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

Austrian Report

by the national reporters:[1]
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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.

In Austria, competition law infringements in the pharmaceutical sector are covered by the general antitrust provisions, i.e. the Austrian Cartel Act 2005 ("Cartel Act")[2] and the Competition Act,[3] which complements the Cartel Act and contains rules on the Federal Competition Authority (*Bundeswettbewerbsbehörde* – "FCA"), its tasks and some procedural rules.

Concerning these acts, the most recent amendment[4] entered into force on March 1, 2013. In addition to bolstering public enforcement of the competition rules by the FCA (*inter alia*, the FCA now has the right to enforce its information requests by way of fines and, during dawn raids, may questions any representative or employee of the raided undertaking), the Cartel Act now contains a number of measures intended to strengthen private enforcement (civil courts bound by decisions of competition authorities, etc)[5]. Further, there have been a number of modifications in substantive competition law. The *de minimis* rules have been revised, which henceforth, not apply to hard core restrictions.[6] Moreover, the notion of collective dominance has been extended.[7]

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.

It can be assumed that the market definition approach in the pharmaceutical sector is not different than in other business segments. The term "assumed" is based on the fact that although there had

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[2] Bundesgesetz vom 5.7.2005 gegen Kartelle und andere Wettbewerbsbeschränkungen (Kartellgesetz 2005), BGBl I Nr. 61/2005 idF BGBl I Nr. 51/2012.

[3] Bundesgesetz, mit dem das Bundesgesetz über die Einrichtung einer Bundeswettbewerbsbehörde (Wettbewerbsgesetz—WettbG) erlassen und das Kartellgesetz 1988, das Strafgesetzbuch und das Bundesfinanzgesetz 2002 geändert werden, BGBl I Nr. 62/2002.

[4] Kartell- und Wettbewerbsrechts-Änderungsgesetz 2012 (KaWeRÄG 2012), BGBl. I Nr. 13/2013.

[5] Cf. new Sect. 37a Cartel Act.

[6] *See* revised Sect. 2(2) No. 1 Cartel Act.

[7] *See* new Sect. 4(2a) Cartel Act.

been some decision (see below), which, at least partly, touched the pharmaceutical sector, the court decisions so far did not define in detail the relevant market.

To the individual decisions:

In (a merger control case) the Cartel Court defined a pharmacy / retail market for pharmaceuticals and a wholesale-market for pharmaceuticals as the relevant markets.[8]

In private enforcement claims, there had been some decisions where the claimant argued that the respective (public) body / sickness fund is an undertaking in the meaning of the Austrian Cartel Act (and can be therefore, e.g., be held liable for an abuse of dominance according to Art 5 Cartel Act):

- In 16 ok 13/03[9] the public association of the (public) social security providers („*Hauptverband der österreichischen Sozialversicherungsträger*", ASSA) was not considered of being an undertaking in the meaning of the Cartel Act when deciding whether a pharmaceutical will be listed on the Austrian register of pharmaceuticals (which is a precondition for the patient to get prices refunded for the respective pharmaceuticals). The applicant, who was active in the development, manufacture and distribution of medicinal products, tried to keep his products on the register and claimed that the association was dominant in the respective market, i.e., the "demand for pharmaceuticals in Austria". Following the claim, the association was abusing its dominance by withdrawing the applicant's products from the register. The claim was denied. In the Cartel Supreme Court's view, the register's legal nature was a regulation. Therefore the association acted in the exercise of public authority. The Cartel Supreme Court itself did not define the relevant market.

- In 16 ok 12/03[10] it was ruled that a public sickness fund is an undertaking in the meaning of the Cartel Act. The claimant was a provider of lab diagnostics and had a contract with the defendant, which was a public sickness fund, which directly refunded the patients of the claimant. Based on complaints and investigations, the sickness fund decided to withdraw the contract with the claimant. As the agreement between claimant and defendant was a based on private law, the Cartel Supreme Court decided that the sickness fund can be considered of being an undertaking. Further, the Cartel Supreme Court decided that the sickness fund did not have any competitors on the market and was therefore dominant in the respective market, which was the market for lab diagnostics in a certain area of Austria. However, as there had been objective reasons for withdrawing the contract, the Court denied the alleged abuse of dominance.

