Questionnaire A for National Reporters of LIDC Geneva 2016

"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.

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.

Chapter I of the Competition Act 1998 ("*CA1998*") prohibits all agreements between undertakings and concerted practices which have the object or effect of preventing, restricting or distorting competition, and which are capable of having an effect on trade in the UK (section 2). If the arrangement in question affects trade between Member States, Article 101 TFEU may apply. Section 9 provides for an exemption where the arrangement meets four criteria ensuring, on balance, pro-competitive effects (mirroring Article 101(3) TFEU).

Chapter II of CA1998 prohibits any abuse of a dominant position which is capable of having an effect on trade within the UK. An abuse may also breach Article 102 TFEU if there is an effect on trade between Member States.

Part 6 of the Enterprise Act 2002 ("*EA2002*") established the "*cartel offence*" for individuals. Section 188 of EA2002 provides that an individual who is involved in the most serious anti-

competitive agreements can face criminal prosecution and face a term of imprisonment of up to five years and/or an unlimited fine. There are a number of exclusions from and defences to the offence (sections 188A and 188B of EA2002). Where the conduct pre-dated 1 April 2014, it was necessary to show that the individual behaved dishonestly. The cartel offence has only rarely been utilised and has not been applied in any pharmaceutical cases but it could potentially be utilised in the future.

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.

The legal framework used to define the relevant market in pharmaceutical cases in the UK is the same as used for market definition in other industries (primarily encapsulated in the European Commission's Notice on Market Definition, OJ 1997, C372/5).

However, market definition is an economic exercise and is strongly influenced by the specific economic circumstances at play in pharmaceutical cases. A number of specific features are relevant.

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).

Second, 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).

Third, and similarly, neither patients nor doctors pay for the bulk of the costs of prescription medicines and the UK regulates, to some degree (albeit perhaps in a less interventionist manner than other countries), the pricing and reimbursement of medicines (Reckitt Benckiser,

paragraph 4.19). This feature can again affect the extent to which demand for a product and the behaviour of other suppliers, can respond to a change in price. In the Servier decision of 9 July 2014 (C(2014) 4955), the European Commission assessed efforts by UK Primary Care Trusts[1] to persuade doctors to prescribe cheaper medicines but considered that this was insufficient to impact sales of perindopril to a material level (paragraph 2280). In the Shire / Viropharma merger case, after mentioning that doctors are primarily motivated by clinical efficacy, the OFT noted that their "*prescribing behaviour may nevertheless be indirectly informed by price insofar as they are encouraged to follow prescribing guidelines (which often take into account the cost-effectiveness of treatments) and to meet certain budgetary objectives*" (ME/6331/13, paragraph 20).

Fourth, in practical terms, a feature of UK market definition in the pharmaceutical sector is the use of the Anatomical Therapeutic Chemical ("*ATC*") system as a starting point for the classification of medicines. In line with the European Commission's approach, the ATC has been referred to in a number of CMA / OFT decisions as a frame of reference, including Napp (abuse of dominance decision, cited above), ProStrakan Group plc / Archimedes Pharma Limited (merger decision of 14 November 2014 (ME/6465/14)) and the recent Leo Pharma / Astellas merger decision (merger decision of 11 March 2016 (ME/6581/15)).

Fifth, supply side substitutability may be slower in the pharmaceutical sector than in certain other industries because of regulatory constraints. In Napp, the OFT noted that if the price of morphine products rose, it would not be possible for manufacturers of non-morphine analgesics to enter the market within a short space of time and thus constrain the price of morphine because firms would need a marketing authorisation to market morphine products as opposed to non-morphine products (at paragraph 65; see also Genzyme (decision of 27 March 2013; CA98/3/03), at paragraph [151]).

Sixth, unlike many other product markets, geographic markets in the pharmaceutical sector tend to be defined nationally as a result of differences in national authorisation procedures, price regulation and clinical guidelines (see, e.g., Reckitt Benckiser, paragraph 4.171).

There have been numerous UK competition law cases where relevant pharmaceutical markets have been defined. Due the space considerations, the following summarises the main decisions in this field:

- ***Napp* (2001)**: the OFT found that Napp behaved abusively because *inter alia* it charged excessive prices for its sustained release morphine medicine (referred to as "*MST*"). The relevant product market was defined as the market for sustained release morphine tablets and capsules. On grounds of lack of substitutability, the OFT excluded various other products from the market, including immediate release morphine and non-morphine products such as Durogesic (the brand name for fentanyl) which is a strong opioid analgesic delivered in an adhesive patch. Non-morphine drugs tended to be used only when patients were sensitive to the side effects of morphine and could not tolerate the drug. The OFT also noted that non-morphine products were far more expensive than morphine and this was a strong indication that they did not act as a competitive constraint on each other (paragraph 61).

[1] Primary Care Trusts ("*PCTs*") were statutory NHS bodies responsible for commissioning most health services at a local level. As a result of the Health and Social Care Act 2012, the work of PCTs has been taken over by the NHS and clinical commissioning groups ("*CCGs*") since 31 March 2013.

