysis. However, with the exception of the French and German reports, the majority of respondents suggested that competition law applies to almost all relevant bodies in the supply of pharmaceuticals.

ii. Price regulation

75. The reports detail highly nuanced pricing regulation at the national level, usually involving elements of the categories of pricing models:

a) Mandatory drug pricing;
b) Blended systems;
c) Models setting specified price adjustments;
d) Reference pricing.

76. Alongside drug pricing, distribution pricing is often regulated. The use of specified distribution margins and distribution monopolies raise some competition law concerns and will be discussed below at (e).

a) Mandatory drug pricing

77. A common practice across several jurisdictions is to control drug prices direct, whether under a stand-alone price regulation power, or pursuant to the application of public funds. A stand-alone pricing power can be seen in Belgium, whose national report describes the system for setting a drug price:

> The Minister of Economic Affairs determines on a case-by-case basis the maximum ex-factory price (*i.e.*,the sales price excluding VAT as invoiced by the manufacturer or importer to the wholesaler) of ***all*** **medicines that are marketed for the first time in Belgium, irrespective of whether they are (i) reimbursable or non-reimbursable; (ii) available prescription-only or over-the-counter (OTC), or (iii) innovative or generic.**
>
> The Minister of Economic Affairs must also approve any requests to increase the approved maximum ex-factory price. In addition, the Minister of Economic Affairs fixed by Ministerial Decree the maximum distribution and dispensing margins applicable to respectively wholesalers and pharmacies as well as the pharmacies' maximum sales prices to the public.
>
> The distribution and dispensing margins vary, and their calculation basis differs, depending on whether or not the medicine concerned is reimbursable. For non-reimbursable medicines, a further distinction is made according to whether the medicine concerned is (i) an originator or hybrid medicine or a medicine that was registered on the basis of published scientific literature; or (ii) a generic medicine (including generic versions of reference medicines that were authorised by the Commission).

78. The national report notes that the result is somewhat restrictive, because it regulates all pricing, including that of generic products and non-reimbursable over-the-counter drugs; the reporter suggests that in non-reimbursable cases, a greater role for market mechanisms might be helpful, while preserving the cost-saving and public health considerations motivating the restriction for reimbursable drugs.

79. In other jurisdictions, de facto price control arises from the application of public funds, which can only be spent on drugs whose prices are regulated. In Sweden, for example, a regulatory body (the TLV) determines the price for drugs that are accepted for government-funded

pharmaceutical benefits, and sets the wholesale price for pharmacies as well as the sale price to consumers. In the Czech Republic, prices for products covered by public insurance are set by the State Institute for Drug Control ("SKUL") using a combination of a regulated wholesale price, and a regulated margin for distribution.

b) Blended systems

80. Some pricing systems regulate only some drug prices, while leaving others to the market. Some (Malta, the UK) operate a hybrid system involving mandatory and voluntary elements.

81. A prominent example of a system displaying a blend of market and regulated elements is the Dutch system, which is reported to have met with some success in lowering prices. Under the Dutch system, drug pricing is not generally regulated, with two particularly prominent exceptions:

- A requirement for insurers to reimburse at least one variety of each covered active substance.
- Some price caps are applied in the case of the most expensive medicines where hospital procedures involve pharmaceutical products or they are consumed in nursing homes.

82. The operation of this framework is described in detail in the report:

> Non-hospital pharmaceutical care, i.e. care obtained by the patient directly from pharmacies, is in principle exempted from product and price regulation by the NZa [the Dutch Healthcare Authority]. However, product and price regulation does apply to pharmaceutical care that is a part of another type of healthcare, most notably administration of pharmaceuticals as a part of hospital care and care in nursing homes.
>
> The product and price regulation for hospital care is of particular importance. Hospitals in the Netherlands can only send invoices for products consisting of a complete trajectory of diagnosis and treatment (called *DBCzorgproducten* or *DOT's*). This system is loosely based on the American diagnosis-related-groups (DRG's). The Dutch system uses approximately 3.000 unique products to describe (almost) every possible trajectory a hospital might offer.