- Based on preliminary rulings of the ECJ[11], the Cartel Supreme Court decided in 16Ok5/04[12] that the 16Ok12/03 ruling must be reversed. Following the Cartel Supreme Court, a public sickness fund, which is legally founded must not be considered as an undertaking in the meaning of Section 1 Cartel Act / Art 101 TFEU if – with regard to the sickness fund's respective behavior - the following five criteria are fulfilled: 1 Participation in administrating a system of social security, 2. Acting under the principle of solidarity, 3. Operating on a not-for-profit basis 4. Law based fees

8 Decision of the Cartel Court, 24 April 2004, 27kt446/02. On substance, the court stated that if a wholesaler of pharmaceuticals with a market share of 46% on the wholesale market for the sale to pharmacies (i.e. retailers) acquires pharmacies with a respective market share of <3% on the retail market, it cannot be assumed that the wholesaler will strengthen its market position on wholesale level. According to the judgement (and based on a , such strengthening can be only assumed if the wholesaler achieves a market share of min 10% -12% on the retail pharmacy market.

9 Cartel Supreme Court, 16Ok3/03, Decision from 17 November2003.

10 Cartel Supreme Court, 16Ok12/03, Decision from 15 December 2003.

11 ECJ, C-264/01, C-306/01, C-354/01 und C-355/01, Decision from 16 March 2003.

12 Cartel Supreme Court, 16Ok5/04, Decision from 14 June 2004.

/ law based obligatory services and 5. Independency between services and fees. The Cartel Supreme Court stressed that in this case, a sickness fund, even if it is agreeing by private law contracts with (here) outpatient clinics concerning the reimbursement of medical costs of patients, is not an undertaking in the meaning of Art 102 TFEU.

In the *Apothekerpreisliste* case,[13] the Cartel Court dealt with a price list issued by the Austrian Pharmacists Publishing Company ("*Österreichischer Apothekerverlag*"), 50 percent of which were held by the Association of Pharmacists. The price list was available to all Austrian pharmacists and, although it was explicitly stated that the prices were non-binding for its members, it served as a "medium" for the concerted pricing of pharmaceutical products all over Austria. The Court found evidence of compliance with the price list by almost all Austrian pharmacists (in fact, the prices of the relevant products were the same on the entire Austrian market). Consequently, the Cartel Court held that the concerted use of the price lists by the Austrian pharmacists constituted a cartel within the meaning of the Cartel Act. This finding was upheld on appeal by the Cartel Supreme Court in 1997.[14] In its ruling the court did not define a relevant market, but referred to "*independent Austrian pharmacists*".

In a case concerning a cooperation agreement between two large pharmaceutical companies,[15] which contained an exclusive distribution agreement (vertical restraints) as well as covenants not to compete for certain products (horizontal restraints), the Cartel Court held that the arrangement constituted a cartel by agreement. The cartel, however, was approved because the Cartel Court found that such an agreement was justified on macro-economic grounds (a defense available under the Cartel Act 1988) due to the high investment costs for research and marketing for the products concerned. The decision itself (and therefore potential remarks concerning the relevant market) is not published.

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 Austrian cartel courts, e.g. in 16 Ok 51/05[16], 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*".[17]

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.

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[13] See Case No. 25 Kt 559/96, Apothekerpreisliste.

[14] *See* Case No. 16 Ok 14/97.

[15] *See* Case No. 26 Kt 8/97, *Glaxo Wellcome/Warner-Lambert*.

[16] Cartel Supreme Court 16 Ok 51/05, Decision of 26 June 2006.

[17] 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.

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

As outlined above, Austrian Cartels Courts in the past dealt with the question, if public sickness funds must be considered as an undertaking in the meaning of Section 1 Cartel Act / Art 101 TFEU. Concerning the pharmaceutical sector as such, no special aspects were issued so far.

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, as outlined in 1.b above, cases with reference to the pharmaceutical sector are based on Art 101 TFEU, Art 102 TFEU and merger control law.

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.

Based on Reg (EC) No 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws, the Austrian Federal Competition Authority ("Bundeswettbewerbsbehörde", "BWB") has been named by Austrian Law[18] as one of 5 Austrian authorities for the enforcement of consumer protection laws. The BWB hereby deals with general (not individual) intra-Community infringements. In this function, the BWB, e.g., is entitled to file a claim for a restraining order at a civil court against undertakings which (allegedly) infringes consumer protection law. Furthermore, the BWB can request cease-and-desist declarations of the respective undertakings.

In terms of law, Austrian competition law does not interact with consumer protection law. Rather, the latter is assigned to the Austrian Civil Code ("ABGB").

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.