- ***Genzyme* (2003)**: the OFT found that Genzyme breached section 18 of CA1998 by behaving abusively (bundling and margin squeeze) with respect to its Cerezyme medicine which was used for the treatment of Gaucher's disease. The OFT found that there were two relevant markets (one "*upstream*" and one "*downstream*") but the abuse related to the upstream market. The upstream market was for the supply of drugs for the treatment of Gaucher's disease in the UK (the "*downstream*" market was for the supply of Cerezyme and the provision of delivery and related homecare services to the NHS). The OFT found that the market was limited to Cerezyme and, to a minor extent, Zavesca. On appeal, the Competition Appeal Tribunal ("*CAT*") upheld the OFT's conclusion on market definition, finding that it was correct to use demand-side substitutability as the main tool in that regard (*Genzyme Limited v the Office of Fair Trading* [2004] CAT 4, at [199]-[200]). The CAT agreed that there was a group of patients suffering from Gaucher's disease who had a constant need for effective treatment of that disease. The CAT considered that the OFT was correct to find that, apart from those two medicines, there were no other alternatives available for the treatment of Gaucher's disease during the period of the abuse (at [210]; see also [216]).

- **Reckitt Benckiser (2011)**: the OFT defined the market as including alginates and antacids in the UK prescription market, and that those medicines are not meaningfully constrained by proton pump inhibitors ("*PPIs*") and histamine 2 receptor antagonists ("*H2RAs*"). The key factors in that assessment were: (i) the fundamentally different modes of action of alginates and antacids from the other medicines considered; (ii) the evidence of medical / prescription practice demonstrated that alginates and antacids were used in different circumstances from the other medicines; (iii) sales and prices of alginates remained broadly constant from 1991 to 2008, in spite of the fact that several branded H2RAs and PPIs lost patent protection, and their prices dramatically decreased; and (iv) the treatment cost and sales of alginates remained largely unaffected by significant market "*events*" such as the entry of generic versions of popular H2RAs and PPIs, such as Zantac and Losec.

- ***Chemistree* (2013)**: in this case, the High Court (Roth J) refused Chemistree's application for an interim injunction compelling AbbVie to supply Keletra, a protease inhibitor used in treatments of patients with HIV. With respect to market definition, the High Court accepted that it is "*very possible for a single patented drug...to constinute a distinct market of its own"* but found, on the facts, that there was insufficient evidence to show that Keletra constituted a distinct market. Roth J found that the primary issue with respect to the relevant product market was demand substitution and referred to the SSNIP test as the applicable test. With respect to "*naïve*" patients (namely those who were being prescribed a HIV drug for the first time), the evidence showed that there were a number of substitutes in the same market as Keletra. With respect to "*stable*" patients (those already under treatment), Roth J accepted the submission that there would be some patients for who Kaletra was a "*must have*" medicine and for whom a 10% or an even higher price increase would not lead to a shift to another medicine. However, that did not by itself, and without any evidence identifying the share of the Kaletra market occupied by those stable patients and the share of purchases are accounted for by naïve patients, enable any

conclusions to be drawn regarding the impact of a small but significant price increase on Kaletra's share of the market (at [35]). On appeal, the Court of Appeal upheld the High Court. Notably, the Court of Appeal rejected Chemistree's argument that pharmacists, rather than doctors, are the relevant purchasers of medicines and therefore are the relevant customers. The Court found that the pharmacist's role in the economic chain is irrelevant to the identification of the product market (at [46]).

- **Paroxetine (2016)**: in February 2016, the CMA found that patent settlement agreements between GlaxoSmithKline ("*GSK*") and a number of generic companies infringed Chapter I and Chapter II (the "*Paroxetine decision*"; CE/9531-11). At the time of writing, the decision has not yet been published due to confidentiality concerns. However, GSK's notice of appeal before the CAT shows that the CMA has defined the relevant product market as the market in a single molecule, namely Paroxetine.

It will be interesting to see how the CMA defines markets in biosimilar cases. Biological medicines have an active substance made of or derived from living organisms. Biosimilars are almost copies of biological medicines: an exact copy is typically not possible. In the recent Pfizer/Hospira merger decision of August 2015 (M.7559), the European Commission found that the originator and its biosimilars were part of the same market.

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.

The "*by object*" rule applies in the UK, both under national competition law and under EU law. There is no "*per se*" rule as such in UK competition law.

Most of the OFT / CMA regulatory decisions regarding pharmaceuticals have been abuse of dominance cases. The Paroxetine decision with respect to patent settlement agreements was the CMA's first major Chapter I / Article 101 TFEU decision in the pharmaceutical sector. In that decision, the CMA applied both a "*by object*" and "*by effect*" assessment. As noted above, that decision has not yet been published. However, the "*by object*" assessment was apparently highly detailed.

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?

There is no legislation or guidance limiting the ability to raise justifications of restrictions of competition in pharmaceutical law cases.

There is no legal rule which limits the scope to argue justifications for potentially restrictive conduct. Section 9(1) of CA1998 can be used to exempt any agreement falling within the

scope of section 2, whether it is a "*by object*" or "*by effect*" restriction. This is in line with the approach taken by the EU courts: see, e.g., Case T-17/93 *Matra Hachette* [1994] ECR II-595, at [85] and Case C-439/09 *Pierre Fabre* [2011] ECR I-9419, at [57].

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

No, there is no special legislation defining excessive or discriminatory pricing. However, pricing regulation may be relevant in these kinds of cases.