The definition of each trajectory includes regular pharmaceutical treatment that is (or should be) part of good (hospital) healthcare. Expensive pharmaceuticals, however, are not included because of the (possible) distortive effects on the price for each trajectory. Instead they can be recorded and invoiced separately as an "add-on" to a trajectory.

Since 2012, for approximately 80% of Dutch hospital care products there is no mandatory or maximum price set by the NZa. Therefore, healthcare providers and health insurers are free to negotiate any price for the trajectories falling within this 80%. A maximum price is set for the remaining 20% of hospital care, giving healthcare providers and health insurers freedom to negotiate any price not exceeding that maximum.

The same system of maximum prices applies to the aforementioned add-ons for expensive pharmaceuticals. The maximum price for each add-on is set yearly by the NZa based on the lowest pharmacy procurement price (*apotheekinkoopprijs* or AIP). The NZa bases the AIP on pricing data provided by pharmaceutical companies to an online database.

83. From a competition law perspective, this approach is notable because it separates markets that might be considered competitive, from those where limited consumer choice or bundling effects might increase market power issues (especially arising from bundled drug provision). It ensures access by requiring insurers to provide a drug, while still preserving competition in the manufacture and distribution of the drug to the patient, by allowing the insurer to choose the cheapest supply in fulfilling its obligation to supply.

84. The Minister of Healthcare preserves a power to set a maximum price where necessary for public access, based on reference pricing described at (d) below. Additionally, a new "lock chamber" power allows the minister to "lock away" expensive new drugs for further expert review while their merits are evaluated; it remains to be seen how this will apply in practice.

85. The Austrian report notes that the power to intervene in cases of excessive pricing, although in theory possible, is very rarely used.

c) Models setting specified price adjustments

86. A number of jurisdictions provide for regulation of price adjustment. In theory, the UK position is that a voluntary price cap exists under the PPRS system for self-regulation of drug prices. However, in the absence of voluntary self-regulation, a residual power exists to reduce prices. In cases where companies have not agreed to PPRS price regulation, a 15% reduction in maximum prices has been applied from a 2013 baseline.
87. In Brazil, a detailed model providing for limited adjustment from a Drug Market Regulatory Chamber published price for covered products. This adjustment reflects inflation, market concentration, cost variations, and an estimate of manufacturer efficiency gains.

d) Reference pricing

88. It is very common to employ reference pricing to determine prices, or price caps, based on a blend of prices used for similar products in similar countries. By revealing a proxy for a reasonable price, reference pricing can be a helpful tool for competition law analysis in three main ways:

1. Reference pricing as a meaningful excessive price cap

89. As noted above, there are relatively few cases on excessive pricing under dominance law in Europe. This is likely to reflect the widespread application of price caps based on blended pricing. A typical approach to setting a blended price can be seen in the Dutch report:

> A maximum price for a (group of) pharmaceutical(s) is determined by comparing the average accepted prices as set per unit in Belgium, Germany, France and the United Kingdom.[1] If, in accordance with this comparison, a maximum price is set, then it is subsequently prohibited to offer, sell or distribute this (group of) pharmaceutical(s) to healthcare providers, including pharmacies and hospitals[2], or to patients for a price higher than the set maximum price.[3]

[1] Dutch Medicines Prices Act, section 2 subsection 2.

[2] Dutch Parliamentary Papers (*Kamerstukken*), 1994-1995, 24266, 3, p. 28.

[3] Dutch Medicines Prices Act, sections 4 and 5.

90. In Germany, a similar blended price approach applies under a fall back arbitration provision, in the event that payers and producers fail to agree pricing on a new drug under a partially-regulated framework.

2. Reference pricing as a reference point for predatory pricing cases

91. A blended price can also be used to help determine a benchmark for predatory pricing, because a carefully calibrated blended price, e.g. of generics in other countries, is a fair proxy for the reasonable costs of other operators. The French report notes this innovative use of a benchmark price used to ensure that sufficient returns to innovation are preserved when the relevant committee sets a drug price:

> In the context of the estimation of the improvement of the medical-economic service, the price of the innovative and intermediary products could not be lower than the lower price implemented under a period of five years in Germany, Spain, Italy and the UK.