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

[18] Bundesgesetz über die Zusammenarbeit von Behörden im Verbraucherschutz (VBKG) mit Wirkung vom 29.12.2006

activities?

So far, there have not been any sector-specific reviews of competition law in the pharmaceutical sector in Austria.

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. Only in its very short "point of view" concerning franchising[19], the FCA also refers to accompanying intellectual property issues. E.g., to the fact that post-contractually the use and disclosure of secret Know-how can be prohibited for an unlimited period of time.

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

Concerning key pharmaceutical cases, the cases were exclusively public in character (see above (1b)). With regard to alleged infringements of (public) sickness funds, the cases initiated were private in character. The reason is that in these cases the respective applicant (pharmaceutical companies, clinic operators) had an essential economic in claiming that the respective fund was considered dominant on the respective market. However, as outlined above, all private claimants failed to succeed.

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

So far, no remedies were applied in Austria. The above mentioned Apothekerpreisliste[31] case was based on a complaint for declaratory judgment and therefore did not result in a fine.

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 mechanism for the monitoring o patent settlements in the pharmaceutical sector in place in Austria.

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 suppliers are not obliged to make available pharmaceutical products they are licensed to sell.

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?

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[19] http://www.bwb.gv.at/Fachinformationen/Standpunkte/Seiten/Franchisevertr%C3%A4ge.aspx

[31] *See* Case No. 25 Kt 559/96, *Apothekerpreisliste*.

As already mentioned in 1.b. Glaxo Wellcome and Warner-Lambert had agreed in a cooperation agreement, which contained an exclusive distribution agreement (vertical restraints) as well as covenants not to compete for certain products (horizontal restraints). The Cartel Court[48] held that the arrangement constituted a cartel by agreement. The cartel, however, was approved because the Cartel Court found that such an agreement was justified on macro-economic grounds (a defense available under the Cartel Act 1988) due to the high investment costs for research and marketing for the products concerned. The decision itself (and therefore potential remarks concerning the relevant market) is not published.

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 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.

The Austrian law has transferred the European directive 2001/83/EC on the community code relating to medicinal products for human use. Consequently all data protection rules and marketing authorisation rules apply accordingly. There is nevertheless one incentive for generics to launch first: The first generic the market gets a better price compared to other generics being launched later.

The first generic is required to be priced at least 48% below the originator.[20] The second generic needs to reduce its price by at least 15% from the price from the first generic and the originator by at least 30% within three months after the inclusion of the first generic into reimbursement list of the Austrian health funds. The third generic needs to reduce its price by at least 10% from the price from the second follower.[21] At this time all of the products have to reach the price level of the third follower within three months after the inclusion of the third follower.[22]

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)?

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[48] *See* Case No. 26 Kt 8/97, *Glaxo Wellcome/Warner-Lambert*.

[20] § 351c para 10 Austrian Social Security Code (ASVG), § 25 para 2 Reimbursement Code (VO-EKO)

[21] http://generikaverband.at/generika/erstattung/

[22] § 351c para 10 ASVG

The Austrian case law applies the scope of the patent approach.[23] Activities of right holders which do encompass solely those rights actually conferred by IP-rights are considered justified by these rights. IP-rights do not excuse other abusive practices which do not fall within their scope.

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?

Consequently the mere presence of intellectual property does not trigger an absolute bar to competition law enforcement. As a rule of thumb, it can be stated, that enforcing IP can never be considered abusive, settlements and other agreements however can and have to be measured on the scope of the respective IP right. Licence agreements will not infringe anti-trust rules if the limitations of the licensee do not go beyond and the typically extent of the enforcement of an IP right. Limitations of the free movement of goods are allowed only to the extent conferred by the law to the respective IP right.[24] Therefore only such limitations are justified, which do respect the character of the IP right. All commitments and limitations associated thereto are admissible. Right holders do not violate Articles 34 to 36 of the EU-Treaty, if they use their rights to hinder importations of infringing products from third party countries into the EU.

The ECJ already has ruled on the scope of the various IP rights (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).

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 Austrian case law does not provide for examples showing the difference between acceptable settlement payments and unacceptably restrictive settlement in Austria.

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

There is no Austrian case law in place stating that the date of the settlement in relation to a patent term provides an indication about any anti-competitive behaviour. Rather each court has to decide on the individual case.