As explained further below (see reply to Question 4(c)), the Pharmaceutical Price Regulation Scheme ("*PPRS*") governs the pricing of branded medicines in the UK and was invoked by Napp, unsuccessfully, as an attempted defence to excessive pricing.

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 CAT 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.

Separately, an ongoing CMA investigation of abusive behaviour (excessive pricing) by Pfizer and Flynn Pharma may provide useful guidance in this area. At the time of its SO in August 2015, the CMA published a press release which provides some information on the case. Also, in a separate parallel importing case involving Flynn and the relevant medicine, the High Court has provided a general summary of what is likely to be relevant factual background: *Flynn Pharma Limited v Drugsrus Limited and Tenolol Limited* [2015] EWHC 2759 (Ch).

The case concerns the anti-epilepsy drug phenytoin sodium which was sold under the brand name Epanutin. Pfizer was the originator of phenytoin sodium and has manufactured and marketed it over many years. Until 2012, the price of Epanutin was controlled by the PPRS

as a branded medicine with the result that it was sold at very low prices (£3 per bottle of 84 100mg capsules). This low price meant that, although phenytoin sodium was no longer protected by patent, there was no generic alternative on the market.

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.

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.

In principle, competition law is applied in a consistent manner across sectors, including in the pharmaceutical field. However, there are certain aspects of the pharmaceutical sector which influence the application of competition law. In addition to points already mentioned (see reply to Question 1(b)), these include the fact that intellectual property is of central importance in the pharmaceutical field which can result in tension between IP rights and the application of competition law (e.g. in the reverse patent settlement agreement cases).

Separately, this is a special sector because of the high level of public financing of pharmaceuticals. In England alone, the NHS spends approximately £15 billion annually on medicines. Although this is speculative, it would not be surprising if the impact of this area on public finances (and the cost of any competition law infringements) *may* mean that the CMA is particularly enthusiastic to investigate any infringements in this area (see also the reply to Question 4(e) below). Certainly, in private damages cases, the public authorities have been particularly active in claiming damages arising from competition law infringements (see the reply to Question 2(f) below).

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?

The CMA (and its predecessor, the OFT) have taken a number of significant decisions under Chapter II / Article 102 TFEU. Those cases include Napp, Genzyme, Reckitt Benckiser and Paroxetine. If a comparison is made across sectors, there has been a relatively high number of abuse of dominance investigations in the pharmaceuticals sector.

The Paroxetine decision of February 2016 is the first major infringement finding by the CMA under the Chapter I prohibition (the Article 101 TFEU equivalent) with respect to pharmaceutical arrangements. In December 2013, the OFT announced a settlement with Hamsard 3149 Limited (Hamsard), its subsidiaries Quantum Pharmaceutical Limited (and related companies) for entering into a market-sharing agreement with Lloyds Pharmacy Limited in relation to the supply of prescription medicines to care homes in England.

More generally, the CMA has been particularly active in investigating pharmaceutical cases. It is currently running a number of pharmaceutical investigations under Chapter I (and/or Article 101 TFEU) and Chapter II (and/or Article 101 TFEU) of CA1998.

There have been relatively few UK phase II merger decisions in the pharmaceutical sector in recent times, as many such transactions are caught by the EU merger thresholds.

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.

I am not aware of any examples of interaction between consumer protection law and competition law in this field.

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.

The CMA is the UK's main competition law regulator. It was established under the Enterprise and Regulatory Reform Act 2013. Since 1 April 2014, the CMA has assumed the functions of the OFT and the Competition Commission (both of which have closed). The CMA has competence over competition law issues in the pharmaceutical sector. It also enforces consumer protection legislation to tackle practices and market conditions that make it difficult for consumers to exercise choice.

Monitor, the sector regulator for health-care services in England, has concurrent (shared) powers to enforce competition law alongside the CMA in relation to any case that is principally concerned with the provision of health-care services for the purposes of the NHS in England (under the Health and Social Care Act 2012).

The Medicines and Healthcare Products Regulatory Authority ("*MHRA*") is an agency of the Department of Health which is responsible for ensuring that medicines (and medical devices) are safe and function properly. It is responsible for granting marketing authorisations through the UK national process. The MHRA does not have competition law competence.

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?

Under Part 4 of EA2002, the CMA may carry out market studies where there are concerns that competition may not be functioning effectively. Upon conclusion of the study, the CMA may decide that the market is operating well, take enforcement action or make recommendations to the Government for a change in regulation or public policy. The CMA may also decide to carry out a more detailed inquiry under a market investigation (section 131 of EA2002). Market investigations can lead to remedies without any breach of competition law being established.

The OFT conducted the following two markets studies in the pharmaceutical sector in 2007:

First, the OFT carried out a study of the PPRS. The conclusion was that the PPRS system in operation at the time did not enable the NHS to obtain value for money in respect of its purchase of branded medicines. The study recommended that they be replaced with value-based pricing which was focussed on patients and the cost effectiveness of medicines.

Second, the OFT examined the distribution of medicines and, in particular, the "*direct to pharmacy*" ("*DTP*") arrangements whereby manufacturers can supply pharmacists directly, rather than operating through wholesalers. The OFT expressed some concern that DTP arrangements would result in higher costs to the NHS and a reduction in the level of services to pharmacies and patients, and recommended changes in the PPRS to counter these risks.