92. A similar benchmark could be applied to predatory pricing cases, to avoid the issue faced by the Belgian court in Ely Lily in which it proved difficult to distinguish beneficial price cutting from predatory pricing; the benchmark would, of course, need careful calibration to ensure that similar products are being compared (e.g. a basket of generics in similar circumstances).

3. Market interdependency from blended pricing (potential MFN effect)

93. The prospect of blended pricing introducing interdependency raises potential competition law concerns, in that interdependency in reference pricing can act in a similar manner to a most-favoured-nation (MFN) clause in distribution pricing. Since cases such as Booking.com, these have attracted increasing scrutiny because, by requiring a price cut on one platform to be matched in all, MFNs can potentially discourage discounting in smaller markets.

94. The German report notes significant issues potential issues with reference pricing (emphasis added):

> Germany is crucial for market access in Europe due to its market size and International Reference Pricing. **Seventeen European countries alone reference to the German price. A successful**

AMNOG submission and price negotiation is therefore a cornerstone for any market launch in Europe.

95. If the German market is competitive, the widespread practice of following the German price could be beneficial. In line with the analysis in the MFN cases, however, care is needed to ensure that potentially pro-competitive price discrimination is not being foreclosed, especially in smaller or lower income markets where a lower price may induce increased output (an instance of Ramsay pricing).

4. Information exchange concerns

96. Additionally, concerns arise about improper information exchange as reference pricing systems become increasingly automated:

> The aspect of **international (external) reference pricing** – often not regulated by law but widespread in practice – becomes increasingly important in Europe as prices tend to become more transparent and payers are more frequently exchanging about prices of individual pharmaceuticals.
>
> The ERIPID database is one example in this respect where several EU Member States are collaborating regarding pharmaceutical prices. Certainly a practice problematic from the competition law perspective in general terms but less so if payers are exempt from competition law.

97. The German report perceptively notes the **potential for the importation of the price of the other countries, rather than the product itself**, in an interesting twist on parallel trading cases.

98. In summary, care may be needed to balance the pro- and anti-competitive potential of reference pricing.

e) Regulation of distribution margins and monopoly distribution

99. Drug distribution has taken a number of forms in the respondent countries. The Swedish report notes the abolition of an earlier distribution monopoly, which seems to be welcome

from a competition law perspective in the absence of evidence that a distribution monopoly was efficient or otherwise more beneficial to consumers than monopoly distribution.

100. The practice of regulating distribution margins is widespread. In some cases, this takes the form of a maximum distribution margin. In some cases, the margin is even set in law; in Italy, for example. Law 662/96 sets a fixed margin of 6.65% and 26.7% for wholesalers and retailers respectively.

101. This raises potential issues because of the unusual features of healthcare markets. As the retailer often chooses which drug to prescribe, there is scope to abuse a fixed retail margin. The Italian report wryly notes the resulting incentive to sell high priced drugs:

> There is no correlation between the distribution prices and the costs actually faced by the distributors for selling the drugs, and the mechanism creates a clear incentive to sell higher price drugs. [Despite the introduction of some modest discounting measures], generics manufacturers have faced difficulties in placing their products since the regulation still provides an incentive for pharmacists to dispense higher price products.

102. Other systems applying a cap to distribution margins, rather than a set amount, might potentially be favoured. The Ukrainian report notes the application of a margin cap, set at 10% for wholesale to retail and 25% for retail to the consumer.

103. Additional restrictions on retail competition include promotion and discount bans. Some of these bans, e.g. advertising bans, may be justified with reference to social and public health objectives. However, the Czech report singles out a number of bans which seem to limit retail competition without corresponding justification:

> According to the Article 32 subsection 4 of Act on public health insurance the only acceptable form of benefit connected with dispensation of drug prescribed by a doctor and paid form public health insurance is reduction of final price when such drug is dispensed in form of general discount, discount for specific item or discount for supplementary payment. Any other forms of benefits such as loyal cards, coupons, discounts for next purchases, volume discounts, discounts for other goods etc. are restricted. Such regulation seems to be unnecessary anticompetitive and makes no sense from a competition point of view.