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

[23] *Gamerith*, Wettbewerbsrecht II[5], 60; *Barfuss/Wollmann/Tahedl*, Österreichisches Kartellrecht, 34, *Koppensteiner*, Österreichisches und europäisches Wettbewerbsrecht[3], § 7 Rz 94; *Wiebe* (HG), *Appl* Wettbewerbs- und Immaterialgüterrecht², 437

[24] Austrian Supreme Court– Coca-Cola, 23. 1. 1978, Okt 4/77

law claims.

n.a.

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 official Austrian pharmaceutical price index ("*Warenverzeichnis I der österreichischen Apothekertaxe*") is the listing of products distributed by public pharmacies. The listing is usually tied to a confirmation that the product is readily available, unless stated otherwise. The listing of the products in this price index is therefore a prerequisite for applying for cost reimbursement by health funds. The fact, that the price index is issued only once a month, together with the Austrian case law according to which the mere listing in the price index (even when indicating that the products will be available solely upon patent expiry) is considered a patent infringement results in a factual patent term extension of up to one month minus one day in the worst case. Such an extension is not justified by a patent right (being an extension of the principle of free movement of goods).[25]

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?

The Cartel Act does not grant any exemptions for the healthcare industry as such. The exemptions for sickness funds, etc, as outlined in 1.b. above, are therefore based on Austrian and EU case law.

In a recent merger control decision[26], the Cartel Supreme confirmed a decision of the Cartel Court as court of first instance following which a rehabilitation centre was considered as an undertaking in the meaning of the Cartel Act[27]. The decision was based on the following facts:

A subsidiary of a public sickness fund acquired 49% of the stake in a rehabilitation centre and the right to appoint the management. Following the planned transaction, the purchaser of the 49% stake, the Austrian Social Insurance Authority for Business ("SVA") remained as a 51% shareholder. The Cartel Court as court of first instance decided that the acquirer, by refraining to notify the acquisition, hereby infringed the standstill obligation. A fine of EUR 155.000 was imposed on the acquirer. The acquirer appealed the decision and argued that the rehabilitation centre acts in the exercise of public authority with the consequence that the centre does not qualify as an undertaking (and therefore the planned transaction would not have to be notified).

In order to examine the question concerning exercise of public authority, the Cartel Supreme Court first cited EU case law, inter alia *C-159/91*[28], following which in general "*sickness funds, and the organizations involved in the management of the public social security system, fulfil an exclusively*

[25] *Schultes*, Patentverletzung durch Arzneimittel im Warenverzeichnis vs Warenverkehrsfreiheit in ÖBl 2013,51

[26] Supreme Cartel Court, 16Ok3/15z, Decision of 08 October 2015.

27 Cartel Supreme Court, Case No 16Ok3/15z, Decision of 08 October 2015.

[28] ECJ, Joined Cases C-159/91 and C-160/91, Christian Poucet / Daniel Pistre, Decision of 17 February 1993.

social function" if an activity "*is based on the principle of national solidarity and is entirely non-profit-making. The benefits paid are statutory benefits bearing no relation to the amount of the contributions*."[29] However, in the given case the Cartel Supreme Court denied exercise of public authority. The Cartel Supreme Court hereby referred to the criteria defined in its judgment in the above mentioned 16Ok5/04 decision[30]. Following the Cartel Supreme Court, the given rehabilitation centre did not participate in the administration of a system of social security and did not act under the principle of solidarity. By competing also for private patients, the rehabilitation centre furthermore provided services to the private market.

The acquisition of the shares was therefore a notifiable merger between two undertakings. The Cartel Supreme Court confirmed the fine of EUR 155.000 imposed by the Cartel Court on the acquirer for infringement of the standstill obligation.

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.

The sickness funds represented by the public association of the (public) social security providers (ASSA), so far has never enforced any claims arising by IP or antitrust. In any case the Austrian law does not provide for any differences regarding the person seeking that kind of enforcement.

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

In Austria, the price of pharmaceuticals is determined by law under the competence of the pricing committee of the Federal Ministry of Health. For innovative medicinal products which shall be included into the reimbursement list of the Austrian Social Securities Association (ASSA), the EC-average price is relevant. This average price represents the maximum of a possible selling price ex works. For pharmaceuticals, which shall not be listed in the reimbursement list of the social securities, the selling price ex works may be fixed free from legal determinations but has to be communicated to the Federal Ministry of Health. The price of generics which shall be included into the reimbursement list of ASSA, is determined by a binding regulation concerning the publication of the reimbursement list (VO-EKO). Prior to an application for reimbursement, a product has to be listed in the product list of the "Apothekertaxe" (the pharmacists' database), which upon registration is available also in the internet (http://warenverzeichnis.apoverlag.at/).

