

LIDC 2016, Question A: The pharmaceutical sector and competition law

German Report

by the national reporter¹:

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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.

Competition (or Antitrust) law is governed in Germany by the Act against restraints of Competition (*Gesetz gegen Wettbewerbsbeschränkungen*, GWB). The law is enforced by the Federal Cartel Office (*Bundeskartellamt* http://www.bundeskartellamt.de/EN/Home/home_node.html) and, to a lesser extent, by the respective authorities at regional level in the federal states (*Landeskartellbehörden*).

German Antitrust law mainly consists of provisions:

1. The prohibition of agreements restricting competition (**section 1, Competition Act**, which corresponds to Article 101(1) of the Treaty on the Functioning of the European Union (TFEU)).
2. The prohibition of abusive behavior by market dominant and market relevant undertakings (**sections 18 to 20, Competition Act**, which can also be stricter than Article 102 of the TFEU).
3. Merger control (**sections 35 to 43, Competition Act**, which were further aligned with EU law in 2013 by the 8th Amendment to the Competition Act).

The Bundeskartellamt is also responsible for the review of procedures relating to public procurement law (*sections 97 et seq, Competition Act*). The powers of the Bundeskartellamt include to impose fines on companies (up to 10% of a group's worldwide annual turnover) and on individuals (up to 1 million EUR).

The pharmaceutical sector, in particular the reimbursement by public insurances, is one area under permanent scrutiny of the Bundeskartellamt. In **merger control** proceedings the Bundeskartellamt ensures that a merger does not significantly impede effective competition and that relevant alternatives remain for the patients. With the entry into force of the 8th Amendment to the German Competition Act in 2013 the Bundeskartellamt also became responsible for examining voluntary mergers or consolidations of health insurance funds.

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In the area of **antitrust and abuse control** it has to be clearly distinguished who is conducting the agreement or acting in the individual case as the law exempts certain practices. For example, the legislator offers the health insurances a wide scope of action in competing for members. Hence, agreements between the public health insurance companies restricting competition in relation to the insurance holders in terms of patients fall outside the Competition Act.

On the other hand, the practices of pharmaceutical manufacturers are unreservedly subject to antitrust and abuse control. In addition, the general antitrust law provisions will apply to the relationship between an individual public health insurance and service providers (*Leistungserbringer*), that is, medical practitioners, pharmacies, pharmaceutical companies when it comes to **voluntary agreements** for example rebate contracts with pharmaceutical companies (see § 69 SGB V). If the public health insurance – on the other hand – is obliged by law to sign a certain agreement with medical practitioners, pharmacies or pharmaceutical companies, the practice is exempt from national antitrust law.

Examples of the enforcement of the Bundeskartellamt in the area of **antitrust and abuse control** are:

[Pharmacists lift their prohibition of the control of health insurance funds in the sale of blood glucose strips](#)

(Press release of 1.10.2014)

[Link to case summary](#) (German version)

[Link to decision](#) (German version)

[Bundeskartellamt opens up competition among ophthalmologists from different federal states in Germany](#)

(Press release of 2.7.2013)

[Link to case summary](#) (German version)

[Link to decision](#) (German version)

[Restriction of competition caused by rebate agreements between the Federal Guild of Hearing Aid Acousticians \(BHA\) and health insurance funds](#)

(Press release of 24.11.2011: "Bundeskartellamt eliminates competition restraints in the distribution of hearing aids.")

[Link to decision](#) (German version)

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 Bundeskartellamt describes its approach as follows²:

*„From a competition perspective the health markets are **frequently regional markets**, e.g. in the area of acute in-patient hospital treatment, **or even local markets**, as in the area of general out-patient medical care. By contrast the markets for the **manufacture of pharmaceuticals and medical aids** such as e.g. hearing aids, glasses or wheelchairs, **are normally national supply markets**. The Bundeskartellamt examines in particular whether patients in the regions affected will still have an adequate number of alternatives and what*

² See for details:

http://www.bundeskartellamt.de/EN/Economicsectors/Health%20sector/health_sector_node.html.

effects the transaction will have on competition. In the case of amalgamations between health insurance funds, it also examines whether the transaction will significantly impede effective competition on the demand side for the services of health care providers.”