104. Of course, discount schemes can sometimes be anti-competitive if applied by a dominant market, but a blanket ban without reference to dominance criteria may limit competition in distribution.

iii. Parallel trade restrictions

105. Issues can arise in EU countries where parallel trade in pharmaceutical products is protected by competition law, leading to incentives to engage in parallel trade between EU Member States where price differences exist. EU competition law has historically protected the right of parallel traders to operate across EU borders with a view to encouraging integration of the single EU market.

106. A number of EU respondents noted this issue and the application of the ban on parallel trade restrictions. For example, the Austrian report notes the parallel import proection as a "fundamental principle of the free movement of goods in the EU," although it queries whether it should be applied without any exception.

107. Interestingly, the British and French reports noted cases in which some restriction on parallel trade might be tolerated, in contrast with the usual starting point that parallel trade restrictions in the EU are not permitted once a product is released onto the single EU market.

108. In Chemistree, the English High Court ruled that AbbVie was not dominant in the relevant product market, and was therefore entitled to refuse supply of a product to a parallel importer. Although strictly speaking obiter dictum, there may be some significance in Roth J's suggestion that it may not be abusive to refuse supply where a justification exists, as where a pharmaceutical company supplies products for retail rather than wholesale use, with legitimate cause (here, there was evidence that AbbVie wanted to monitor its own supply chain and had only supplied the drugs in question to the customer in its capacity as a homecare provider). Commenting that Article 102 TFEU "never been held to oblige a supplier to adopt a particular manner of distribution of its own products", the Court suggested that the mere presence of parallel importing would not itself convert non-abusive

conduct into abusive conduct. It remains to be seen whether this objective justification would be followed in future cases, as these aspects of the case were not dispositive given AbbVie's lack of dominance in the relevant market.

109. The French report also contains a suggestion that some parallel trade restrictions could potentially be justified: restrictions on wholesale supply designed to prevent the purchase of drugs at regulated prices for resale in higher priced markets might be tolerated, in cases where public service obligations apply:

> In the case of restrictions on parallel trade by "simple exporters", the Competition Council considered that pharmaceutical companies, that limited or denied deliveries of medicines to exporters, wishing to purchase medicines in France to at an administered price, in order to re-sold abroad at a higher price, didn't commit an abuse of dominant position According to the Competition Council, the discrimination against wholesaler-distributors is justified by the supply constraints to which wholesaler-distributors are subject under their public service obligations.

110. The French report also notes that quota systems for medicines may be permitted where necessary for reliable supply, providing another potential argument that restrictions on parallel trade could potentially be justified more than is commonly thought to be the case in the EU.

iv. Generic entry promotion

111. Many jurisdictions promote generic entry. In the EU, this occurs under harmonised law on marketing authorisations, excusing the generic entrant from providing results from pre-clinical tests and clinical trials. The process is described in detail in paragraph 74 of the EU Commission's Servier decision.

112. Additionally, the reports identify as areas for possible focus with a view to lowering barriers to entry: (a) the scope for generic substitution, (b) scope for supply obligations to discourage entry, and (c) the prevention of generic denigration.

a) Legal protection of the substitution of generics for branded drugs

113. In many countries, it is permissible for the insurer or the pharmacist to elect to use a generic if desired, as noted above in relation to the Dutch insurers' ability to substitute a generic. There is also legal protection of generic substitution in France. A similar substitution mechanism exists for the UK under the system of "closed scripts" for which a branded drug must be prescribed, and "open scripts" where the law protects generic substitution. This widely-shared substitution power would seem to have significant pro-competitive potential.

114. The UK report notes the Reckitt Benckiser case, in which a drug was deliberately withdrawn and delisted to prevent its availability as a generic substitute shortly before its name would have become available for generic listing. In assessing this conduct, regard was had to whether there was a valid economic basis for the delisting decision; that the delisting would have been irrational in a competitive market, strongly suggested that the profits on the sales for the older drug were being foregone in order to protect or promote sales of a newer drug held by the same company.

b) Barriers to entry from supply obligations

115. An area potentially requiring further attention is that wholesale supply obligations requiring wholesalers to supply all pharmacies in the relevant jurisdiction can act as a barrier to entry. For example, the Swedish report notes that the supply obligation is carefully calibrated to mitigate this issue:

> The requirement for wholesale traders to supply pharmacies (see above question 2(i)) covered by their license may in practice restrict parallel trade as this may be a difficult requirement to meet for parallel imported medical drugs. In fact, the reason why the supply obligation has not been extended to include all medical drugs sold by pharmacies is that such a requirement would constitute an entry barrier at the wholesale level (prop. 2008/09:145, pp. 157-160).