Details:

1. OTC:

In general non reimbursable pharmaceuticals (OTC) fall under the price notification system (at the ex factory level) and pharmaceuticals applying for reimbursement fall under the statutory price system where Federal Ministry of Health - advised by the Price Committee - sets the EU average price.

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[29] ECJ, Joined Cases C-159/91 and C-160/91, Christian Poucet / Daniel Pistre, Decision of 17 February 1993, Para 18.

[30] As outlined above, following the Cartel Supreme Court in 16Ok5/04, a public health insurance must not be considered as an undertaking in the meaning of Section 1 Cartel Act / Art 101 TFEU if, in its respective behavior, the following five criteria are fulfilled: 1 Participation in administrating a system of social security, 2. Acting under the principle of solidarity, 3. Operating on a not-for-profit basis 4. Law based fees and law based obligatory services and 5. Independency between services and fees.

The price notification system is in place for all drugs not seeking reimbursement. The Price Committee within the Federal Ministry of Health is responsible for verifying the ex factory price notified by the manufacturer. If the Federal Ministry of Health does not oppose this price within 6 weeks the price automatically takes effect. If the price is deemed too high, the Federal Ministry of Health has the option to assign a price, a very rare practice.

The price ex-works for OTC-products is therefore formally free. There is not linkage to the average EC-price but the price has to be communicated to the authorities. Theoretically the Federal Ministry of Health can convoke a pricing comity, if the price is considered too high.

While the price of the manufacturer (distributor) therefore is relatively free, the margins for the further distribution chain is then regulated.

There is no reimbursement for OTC-products in Austria.[31]

2. Prescription drugs

2.1 Outpatient care:

Austria applies a positive list for pharmaceuticals in outpatient care, which is called the Reimbursement Code ("*Erstattungskodex", "EKO*"). Pharmaceuticals are granted reimbursement by the statutory health insurance which covers 98% of the Austrian population. The 19 sickness funds are represented by the public association of the (public) social security providers (ASSA). The ASSA is consulted by the Drugs Evaluation Commission ("*Heilmittel-Evaluierungs-Kommission", "HEK*",), which provides the ASSA with reimbursement status recommendations. Acc. to § 351g para 3 of the Austrian Social Security Code (ASVG), the HEK consists of 20 members (representatives from sickness funds, government, doctors and pharmacy chambers) HEK is responsible for deciding on reimbursement of a drug. The following decision criteria are applied for the assessment according to §§ 22ff of the Rules for the Issuance of the Reimbursement Code ("*Verordnung zur Herausgabe des Erstattungskodex", "VO-EKO*"):

1. Pharmacological analysis (comparison with therapeutic alternatives and perceived degree of innovation),
2. Medical-therapeutic evaluation (target patient group, effectiveness, expected duration and treatment frequency)
3. Economic considerations (this includes budget impact and PE evidence).

Additionally manufacturers must submit pricing comparisons (at ex-factory level) with the same or similar products in Austria as well as all available EU prices of their own drug. They are also required to generate a 3 year sales volume forecast and submit current sales data.

Pricing and reimbursement systems are closely linked. There are special pricing rules for pharmaceuticals applying for inclusion into the reimbursement code (EKO).

The holder of the Marketing Authorization applying for the inclusion of the pharmaceutical into EKO has to provide information on whether the pharmaceutical is on the market in other EU member states and if so has to submit the manufacturer price and wholesale price of the pharmaceutical in each of these markets (external reference pricing).[32] The Austrian Health Institute ("*Österreichisches*

[31] https://www.ispor.org/HTARoadMaps/Austria.asp#10; **Patricia Buchholz, RPh, PhD,** PBC Patricia Buchholz Consulting, Germany

[32] http://bmg.gv.at/home/Schwerpunkte/Medizin/Arzneimittel/Arzneimittelpreise/EU-Durchschnittspreise_laut_ASVG

Bundesinstitut im Gesundheitswesen", "ÖBIG") is responsible for checking the prices submitted by the industry; the EU average price is then calculated by the Price Committee and set by the Federal Ministry of Health. A price can only be set if the product is marketed in at least half of the EU-member states. If this is not the case, the Price Committee will re-evaluate pricing data every 6 months. If a price cannot be set at the second re-evaluation, an average EU ex factory price is calculated based on available EU pricing data. Until a final price can be set, the ex factory price submitted by the manufacturer is temporarily applied for reimbursement purposes. If this price is subsequently found to be above the EU average, the manufacturer has to pay back the difference to the sickness funds. [33]