Neither of the above market studies led to enforcement actions. However, the agreements at issue in the CMA's Paroxetine decision were brought to the attention of the OFT in 2010 by

the European Commission and, given the proximity in time, it may be that these agreements were uncovered as part of the Commission's sector inquiry.

The Enterprise and Regulatory Reform Act 2013 gives the CMA formal powers to require undertakings to provide information for the purposes of market studies which were not available previously. This may give more teeth to market studies in the future.

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?

There are no pharmaceutic-specific competition law guidelines.

However, on 26 June 2015, when closing an investigation into an alleged loyalty-inducing customer discounts schedule in the pharmaceutical sector, the CMA issued guidance on potential competition concerns arising from the offering of discounts and rebates.

The CMA has also published a range of guidance on various issues relating to competition law enforcement (e.g. prioritisation principles, investigatory powers, etc.) which would be relevant to an investigation into the pharmaceutical sector.

There are no UK guidelines on technology licensing agreements. The European Commission's Technology Transfer Block Exemption Regulation (Regulation (EU) No 316/2014) and related guidelines are of importance in this field.

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

Overall, there has been active public enforcement in this field and a relatively significant number of private damages actions.

As noted above (see, e.g., response to Question 2(a)), the CMA (previously the OFT) has been active in this field. This can be based on complaints by private parties but is essentially public enforcement.

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 anti-competitive 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.

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.

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

There are various remedies available:

- The CMA can impose fines up to 10 per cent of an undertaking's worldwide turnover for the previous financial year. For instance, the OFT imposed fines on Napp (£3.21 million), Genzyme (£6.8 million; reduced to £3 million on appeal), and Reckitt Benckiser (£10 million) for abuse of dominance. More recently, in the Paroxetine

decision, the CMA imposed fines totalling £45 million on a number of pharmaceutical companies for entering into patent settlement agreements.

- Under section 35 of CA1998, the CMA can impose interim measures to terminate the relevant commercial practices pending the final outcome of an investigation where continuance of the conduct would cause "*significant damage*" to another business.

- The competition authorities have the power to order companies that have infringed the rules to cease or modify their activities (sections 32 and 33 of CA1998). For example, the OFT ordered Napp under section 33 of CA1998 to amend its prices for certain morphine medicines in order to bring the abuse to an end.

- The CMA can accept binding commitments from companies under investigation (section 31 of CA1998).

- An individual found guilty of the cartel offence can be liable for a criminal sentence of up to five years' imprisonment and/or an unlimited fine (see reply to Question 1(a) above).

- Company directors found to have infringed the competition law rules can face disqualification for a maximum period of 15 years.

- Parties can also seek injunctions in the courts. For instance, in 2007, following a change in its distribution arrangements, Pfizer stopped supplying various wholesalers and appointed Unichem as its sole logistics services provider to supply its prescription medicines to pharmacists and dispensing doctors. The wholesalers sought an injunction preventing Pfizer from refusing to supply. The High Court (Richards J) accepted that the claimants had a seriously arguable case, but there was insufficient evidence to show that they would suffer irreparable harm if the injunction was not granted (*AAH Pharmaceuticals Ltd & Others v Pfizer Ltd* [2007] EWHC 565 (Ch)). Richards J considered that the Claimants had unduly delayed their application to the court having earlier sought (and failed to obtain) interim measures from the OFT. The High Court also rejected an application for an injunction in *Chemistree*. Given the judge's finding that there was no serious issue to be tried (see replies to Question 1(b) above and 2(j) below), the judge examined the risk of injustice of not granting an injunction only briefly. He considered that any damage that would be caused to the claimant was purely financial and could be compensated in damages.

- Parties who have suffered loss due to competition law breaches by pharmaceutical companies can seek damages in the courts, either in follow-on damages actions or stand-alone cases. As noted above (see reply to Question 2(f)), there have been a number of examples of damages cases with respect to breaches of competition law in the pharmaceutical sector.

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

No, the CMA does not carry out monitoring of patent settlement agreements. It can rely on DG Competition's annual monitoring reports.

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?

The Human Medicines Regulations 2012 (SI 2012/1916) impose an obligation to supply on licensed manufacturers and licensed wholesalers. In particular, the licence holder must ensure "*within the limits of the holder's responsibility, the continued supply of medicinal products to pharmacies, and other persons who may lawfully sell medicinal products by retail or supply them in circumstances corresponding to retail sale, so that the needs of patients in the United Kingdom are met*" (see sections 39(8) and 43(2)).

This issue came up incidentally in the *Chemistree* case. As outlined in detail below (see reply to Question 2(j)), AbbVie was accused of abusively refusing to supply Kaletra. The Claimant (Chemistree) was seeking significant increases in Kaletra which put pressure on AbbVie's ability to supply the UK market. The Court noted that AbbVie was only able to satisfy its supply obligations by "*diverting to England a delivery from its Dutch manufacturing affiliate that had been destined for Ireland and thus reduced supplies there. Every drug supplier, of course, seeks to plan its stock levels and ensure continuity of supply*" (at [11]).