116. The Belgian report notes a similar mandatory supply obligation requiring that "once the medicine has been placed on the market, it is available on a continuous basis and in sufficient quantities to persons who are entitled to supply pharmaceuticals to the public."

117. Care may be needed to ensure that mandatory supply obligations are tailored to their objectives, and do not inadvertently act as a barrier to entry for new wholesalers.

c) Protection of generic products from reputational denigration

118. In some countries, generic drugs suffer from reputational issues, despite being chemically identical to their branded counterparts. The French report notes deliberate attempts to denigrate generic drugs in cases such as Plavix and Subutex. On the strict approach adopted by the French competition authority, confirmed by the Paris Court of Appeal, generic manufacturers can challenge conduct unduly casting doubt among health operators on the efficacy of generic substitutes. The interplay of competition law and the protection of trading goodwill (e.g. denigration law, passing off law, product imitation law) is an area that could potentially be explored in greater detail.

C. Conclusion and draft recommendations

119. This report has reviewed law and practice across several jurisdictions relating to:

1. The legal context of pharmaceutical competition law cases;
2. The enforcement pattern associated with such cases;
3. The interplay of innovation policy and competition law;
4. The interaction of competition law with public finance and other public interest goals, including the promotion of generic entry.

120. On several points, there is insufficient shared practice to suggest specific recommendations. On certain points, however, practice is sufficiently widespread, or in a particular instance sufficiently desirable, to form the basis of draft recommendations for further review and discussion at the Congress.

121. In section (1), the questionnaire responses suggested that there is no widespread practice to distinguish pharmaceutical cases as a matter of law, and many respondents noted the satisfactory application of general competition law to the sector. However, there may be some scope to consider adopting sector-specific law as related to market power short of dominance, as seen in the Netherlands, to address situations where market power issues short of dominance can arise because of the specificities of pharmaceutical markets. This forms the basis of the first Recommendation.

> ***Recommendation 1:*** **No specific legal differentiation of pharmaceutical products is recommended, as there is no widespread and shared practice suggesting that pharmaceutical products should be distinguished as a matter of basic competition law. However, there may be scope to consider pharmaceutical-specific rules or reviews to address market power issues that can arise even in the absence of dominance.**

122. Many respondents strongly emphasised the importance of sensitive market definition, having regard not only to drug categories used by drug companies and bodies such as the WHO, but also to the specific use and application of the drug in its consumer context. In turn,

this use should consider the role of insurance in substitution patterns, and also the role of those selecting drugs, who may be different from end consumers. This forms the basis of Recommendation 2.

> ***Recommendation 2:*** **Market definition should operate with due regard to the specifics of the pharmaceutical market, notably the role of insurance and the role of medical professionals in prescribing products. These factors should inform a context-sensitive market definition survey that does not apply the WHO ATC categorisation without further calibration to market context.**

123. A potentially controversial recommendation looks to the increased scope for private enforcement seen in some jurisdictions. This reflects the complementary role private enforcement appears to have had in some jurisdictions, bring redress and deterrence in markets where repeated anti-competitive actions appear to have been seen. Although this recommendation may lack universal appeal, there would appear to be a case that opening the door to increased private enforcement has driven significant settlements from patent holders, to the benefit of payers. If a jurisdiction faces an enforcement gap, it might therefore seek to consider increasing the scope for private enforcement, to complement public enforcement of the law. The established position of payers seems to make them effective litigants who succeed in gaining redress.

> ***Recommendation 3:*** **Increased private enforcement could be considered in jurisdictions which may have an enforcement gap, reflecting experience suggesting that private enforcement having a significant role to play in *complementing* public enforcement efforts.**

124. In some markets, joint purchasing activities can offset market power issues. A powerful example of this possibility is contained in Guidelines issued in the Netherlands providing a safe harbour for joint purchasing activities below a moderate market share threshold. Allowing this vertical integration of purchasing could drive increased efficiencies, and forms the basis of Recommendation 4.