(bold type added)

The Bundeskartellamt has taken the following individual merger control decisions:

Control of hospital mergers:

[Rhön-Klinikum AG can acquire Kreisklinik Bad Neustadt a. d. Saale](#)

(Press release of 15.09.2015)

[Bundeskartellamt clears merger between Friedrichshafen und Tettngang clinics](#)

(press release of 14.11.2014)

[Link to case summary](#) (German version)

[Bundeskartellamt prohibits merger between hospitals in Esslingen](#)

(Press release of 15.05.2014)

[Link to decision](#) (German version)

[Bundeskartellamt clears acquisition by Helios Kliniken \(Fresenius\) of 40 clinics and 13 medical care centres operated by Rhön-Klinikum AG](#)

(Press release of 20.02.2014)

Merger control in the market for medical products:

[Blood products: Bundeskartellamt clears acquisition of Fenwal by Fresenius](#)

(Press release of 12.12.2012)

Pre-filled syringes: Becton Dickinson and Company / Safety Syringes Inc.

[\(Case summary of 21.12.2012: Bundeskartellamt clears acquisition of Safety Sy-ringes Inc. by Becton Dickinson and Company\)](#)

[Link to the decision](#) (German version)

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.

To the author's knowledge, there are no pharmaceutical cases addressing special per se rules of infringement. In general, the German courts are following the EU-law approach following which *“restrictions of competition by object are those that by their very nature have the potential to restrict competition within the meaning of Article 101 (1) TFEU. It is not necessary to examine the actual or potential effects of an agreement on the market once its anti-competitive object has been established”*.³

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?

No, there is not.

³ See, e.g., Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, 2011/C 11/01, para 24 ff.

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 not. Discriminatory pricing under German law is dealt with for pharmaceuticals like for any other industry in the GWB.

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 case

In Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01 the European Court of Justice (ECJ) decided that AOKs are not subject to EU competition law as they are no undertakings which restricts the application of EU competition law to German public health insurances significantly until today⁴:

„63 It follows that, in determining those fixed maximum amounts, the fund associations do not pursue a specific interest separable from the exclusively social objective of the sickness funds. On the contrary, in making such a determination, the fund associations perform an obligation which is integrally connected with the activity of the sickness funds within the framework of the German statutory health insurance scheme.

*64 It must accordingly be found that, in determining the fixed maximum amounts, the fund associations merely perform a task for management of the German social security system **which is imposed upon them by legislation and that they do not act as undertakings engaging in economic activity.**“*

(bold type added)

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?

No. All types of enforcement activities exist (see above).

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.

No, not directly in terms of legal provisions. But consumer (patient) protection considerations are to be taken into account in any enforcement activity and thus indirectly play a role.

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

⁴ For details see, ECJ, judgement of 16 March 2004:

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=48991&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=244293>.

a consumer protection body with specialist pharmaceutical competence? If so, please provide a brief description of the body and its powers.

There are no specialized bodies with regard to pharmaceutical competition law.

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?

So far, there have not been any sector-specific reviews of competition law in the pharmaceutical sector in Germany like the European Commission's sector inquiry.

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?

No specific guidelines have been issued yet. The same applies for general intellectual property law issues.

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

Antitrust enforcement - like in any other industry - is done on both levels in pharmaceuticals, private and public. The Bundeskartellamt though has been rather reluctant to act in the field of rebate contracts (tendering) for generics between insurances and pharmaceutical companies although the market shares of the insurance such as the AOKs often amount to almost 40%.

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

In recent years in the field of pharmaceuticals, the Bundeskartellamt has especially sanctioned price agreements and recommendations for resellers and calls for boycott.

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.

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

There is no publically available data for the monitoring of patent settlements in the pharmaceutical sector in place in Germany. However, Germany provided data to the European Commission for its

recent Patent Settlement report where 12 patent settlements have been reported for Germany between January 2014 and December 2014⁵.

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?

Pharmaceutical manufacturers are obliged to make available pharmaceutical products they are licensed to sell in Germany to pharmaceutical full-line wholesalers under § 52b para. 2 German Drug Law (AMG). The same obligation applies to wholesalers when it comes to pharmacists § 52b para. 3 German Drug Law (AMG).