Similarly, in *Intecare Direct Ltd v Pfizer Ltd* [2010] EWHC 600 (Ch), in refusing to grant an injunction obliging Pfizer to supply a medicine to the Claimant, the High Court took into account that Pfizer needed to ensure continuous supply of the medicine to the UK market (for further detail, see the reply to Question 2(j) below).

In December 2015, the CMA closed an investigation into medicine shortages in the UK. The CMA did not find persuasive evidence that the extent of shortages in the UK justified further investigation. Moreover, it did not find reason to believe that a significant proportion of any shortages that do exist could be attributed to causes originating in the UK.

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?

Two court cases are of particular relevance here.

In *Chemistree*, the High Court ruled that AbbVie was not dominant and therefore the Claimant failed to establish a breach of Article 102 TFEU. However, Roth J went on to consider the allegation of abusive refusal to supply and found, *obiter*, that there was no abuse.

The issue was whether AbbVie's refusal to supply additional quantities of Keletra, a patent protected HIV drug, to Chemistree, a long-standing customer, was abusive. The Court recalled the *United Brands* test that a dominant undertaking cannot discontinue supplies to a long-standing customer who abides by regular commercial practice if the orders placed by that customer are in no way out of the ordinary. The Court found that Article 102 TFEU had "*never been held to oblige a supplier to adopt a particular manner of distribution of its own products*". AbbVie had adopted the legitimate strategy of not supplying wholesale distributors in the UK at all and instead had developed its own supply chain coverage. Its supply of Kaletra to Chemistree was in its capacity of homecare provider.

Chemistree argued that AbbVie had been supplying it for wholesale for many months and AbbVie had not discontinued supplies. However, the High Court held that if a pharmaceutical manufacturer is providing a customer with supplies on the basis that it is for retail sale and, unknown to the manufacturer that customer is in fact selling some of those products on the wholesale market, that does not mean that the customers' orders for wholesale constitute "*ordinary orders*" within the meaning of the caselaw. The Court also found that the fact that some or perhaps all of Chemistree's wholesale requirements were for parallel export trade could not convert what would otherwise not be an abuse into an abuse. The High Court interpreted the CJEU's judgment in Case C-486/06 to C-478/06 *Sot. Lelos v GlaxoSmithKline* [2008] 5 CMLR 20, as suggesting that even where a supplier actively supplies wholesalers, it may not be an abuse to refuse to provide supplies which are out of proportion to those quantities previously sold to those suppliers to meet domestic requirements. Therefore, the Court considered that, "*in the particular context of pharmaceutical medicines it may indeed be legitimate to restrict supplies in such a way that parallel exports could be restricted*" (at [47]). The Court did not explicitly link this in its legal assessment to the fact that AbbVie was under an obligation to ensure sufficient supplies to the UK market, but this was an important underlying fact in the case which explained AbbVie's difficulty supplying Chemistree with increased supplies (see reply to Question 2(i))

Intecare Direct Ltd v Pfizer Ltd [2010] EWHC 600 (Ch) is another interesting refusal to supply case (again Roth J was presiding). The case concerned Pfizer's prescription product Sutent which is used to treat specific cancer conditions. Sutent was a very expensive drug and there was a limited supply available in the UK. Pfizer decided to implement a "*Hospital Plus Policy*" to only supply Sutent to hospitals, a very limited number of pharmacies and homecare providers in two circumstances: first, where the customer required the medicine to fulfill hospital prescriptions and second, where there was an urgent patient need on an emergency basis.

Intecare provided a homecare service. It claimed that Pfizer was using its new policy as a constructive refusal to supply it with Sutent and sought an injunction ordering Pfizer to supply it with 60 boxes of Sutent per month.

In his assessment of the application for interim relief, Roth J considered that Intecare fell very far short of showing it had a case that would succeed at trial. He considered that the *United Brands* test would not apply for two reasons. First, on the facts Intecare could not be considered as a "*long standing customer*" of Pfizer's (at [47]). Second, there did not appear to be any distortion of competition or discrimination because Pfizer's policy was applied to all of its customers for Sutent – Pfizer was not favouring itself or an associated company in the downstream market (at [48]).

The specific context of the pharmaceutical sector was relevant in the court's assessment of whether to grant an injunction. The judge accepted Pfizer's argument that there was a risk of a serious shortage of supply of Sutent in the UK if its Hospital Plus Policy was not applied and that this could cause serious harm to patients (at [53] and [66]). This was a relevant factor in his decision not to grant an injunction (along with the low likelihood of success of Intecare's substantive claim).

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.

This interplay has not had a major impact on the application of competition law in the pharmaceutical sector to date. However, the CMA obviously considers consumer interests in applying competition law in infringement cases or merger proceedings.

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.