> ***Recommendation 4:*** **Sector-specific joint purchasing guidelines could be considered as a means to address monopoly supply issues in some markets.**

125. Considerable attention has been paid to the "scope of the patent" test applied in some U.S. Courts of Appeal, following the FTC's high profile litigation before the U.S. Supreme Court in Actavis. The responses noted widespread practices by which intellectual property law and competition law are applied without any starting presumption that one is to predominate, as might happen in a scope-of-the-patent test. This result seems to be favoured because of the scope to consider anti-competitive effects within patent scope, but also pro-competitive effects outside patent scope, which might be more difficult to credit or balance on a more prescriptive approach. Respondents favoured no blanket rule and flexibility should be maintained.

Recommendation 5: **Context-sensitive weighing of intellectual property and competition law concerns should take place, without reference to the scope of the underlying intellectual property law under a patent scope test.**

126. One curiosity in the responses was that, despite the widespread attention to patent settlements in certain jurisdictions, not all jurisdictions seemed to have an enforcement record in relation to patent settlements. Unless companies are not pursuing these settlements other than in countries where enforcement occurs, which seems unlikely, this may suggest an enforcement gap and a need for increased attention to potentially anti-competitive patent settlements.

Recommendation 6: **Increased attention to patent settlements with potentially anti-competitive effects might potentially be beneficial to increase the scope to identify and address competition law issues arising from these agreements.**

127. Detailed information on drug price regulation revealed a range of practice, some of which is more likely to foster efficiency than others. One rapporteur raised the issue of overly broad price regulation, as where price regulation is applied to competitive markets in which public access issues may not arise (e.g. over-the-counter generic medications): in these cases, it might well be sufficient to retain a power to intervene in a case of excessive pricing, rather than to set prices by regulation, and doing so would introduce competition into more of the market. This forms the basis of Recommendation 7, suggesting a more tailored approach to market power issues.

Recommendation 7: **In some instances, international comparisons reveal drug price regulation to be broader than necessary in some instances; it could be curtailed in competitive markets while preserving important protections where there is market power.**

128. Responses revealed reference pricing to be a very widespread practice. It is often beneficial, as where it informs a cost-based price cap; if carefully calibrated, reference pricing could even be expanded to be used as a means to estimate cost levels to help distinguish predatory pricing from legitimate price cutting. However, care is needed that excessive interdependency between markets is not being introduced by reference pricing, which could conceivably operate in the manner of a MFN or price matching clause, discouraging discounting in smaller markets.

Recommendation 8: **Reference pricing could be carefully reviewed for potential competition law issues from price interdependency where benchmarks interact, and for its potential to provide a benchmark for predatory pricing cost measures.**

129. Regulation of retail and wholesale margins appears to be relatively widespread. Where this takes the form of a cap, there is little threat to competition. Where a specific margin is specified, however, significant risks arise that pharmacists may not wish to prescribe cheaper, generic drugs (linking back to Recommendation 2 on the importance of context-sensitive market definition, to take account of the party actually making the product choice). There is no obvious reason for a fixed retail or wholesale margin from a competition law perspective. Bans on loyalty programmes and discounting could also be relaxed in some cases to introduce more competition into retailing.

Recommendation 9: **Retail and wholesale margins, if regulated, should be regulated with reference to costs and not as a percentage of total sales, as a large or fixed retail margin creates a potent disincentive to prescribe generic drugs. Additionally, certain bans on loyalty discounts and other price cuts could be relaxed to enable more retail competition.**

130. Many jurisdictions apply legislation requiring the supply of drugs to all relevant parties (e.g. pharmacies) in a particular jurisdiction. Although well-motivated, this provision could

potentially act as a barrier to entry in the case of distributors who do not have the reach to achieve this, and care should be taken in designing or applying any measure that requires immediate scale because of the risk of inadvertently creating a barrier to entry.