The respective provisions read as follows (§ 52b AMG):

“(2) Pharmaceutical entrepreneurs must guarantee, within the framework of their responsibility, a demand-oriented and continuous supply to the full-range wholesalers of medicinal products. Full-range wholesalers of medicinal products are wholesale businesses which maintain a complete, manufacturer-independent assortment of pharmacy-only medicinal products which, in terms of depth and scope, is constituted in such a way that the demand from patients from the pharmacies with which the wholesaler does business can be met within an appropriate space of time on weekdays; the medicinal products to be kept in stock must correspond, in such a case, to at least the average demand for a period of two weeks. Sentence 1 shall not apply to medicinal products which are subject to the distribution channels specified in Section 47 sub-section 1 sentence 1 numbers 2 to 9 or Section 47a or which, for other legal or practical reasons, cannot be supplied through the wholesale business.”

“(3) Full-range wholesalers of medicinal products must, within the framework of their responsibility, guarantee a demand-oriented and continuous supply to the pharmacies with which they do business. Sentence 1 shall apply mutatis mutandis to other medicinal product wholesale businesses for the totality of the medicinal products they hold in stock in each case.”

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?

No the main case law in that respect are the two ECJ case in GSK (Greece and Spain).

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.

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3. Innovation questions

This section gathers information relating to special treatment of pharmaceutical products to

⁵ See page 8:

http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report6_en.pdf.

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.

Regulatory: German law has transferred the European directive 2001/83/EC on the community code relating to medicinal products for human use. Consequently, regulatory data protection rules and marketing authorization rules apply accordingly. Likewise the ECJ case law on parallel trade.

Reimbursement: There is no direct incentive in the Social Code V (SGB V) favoring generics over originator products except generic substitution under § 129 SGB V for the cheaper product (which applies with some exceptions). However, that might change when it comes to setting out details about the biosimilar legislation where physician quota schemes are discussed.

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 actors 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)?

To the authors knowledge, IP laws are applied similar for pharmaceuticals as in any other sector. However, ECJ case law regarding parallel trade⁶ might be quoted here but should not be dealt with to a greater extent here as it is not German specific but EU 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?

See above.

- 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?

It is not necessary that an agreement excludes rivals to trigger competition law enforcement, rather it is sufficient to exclude only the party of the agreement.

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

The German case law does not yet provide for examples showing the difference between acceptable settlement payments and unacceptably restrictive settlement in Germany. However, that might change depending on the enforcement by the European Commission in this tightly monitored area.

⁶ On trademarks see: Centrafarm/ Winthrop of 31.10.1974, Rs 16/74, Slg 1974, p 1.183; on patents see: Centrafarm/ Sterling Drug of 31.10.1974, Rs 15/74, Slg 1974, p 1.147; on copyrights see: Warner Brothers am 17.05.1988, Rs 158/86, Slg 1988, p 2.605).

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

The author is not aware of any German case law stating that the date of the settlement in relation to a patent term provides an indication about any anti-competitive behavior.

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.

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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?

Different from EU enforcement, there is no case law existing yet in Germany with regards to life-cycle strategies of originators versus generic drug companies. So far, no Bundeskartellamt cases relating to issues associated with the generic entry indicating scrutiny by the authority have been published.

Recently, the question arose whether third parties who manufacture a patented medicinal product to supply a generic company in order to obtain market authorization can also rely on the Bolar exemption. The Düsseldorf Higher Regional Court and the Regional Court held that the EU legislation was not to be interpreted to include such third parties, and submitted a preliminary question to the ECJ⁷. The Bolar exemption allows generic companies to carry out studies (for example, on bioequivalence) that are necessary to obtain a generic version of a patent-protected product. It was introduced into the law of the EU Member States by Article 10(6) of Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive). In Germany, the exemption is regulated in paragraph 11(2b) of the Patent Act.

In relation to competition issues associated with the generic entry of pharmaceuticals, the European Commission launched a sector inquiry in 2008 to identify structural shortcomings and problems in the pharmaceutical sector⁸. The sector inquiry mainly focused on "pay-for-delay-agreements" which involve money transfers by pharmaceutical originators to generic companies, so that the generic company stays out of the market.

So far, there have been two decisions, involving the drugs citalopram (see http://europa.eu/rapid/press-release_IP-13-563_en.htm) and fentanyl (see http://europa.eu/rapid/press-release_IP-13-1233_en.htm).