Broadly speaking, various measures exist to encourage generic entry or at least price competition based on generic entry. These measures include the following:

(i) Generic prescribing: in the UK, if a branded drug is prescribed (a "*closed script*"), that drug has to be dispensed by pharmacists (regulation 214 of the Human Medicines Regulation 2012 (SI 2012 No. 1916)). If a drug is prescribed using the generic name (an "*open script*"), it is permissible for the pharmacists to dispense any branded or generic drug that falls within the relevant descriptor. Generic prescribing is encouraged at all levels of the healthcare system, including by the Department of Health, NHS England, CCGs and Health Boards and by the professions. As noted by Arnold J in the recent *Warner Lambert case*, "*it is standard practice for a prescribing doctor to identify the drug prescribed by reference to its international non-proprietary name ('INN'), that is to say, its generic name*" (see *Generics (UK) Limited trading as Mylan v Warner-Lambert Company LLC v Secretary of State for Health* [2015] EWHC 2548 (Pat) (the "*Warner-Lambert case*"), at [376]). Arnold J noted that almost all prescribers in the UK now use clinical software systems to create prescriptions and that generally encourages the doctor to prescribe generically. This system is intended to ensure vigorous price competition between pharmaceutical manufacturers which have a strong incentive to compete on price to persuade pharmacies to dispense their products (where there is no patent protection) (see also Reckitt Benckiser, paragraphs 2.100-2.101).

(ii) Price reimbursement: in the UK, the Drug Tariff is used to determine how much a dispensing contractor (e.g. a pharmacy) is reimbursed for a generic medicine in question. This is effectively a national price list which is published monthly by the NHS. The Drug Tariff indirectly influences the pricing of generics and encourages competition. For any given medicine, the Drug Tariff is set so that pharmacies have an incentive to buy from the cheapest source and this generates competition between generic suppliers to supply products at a price which enables pharmacies to generate profit (see, e.g., the European Commission's Servier decision, para 2282).

(iii) Marketing authorisation: In accordance with harmonised EU law on marketing authorisations,[2] where a marketing authorisation ("*MA*") is requested for a generic product of an originator's medicinal product which has been authorised for a specified period, the generic applicant is not required to provide the results of pre-clinical tests and clinical trials. Instead, the competent authority can rely on the results of tests and trials submitted in the MA application for the originator product under an "*abridged application*" (see the Commission's Servier decision, paragraph 74).

Reckitt Benckiser is a good example of a competition law case where an undertaking abused its dominant position by seeking to frustrate legislation promoting generic entry.

As noted at (i) above, generic prescribing is encouraged in the UK. However, if a generic name does not exist, doctors cannot write open script prescriptions.

In 1977, Reckitt Benckiser launched Gaviscon Liquid, an alginate based medicine used to treat acid reflux, gastro-oesophageal reflux disease and dyspepsia. The patent expired in 1997. A similar product, Gaviscon Advanced, remained under patent protection.

In June 2005, in anticipation of the publication of a generic name for Gaviscon Liquid, Reckitt Benckiser withdrew and delisted Gaviscon Liquid. This enabled it to avoid full generic competition following the publication of a generic name for that medicine. The contemporaneous evidence showed that Reckitt Benckiser's intention was to switch GPs/patients from Gaviscon Liquid to Gaviscon Advanced, which had patent protection until 2016 and for which no generic was available ("*product hoping*"). In addition, the withdrawal would have been loss-making and not commercially rational, were it not for the prospect of using it to hinder generic entry.

In 2011, the OFT found the Reckitt Benckiser abused its dominant position by withdrawing and delisting Gaviscon Liquid. Reckitt Benckiser admitted to the abuse and the OFT imposed a fine of £10.2 million.

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)?

[2] See Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67-128), as amended.

The CMA does not provide a shield under the "*scope of the patent*" approach. In February 2016, the CMA took its first infringement decision with respect to a patent settlement agreement. The CMA's decision relates to conduct and agreements between 2001 and 2004 in which GSK, the supplier of branded paroxetine (an anti-depressant medicine), agreed to make payments and other value transfers totaling over £50 million to suppliers of generic versions of paroxetine, namely Alpharma Limited and Generics (UK) Limited (their parent companies were held jointly and severally liable). The CMA found that these payments and other value transfers were aimed at delaying the potential entry of generic competitors into the UK market for paroxetine.

The CMA concluded that GSK's agreements with each of GUK and Alpharma infringed the competition law prohibition on anti-competitive agreements. The CMA has also found that GSK's conduct, in making payments to GUK, Alpharma and one further company, Norton Healthcare Limited (IVAX), to induce them to delay their efforts to enter the UK paroxetine market independently of GSK, infringed the competition law prohibition on abuse of a dominant position.

The addressees of the CMA's decision have appealed to the CAT.

Although the Paroxetine decision has not yet been published, it appears that the CMA has rejected arguments that the agreements at issue were within the scope of the patent. At the time of the agreements in question, GSK held patents in relation to paroxetine. When GUK and Alpharma began to take steps to enter the UK market with generic versions of paroxetine, GSK alleged that they would infringe its patents and commenced litigation proceedings. It appears, therefore that the settlement agreements concerned within scope restrictions and yet the CMA has not considered that to be a shield to the application of competition law.

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?

As noted, the CMA does not apply the protection.

More generally, UK judges seek to strike a balance between intellectual property rights and competition law. It could not be said that intellectual property rights are treated as trumping competition law.

However, as noted, there is no UK court judgment as yet on this issue so considerable uncertainty remains. It is perhaps worth noting that Sir Robin Jacob, a former Lord Justice of Appeal of the Court of Appeal, has been highly critical of competition authorities' approach to patent settlement agreements, noting that the Lundbeck decision is "*very worrying*" and a major threat to innovation (see "*Competition Authorities Support Grasshoppers: Competition Law as a Threat to Innovation*" (2013) 2 Competition Policy International, p.15).