Recommendation 10: **Obligations to supply entire markets should be carefully calibrated to ensure that this does not act as a barrier to entry in the distribution market.**

Annex A: Questions for National Reporters of LIDC Geneva 2016

Background

The International League of Competition Law is gathering information relating to pharmaceutical antitrust questions ahead of its October 2016 Congress in Geneva. The Congress will analyse the following question with a view to making recommendations:

> In the case of pharmaceuticals, in what way should the application of the competition rules be affected by the specific characteristics of those products and markets (including consumer protection rules, the need to promote innovation, the need to protect public budgets, and other public interest considerations)?

The interaction of the pharmaceutical sector and competition law is potentially very wide-ranging, encompassing issues such as (i) anticompetitive agreements, such as market sharing and "pay for delay" restrictions on entry; (ii) monopolisation allegations, including price discrimination, excessive pricing, "evergreening" and product hopping; (iii) merger clearances; and (iv) competition law issues in licensing agreements. The special protection of drug originators under intellectual property law has the potential to pose unusually pronounced competition law issues.

With a view to determining whether Recommendations on shared practices can be made, the questions focus on: (i) whether pharmaceutical products receive differentiated legal treatment under competition law; (ii) whether any differentiated enforcement mechanisms exist, with particular reference to consumer protection; (iii) the interaction of pharmaceutical intellectual property protection and competition law; and (iv) whether there is shared practice on budgetary and other public interest considerations.

Your answers to these questions will form the basis of the Report for the Congress, and will be very greatly appreciated. Please do not hesitate to direct any queries to the International Rapporteur, Stephen Dnes, via e-mail at s.m.dnes@dundee.ac.uk.

1. The competition law context of the pharmaceutical industry

This section seeks to determine whether the treatment of pharmaceutical products is differentiated under the competition law of your jurisdiction.

a. Which legislative provisions of your jurisdiction are most likely to be applied to a potential competition law infringement in the pharmaceutical sector? Please provide the text of the key provisions of this legislation.

b. Is market definition in the pharmaceutical sector any different, compared with market definition in other industries, as a matter of law or as a matter of practice in your jurisdiction? Please give a brief account of the main decisions of competition authorities or court judgments on market definition in this sector, or of any specific legislative provision dealing with this issue.

c. Is there a "per se" or "object" infringement rule by which evidence assessment tends to be truncated in pharmaceutical cases in your jurisdiction? If there are cases or decisions of competition authorities showing this rule in operation, please provide brief summaries of them.

d. Is there difference in the scope to argue justification of restrictions of competition in pharmaceutical competition law cases in your jurisdiction, such as specific legislation or guidance? Is there any limitation tending to limit the scope to argue justifications for potentially restrictive conduct, such as a "per se" or "hardcore" rule?

e. Is there any special legislation defining excessive or discriminatory pharmaceutical pricing in your jurisdiction, differentiating it from "ordinary" excessive or discriminatory pricing cases?

f. Please comment on any other aspects that you consider to be relevant in which the legal treatment of pharmaceutical sector cases tends to be differentiated in your jurisdiction, compared with other competition law cases.

2. Enforcement mechanisms, remedies and consumer protection

This section seeks to assess whether there are special patterns of enforcement, such as the use of consumer protection law, specialist bodies, specialised remedies, and whether the balance between public and private enforcement differs in the case of the pharmaceutical industry.

a. Is there any pattern by which pharmaceutical competition law issues in your jurisdiction tend to be dealt with primarily by laws against restrictive agreements, laws against monopoly, or by merger review?

b. Does competition law interact with consumer protection law in your jurisdiction? If so, please provide examples of the interaction of consumer protection law and competition law.

c. Are there any specialist bodies with responsibilities relating to pharmaceutical competition law cases in your jurisdiction, such as a pharmaceutical regulator with a competition law competence, or a consumer protection body with specialist pharmaceutical competence? If so, please provide a brief description of the body and its powers.

d. Please provide details of any sector-specific reviews of competition law in the pharmaceutical sector. Have any such reviews led to increased enforcement activities?

e. Is there any set of guidelines particularly relevant to pharmaceutical competition law cases in your jurisdiction, such as a pharmaceutical-specific set of guidelines or a set of competition law guidelines addressing intellectual property issues?

f. Is enforcement in pharmaceutical cases primarily public or private in character? Does this differ from the situation in other industries?