Once the ex-factory price has been established products are placed into the red box of the reimbursement code, where the permitted maximum price is the EU average price. Once drugs are move into the green box, prices must be below the EU average price. If drugs are in the yellow box, manufacturers may charge a price up the EU average price.[34]

The different categories have been assigned boxes with different colour codes:

- The RED BOX includes newly launched pharmaceuticals and all pharmaceuticals applying for reimbursement. The latter group stay in this box for 90 days and - if reimbursement is granted - are then transferred either to the YELLOW or to GREEN BOX.

- The YELLOW BOXES include drugs that have to fulfil certain criteria to be reimbursed e.g. use in specific disease or age groups. Prescribing physicians will need to get reimbursement approval from the "head physician" (Chefarzt) of the sickness fund for all drugs categorized in the RED and YELLOW BOXES.

- •The LIGHT YELLOW BOX allows prescribers to prescribe automatically for defined indications or a certain volume of a drug once it has been initially approved by the head physician of the patient's sickness fund.

- Drugs in the DARK YELLOW BOX are only reimbursed under certain conditions (disease or age groups/prescribed by a specialist) or if it has been initially approved by the head physician.

- Drugs in the GREEN BOX will be automatically reimbursed. They are defined as first choice drugs and thus can be prescribed by any contract physician. Inclusion is based on certain criteria of drug usage such as disease group or mode of application.

Austria also has a negative list, which includes drugs not eligible for reimbursement ("NO BOX"). This list includes hospital only drugs, lifestyle drugs, and dietary supplements).[35]

Prices for pharmaceuticals included into the Reimbursement Code (EKO) may further be negotiated with the HVB. [36]

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[33] http://bmg.gv.at/home/Schwerpunkte/Medizin/Arzneimittel/Arzneimittelpreise/EU-Durchschnittspreise_laut_ASVG

[34] § 25 para 6 VO-EKO

[35] http://www.pharmig.at/DE/Infothek/Rund%20um%20das%20Gesundheitssystem/Erstattungssystem/Erstattungssystem+in+%C3%96sterreich.aspx

[36] Quelle: https://www.ispor.org/HTARoadMaps/Austria.asp#10; **Patricia Buchholz, RPh, PhD,** PBC Patricia Buchholz Consulting, Germany

When reimbursement is granted pharmaceuticals are fully reimbursed. In this case patients will have to pay out of pocket a fixed prescription fee of 5.70 € (in 2016).

2.2 inpatient care:

Drugs used for inpatient care are included into the Diagnosis Related Groups-remuneration system of hospitals and thus there is neither separate reimbursement nor patient copayment. However there is copayment for hospital inpatient care.

Ex factory prices for hospital only drugs are determined by the Federal Ministry of Health and such prices are the maximum at which the product may be sold. A reference price system is not in place at this moment.

2.3 Pricing Approval Process and Time Frame

The Price Act builds is the overall framework for pricing in Austria. Pricing decisions on pharmaceuticals are taken by the Federal Ministry of Health which is advised by the Pricing Committee (Preiskommission).[37] Furthermore there is a price notification agreement in place between the Federal Chamber of Labour (Bundesarbeiterkammer) and the Federal Chamber of Commerce (Wirtschaftskammer). [38]

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. The Austrian authorities feel bound by the Kohlpharma judgment and therefore do not apply a restrictive practice.

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.

One important aspect which should be dealt with in the League's report, is the admissibility of parallel importation of pharmaceuticals. National price regulations distort the market for pharmaceuticals within the European market. Parallel importers gain profits from the different price

[37] § 9 PreisG

[38] Quelle: https://www.ispor.org/HTARoadMaps/Austria.asp#10; **Patricia Buchholz, RPh, PhD,** PBC Patricia Buchholz Consulting, Germany

levels that are imposed to pharmaceutical companies, without any proper participation of the national health funds on the benefits.

The admissibility of parallel import is a result of the fundamental principle of the free movement of goods within the Community. The framework of parallel import is set by two landmark decisions of the ECJ on the interface between IP and antitrust-law: Dual pricing has not been allowed by the ECJ (C-501/06p), while product allocation was (C-10-468/06-478/07).

It should be discussed whether the national interventions on the prices for pharmaceuticals should not justify an exception from the free movement of goods.