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?

Without access to the Paroxetine decision, it is difficult to answer this question. However, it appears from the available information that the CMA considers that a pay for delay agreement will breach competition law if the parties to the agreement are excluded from the relevant market. The decision undoubtedly assesses the precise nature of the restriction found by the CMA.

iv. Are there examples showing the difference between acceptable settlement payments and unacceptably restrictive settlement in your jurisdiction?

Given that the (unpublished) Paroxetine decision is the only CMA precedent on patent settlement agreements, there is limited information available on where the CMA draws the line between acceptable and unacceptable settlement agreements.

According to the CMA's press release, Norton Healthcare Limited (formerly IVAX Pharmaceuticals UK) and its parent at the time (IVAX LLC) were subject to the Paroxetine investigation. However, the CMA has issued a "*no grounds for action decision*" concluding that the agreement between GSK and IVAX is excluded from the Chapter I prohibition by virtue of the Vertical Agreements Exclusion Order, and the CMA does not proceed to make a finding of infringement. No further detail is available on this at the time of writing. Although this is speculative, it may be that there was a supply arrangement between Norton and GSK which, in the CMA's view, justified its exclusion from the infringement finding.

v. Is the date of the settlement in the context of the patent term a relevant consideration?

There is no publicly available information on this issue.

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.

One aspect of the UK patent system which was considered in the European Commission's Lundbeck decision was the case-law indicating that generics should seek to "*clear the way*", meaning that they should manifest themselves at an early stage, making it clear to

the originator that they intend to enter the market (see, e.g., *Smithkline Beecham PLA v Generics (UK) Limited* (2002) 25(1) I.P.D. 25005 (the Paroxetine case)). In the Paroxetine case, the High Court pointed out that the generic could have said to the patentees, "*We intend (we are not saying when but it is a settled intention) to launch our product within the next five years. If you intend to sue us, sue us now*". In an injunction assessment, when considering the balance of convenience, a generic company's failure to "*clear the way*" would weigh in favour of granting an injunction. A number of the addressees of the Lundbeck decision argued that the "*clear the way*" rule may give companies a stronger incentive to settle litigation than they would have otherwise have had, particularly because of the injunction risk for generics in proceeding to litigation and market entry. This argument was strongly dismissed by the Commission (see paragraphs 153 and 758). It remains to be seen whether it is raised in the CMA's recent decision and, if so, how it is addressed.

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?

The most obvious barrier to entry will be non-expired patents, in the form of either the primary patent or secondary patents.

As an example of artificially raising the patent barriers, in the Servier damages actions the claimants 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.

It has recently been alleged that the owner of a second medical use patent with claims in Swiss form used its patent protection to seek to exclude generic companies from competing over non-patented uses. There has yet to be a binding finding in that regard although Arnold J expressed the interesting *obiter* view in the *Warner-Lambert* case that "*the best solution to the problem of protecting the monopoly conferred by a second medical use patent while allowing lawful generic competition for non-patented indications of the substance in question is to separate the patented market for the substance from the non-patented market by ensuring that prescribers write prescriptions for the patented indication by reference to the patentee's brand name and write prescriptions for non-patented indications by reference to the generic name of the substance (the INN)*" (at [722]). To be clear, that remains a judicial suggestion and has not been incorporated into the law.

Separately, trade mark protection may be a barrier to entry for parallel importers seeking to import pharmaceuticals into the UK market. For example, in *Doncaster v Bolton* [2006] EWCA Civ 1661, AstraZeneca originally owned the KALTEN trade mark in various EU Member States. It assigned the trade market to different assignees in different Member States, including to Bolton in the UK. Doncaster, a parallel importer, purchased

the product in Spain and repackaged and relabelled it for sale in the UK under the KALTEN trade mark. Bolton sued Doncaster for trade mark infringement.

Summary judgment was granted in Bolton's favour before the High Court but this was overturned by the Court of Appeal. The Court of Appeal considered that there was a possible competition law infringement which needed to be examined at trial. Prior to the assignment of the trade marks, when AstraZeneca marketed KALTEN in Spain, it exhausted its rights. The assignment had the effect of putting Bolton in a stronger position and giving it the possibility to invoke its trade mark against Doncaster in the UK. The Court of Appeal considered that the assignment could be "*part of a planned process for deliberately and artificially partitioning and manipulating the EU market for KALTEN so as to amount to a disguised restriction on trade between member states with respect to the product*" (at [79]).

In addition to IP protection, there are regulatory barriers to entry, including the need to obtain a marketing authorisation.

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?

I am not aware of any such exemption for certain bodies in the healthcare industry from competition law.

Yes, competition law is in principle applied consistently to healthcare purchasers and providers in the UK, provided that they are found to be "*undertakings*" and therefore caught by competition law in the first place.

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.

Apart from the option of making a complaint to the CMA, any enforcement actions would need to be taken privately, including in cases involving third party funders.

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

Although the UK is described as a free pricing system, there is some degree of price regulation and this can be important in competition law cases.

The control of the price at which a prescription pharmaceutical product can be sold in the UK depends on whether the product is a branded or generic product, and on whether a public healthcare provider is purchasing the medicines.