g. Which remedies tend to be applied in pharmaceutical competition law cases in your jurisdiction, such as fines, disgorgement of profits, damages, or injunctions?

h. Is there a mechanism for the monitoring of patent settlements in the pharmaceutical sector, such as a register of patent settlements?

i. Are pharmaceutical suppliers obliged in your jurisdiction to make available pharmaceutical products that they are licensed to sell? What is the extent of any such obligations?

j. Are there any decisions of competition authorities or court judgments that deal with the application of the competition rules to agreements or conduct in relation to the distribution of pharmaceutical products (e.g. agreements between manufacturers and distributors or retailers or conduct such as refusal to supply)? To what extent do those decisions or judgments suggest that the application of the competition rules to the distribution of pharmaceutical products is affected by the characteristics of pharmaceuticals?

k. Please comment on any other aspects that you consider to be relevant of the interplay of consumer protection law and competition law in the context of the pharmaceutical sector in your jurisdiction.

3. Innovation questions

This section gathers information relating to special treatment of pharmaceutical products to promote innovation, notably the treatment of originator patent protection by competition law in your jurisdiction.

a. Is there legislation promoting generic entry in your jurisdiction? If so, please provide details of instances in which competition law analysis has been applied in the context of the legislation.

b. A major aim of the report is to identify whether there is consistency across jurisdictions in the factors taken into account to assess the interplay of competition law and intellectual property law claims. Please comment on whether the following factors tend to be taken into account when a court or regulator decides whether intellectual property has been exercised in an anti-competitive way in pharmaceutical markets.

   i. Do courts and regulators in your jurisdiction provide a shield for potentially anti-competitive conduct on the basis that it falls within the scope of intellectual property (sometimes referred to as a "scope of the patent" approach)?
   ii. If so, how expansive is the protection? Does the mere presence of intellectual property trigger an absolute bar to competition law enforcement (e.g. allowing even a large reverse payment provided it is made within the patent term), or is a balance struck between the intellectual property right and competition law?
   iii. Must an agreement exclude rivals to trigger competition law enforcement, or does it suffice for an agreement (e.g. pay for delay) to exclude only the party to the agreement?

iv. Are there examples showing the difference between acceptable settlement payments and unacceptably restrictive settlement in your jurisdiction?
v. Is the date of the settlement in the context of the patent term a relevant consideration?

c. Please comment on any other relevant factors other than those already raised in question 3(b), if any, that tend to be looked at in pharmaceutical cases in your jurisdiction to adjudicate conflicts between competition law and intellectual property law claims.

d. Please briefly comment on the barriers to entry typically faced by a generic drug maker looking to enter the market. Are there examples of these barriers being in any way artificially raised?

4. Public finance considerations

This section seeks to assess whether there is differential treatment of pharmaceutical competition law cases on the basis that public funds are involved, such as parallel trading bans to support price control.

a. Some jurisdictions exempt certain bodies in the healthcare industry from competition law, such as by granting insurers or bodies exercising a public competence blanket exemptions or by not including them as relevant "undertakings". Is competition law applied consistently to healthcare purchasers and providers in your jurisdiction? If it is not, what is the basis for differential treatment?

b. Does enforcement on behalf of third party payers such as insurers or public funding bodies tend primarily to be public or private in character? Please comment on any relevant differences, if any, in the enforcement pattern on the basis that such bodies are involved.

c. Please provide brief details of pricing controls of pharmaceuticals in your country. Do these differ if a public healthcare provider is purchasing drugs?

d. If so, are there restrictions on parallel trade or resales of those drugs subject to price control? Are any such restrictions specific to pharmaceutical products, e.g. a special legislative provision, or do they merely reflect the application of ordinary competition law doctrine?

e. Please comment on any other points of current differentiation that you consider to be relevant in the competition law treatment of pharmaceutical products in your jurisdiction that are made on the basis that public funds are involved.

f. Please comment on any other public interest considerations you believe ought to be relevant to competition law analysis in the pharmaceutical sector, if any.

5. Any other considerations

a. Please comment on any other aspects of the interaction of competition law and the pharmaceutical sector in your jurisdiction that you consider likely to be relevant to the League's Report and Recommendations.