The European Commission basically identified two types of behavior violating competition law which are under scrutiny by the Bundeskartellamt as well:

1. **Reverse settlement agreements** between an originator and a generic company. These agreements terminated a patent dispute and involved settlement payments to the generic company which made it stay out of the market.

2. **Co-promotion agreements** between originators and generic companies. This could effectively encourage the generic company not to launch its own product but instead to promote the originator's product which might decrease generic competition.

⁷ See case C-661/13.

⁸ See: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry>.

In both cases, the European Commission found the behavior to infringe Article 101 of the TFEU.

There is no case law yet in Germany with regard to 'pay-for-delay' agreements. However, the European Commission has already specifically examined 'pay-for-delay' agreements in 2013 in several cases (Lundbeck; Johnson & Johnson/Novartis) and the Commission imposed fines. Thus, it might only be a matter of time before the Bundeskartellamt will examine 'pay-for-delay' agreements in Germany in detail.

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?

This consideration applies in Germany as well. See above under: 1 a) and 1 f). In both cases the notion of an undertaking is the limiting factor to have an effective enforcement towards (public) health insurances.

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.

See above. There is no effective enforcement towards payers.

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

The German public insurance sector (GKV – Gesetzliche Krankenversicherung) covers approximately 90% of the population. Hence, the following section focusses on the GKV only. For private insurances different provisions apply partly.

Innovative Pharmaceuticals (out-patient sector)

Germany is crucial for Market Access in Europe due to its market size and International Reference Pricing. 17 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.

The AMNOG process introduced a mandatory early benefit assessment for any new active pharmaceutical ingredient (API) launched in Germany after January 1st 2011. Manufacturers will only achieve reasonable reimbursement prices for their products if they obtain a favorable additional benefit rating by G-BA (Gemeinsamer Bundesausschuss). After a period of 6 months for the health technology assessment by the G-BA price negotiations with the German payer group GKV-Spitzenverband follow if an additional benefit is acknowledged by the G-BA. The price negotiations might take up to 6 months and are regulated partly by law (SGB V) but also allow for some discretion for the company and the payer group (regarding risk-sharing and/or price volume agreements for example). If price negotiations fail an arbitration board sets the price on the basis of the comparator's price, the G-BA assessment, other similar drugs in Germany and the product price in 15 other European countries. If no additional benefit is acknowledged by the G-BA the price of the standard generic therapy applies.

Contracting and tendering for pharmaceuticals (out-patient sector)

For innovative APIs contracting with individual payer groups is possible under § 130a para. 8 SGB V but rarely takes place as the rebates given in the AMNOG process to all health insurers are usually significant.

By contrast, generic markets since 2006 are mainly driven by tenders of individual health insurances such as the AOK group (approx. 40 % market share) which are governed by EU public procurement law. The company succeeding in tenders obtains superiority at the pharmacy dispensing point (generic substitution) and thus usually gains volume. Even though various forms of tenders exist (one or three partner models / open house contracts) a solid knowledge about the provisions on generic substitution and procurement law are crucial to succeed in tenders and gain market share.

Hospital market (in-patient sector)

The reimbursement in the German hospital market is governed by so-called Diagnosis-Related Groups (DRGs). DRG's are indication-specific lump-sums which are triggered by certain operating procedures (so-called OPS-Codes). For methods that cannot be adequately compensated in this manner, the DRG-system provides for regular additional payments; this is particularly important for medical interventions with high material costs. Since new innovative drugs and medical devices are not immediately integrated in the DRG-system, hospitals are entitled under certain conditions (NUB-status 1 granted by InEK) to agree temporarily on so-called NUB-payments. Recent experience shows that access of new diagnostic and treatment methods becomes increasingly difficult and public health insurances increasingly refuse to pay for methods that have not yet demonstrated their patient-relevant benefits on the basis of sufficient evidence. It is all the more important that companies properly deal with new instruments that have been introduced by the legislator in the last years, such as the so-called testing mechanism in § 137e SGB V or the early benefit assessment in § 137h SGB V.

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?

There are no restrictions on parallel trade or resales of drugs subject to price control. Parallel trade conditions are set by ECJ case law. See above for reimbursement and parallel trade: 3 a).

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.

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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.

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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.

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.

Hence, one might see a trend to import the price of other countries rather than the product itself like in parallel trade constellations.