<u>Branded medicines:</u>

There are two parallel schemes for the pricing of branded medicines, namely the voluntary PPRS and the statutory scheme.

First, the PPRS controls the prices of branded medicines sold through the national health services (i.e. public healthcare providers). The PPRS is a voluntary scheme between relevant government departments and the Association of British Pharmaceutical Industry (the "*ABPI*")

with a 5 year duration (the current scheme runs from January 2014 until December 2018). The main features of the current PPRS scheme are as follows:

(a) The PPRS controls the profits that pharmaceutical companies can make from sales through the health services. This is set based on return on sales or return on capital assessment.
(b) New medicines launched in the UK market following the granting of an EU or UK new
active substance ("*NAS*") marketing authorisation from the appropriate licensing authority may be priced at the discretion of the scheme member on entering the market. However, where a product does not have a NAS marketing authorisation, restrictions are imposed on price changes.
(c) Growth in the branded medicines bill above the agreed level will result in a "*PPRS Payment*" being made by industry back to the Department of Health. The payments are based on the difference between the agreed forecast growth level and the allowed growth level.

The PPRS applies to members of the ABPI and non-members who voluntarily agree to be subject to the PPRS. Those companies are exempted from statutory price regulation because of their compliance with the PPRS.

Second, a statutory scheme applies to all companies who supply branded health service medicines on prescription, but who do not adhere to the voluntary PPRS. The scheme applies a 15% reduction in the maximum price that may be charged from the baseline on 1 December 2013 and new products are priced at the direction of the Secretary of State. The Department of Health has been consulting on significant revisions to the statutory scheme.

<u>Generic medicines:</u>

In principle, manufacturers are free to set their own prices for generic medicines. It is considered that there will be sufficient competition after generic entry to keep prices low, without price regulation.

There is a voluntary scheme applicable to generics called "*Scheme M*". It is negotiated by the Department of Health and the British Generic Manufacturers Association. It requires that the price of unbranded medicine does not exceed that of the equivalent branded medicine. There is no parallel statutory scheme.

The Drug Tariff system is an important part of pricing regulation in the UK and is summarised above in the response to Question 3(a).

The general freedom of price on generic products in the UK contrast with certain other EU Member States where generic prices are fixed by the public authorities. This does mean that undertakings have greater scope to make pricing decisions.

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?

Under the UK's Parallel Import Licensing Scheme, medicinal products authorised in other EU Member States may be marketed in the UK, provided that the imported products have no therapeutic difference from the equivalent UK products (section 172 THMR, which refers to the EU parallel import licensing regime).

There are no restrictions on parallel trade based on price controls.

There has been recent judgments on parallel trade but they more concern repackaging issue and do not relate to competition law: e.g. *Speciality Pharma v Doncaster* [2015] EWCA Civ 54; and *Flynn Pharma v Drugsrus* [2015] EWHC 2759 (Ch) (under appeal).

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.

It is not clear that the competition law analysis changes at all because public funds are involved. However, this may be relevant to the general legal and economic context which needs to be considered in assessing possible competition law infringements. From a policy perspective, the fact that public funds are involved means that the UK has taken steps to stimulate competition as far as possible, in order to ensure lower prices for the national health services (e.g. price reimbursement rules and encouragement for doctors to prescribe generic medicines; see replies to Questions 3(a) and 4(c) above). Those measures can be of central relevance to competition law assessments, as shown by cases like Reckitt Benckiser and, potentially, the ongoing Pfizer / Flynn investigation.

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.

One additional consideration is the importance of innovation in this sector. This has been examined in certain CMA cases. For example, in the decision concerning the merger between Shire and Viropharma (ME/6331/13, 10 February 2014), the OFT assessed a possible reduction in the parties' research and development ("*R&D*") activities post-merger. Due to the high degree of differentiation of the parties' pipeline products and the strong competitive constraint exerted by a competitor, the OFT considered that the parties incentives for R&D would not decrease. The importance of innovation is also reflected by recent European Commission decisions (e.g. M7275 and M7276, Novartis/GSK decision of January 2015; and M.7559, Pfizer/Hospira, decision of August 2015).

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.

One key aspect will be the General Court's judgments in the Lundbeck cases which will be the first EU court precedents with respect to patent settlement agreements. The oral hearings took place towards the end of 2015. Although the dates have not yet been announced, there is a chance that they will be delivered before the summer recess or in September.

The CMA has announced a number of recent new investigations which appear to address the interaction of competition law and the pharmaceutical sector. Further information on those investigations may be made available shortly.

There are a number of areas where the law in this field remains unclear (e.g. patent thicketing; the full scope of patent settlement agreements; product hopping). Further, a number of the questions in this report concerns *generic* medicines. One of the major outstanding issues for competition authorities and courts is how biosimilar products should be treated. Unlike generic medicines, biosimilars may differ from the original biological medicine (so market definition issues may be more complex; see the reply to Question 1(b) above). Biosimilars can also be very expensive to produce and may face higher barriers to entry. However, when they enter the market, they may be capable of leading to significant price drops and therefore leading to significant benefits from a consumer perspective. The biosimilar segment of the pharmaceutical market remains relatively new.

It is unclear whether there will be significant developments in the above areas in time to factor into the League's Report and Recommendations.