EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 726

PHARMACEUTICAL COMMITTEE
27 March 2017

Subject: **Update on Court cases**

Agenda item 1i

- **Case C-148/15 – Dt. Parkinson – Judgement of 19 October 2016**

Background: This preliminary ruling concerns German provisions imposing fixed prices for the sale of prescription-only medicinal products by pharmacies. Those provisions restrict the ability of pharmacies to give discounts through customer loyalty schemes.

In the case under consideration, a Dutch based mail-order pharmacy offered a bonus system to patients suffering from a chronic disease, if medication is regularly ordered from that pharmacy. A German watchdog for fair competition considered that such bonus system infringes the German system of fixed prices and took the Dutch based internet pharmacy to court.

As the German court was unsure whether the German system complies with EU law, namely the Treaty provisions on free movement of goods, it referred the matter to the Court of Justice. Basically two questions were asked to the Court of Justice: (1) whether a system of fixed prices for the sale by pharmacies of prescription-only medicines constitutes a trade barrier within the internal market (Article 34 TFEU) and (2) if this is confirmed, whether such barrier could be justified on grounds of the protection of public health (Article 36 TFEU).

Main considerations of the Court

The ECJ took the view that a system of fixed prices for prescription medicines constitutes a barrier to trade and that Germany was not able to provide convincing argument for its justification. The system was therefore found to infringe general Treaty principles (free movement of goods).

Even if the system of fixed prices applies both to pharmacies established in Germany and to those established in other Member States, it disadvantages foreign internet pharmacies. In this regard the Court considered that internet pharmacies face a competitive handicap compared to traditional pharmacies, as brick and mortar pharmacies would be better placed than mail-order pharmacies to provide patients with individually-tailored advice and to ensure a supply of medicinal products in cases of emergency. Hence, price

competition would provide internet pharmacies with the means to overcome this competitive disadvantage. In turn it means that the current German system of fixed prices has a greater impact for pharmacies established outside Germany than for pharmacies within Germany. On that basis, the Court concluded that a system of fixed prices for prescription medicines is a barrier to trade in the sense of Article 34 TFEU. [para. 27]

As far as a possible justification of the trade barrier is concerned, the Court recognised that the need to ensure a reliable and high-quality system for the supply of medicines is in principle capable to justify a barrier to trade.

Germany argued that a system of fixed prices is needed to avoid that pharmacies engage in ruinous price competition which would result in the closure of traditional pharmacies, especially in rural areas. The burden of proof for this effect is however with Germany and according to the Court Germany made only contentions of general nature without providing specific data or evidence substantiating the risk. [para. 38]

Similarly, the Court concluded that the elements laid before the Court in the present case did not suffice to show that price competition for prescription-only medicinal products would adversely affect traditional pharmacies in performing certain activities in the general interest, such as emergency services, producing prescription medicinal products or maintaining a given stock and selection of medicinal products. [para. 40]

Additionally, the Court was also not convinced by the argument that a 'bonus system' may entail the risk that patients might attempt to pressurise doctors to obtain prescriptions of convenience. [para. 42]

Of note, the judgement is only based on a legal analysis against the Treaty provisions on free movement of goods. Article 85c of Directive 2001/83 dealing with distant sales of human medicinal products was not considered by the Court (and not even mentioned in the judgement).

- **Case T-672/14 – August Wolff – Judgement of 20 October 2016**

Background: In September 2014 two marketing authorisation holders brought the Commission to court and requested the (partial) annulment of the Commission decision that completed a Union interest referral under Article 31 of Directive 2001/83 on high-concentration estradiol containing products (national marketing authorisations). Those 'referral procedures' are used to address concerns regarding the safety, efficacy or quality of authorised products with the aim to come to a harmonised view whether the marketing authorisation should be varied, withdrawn or maintained. In this case, it was concluded that the risk of this hormone therapy with estradiol is higher than previously thought and that the use of the products should be restricted.

The applicants alleged several procedural mistakes (related to the timing of the initiation of the procedure and the handling at EMA), as well as the scientific soundness of the EMA opinion (CHMP) on which the Commission decision is based.

Main considerations of the Court

The General Court dismissed the claims against the legality of the Commission decision in their entirety.

With regard to the initiation criteria, the General Court considered that those criteria should be interpreted broadly taking account of the general purpose of this referral procedure to allow for a common assessment of quality/safety/efficacy concerns of nationally authorised products at EU level.

The Court also confirmed the 'Union interest', which is another criterion under Article 31, due to the fact that the products concerned were authorised in several Member States. [para. 56-66].

As far as the legal scrutiny of the EMA scientific opinion is concerned, the General Court repeated its constant case law that the Court's review of the scientific assessment is limited. The General Court has to reassure itself that, in accordance with the general rules of evidence, the scientific assessment provides solid and convincing evidence which, while not resolving the scientific uncertainty, may reasonably raise doubts as to the safety and/or efficacy of the medicinal product concerned (taking the precautionary principle into account). In the case under consideration the scientific opinion fully complied with those requirements.

The first instance ruling is however currently under appeal (case C-680/16P).

- **Case C-276/15 – Hecht Pharma – Judgement of 26 October 2016**

Background: Hecht Pharma, the applicant in the national court case, sells incense capsules as a food supplement in Germany. The defendant operates a pharmacy in Germany and sells via his premises incense extract capsules as medicinal product. The defendant does not have a marketing authorisation for those capsules, but relies on a specific derogation in German pharmaceutical law, which allows pharmacists to manufacture and sale ready-made medicines under certain conditions. The derogation applies, if the essential manufacturing steps for such products are carried out in a pharmacy as part of normal business activities producing a limited quantity per day and intended for clients of the pharmacy only.

The national court referred the case to the ECJ in order to review whether the specific derogation in German law complies with Directive 2001/83. More concretely, the national court asked whether the specific derogation in German law complies with one of the two 'pharmacy'-exemptions provided by Article 3(1) and (2) of Directive 2001/83.

Main considerations of the Court

With its ruling the ECJ took the view that the incense products manufactured by the pharmacy do not require a marketing authorisation, as they do not come in the scope of Directive 2001/83.

The Court considered though that the questions of the national court were to narrow and should be extended to include Article 2 of Directive 2001/83, i.e. whether the product in question is 'prepared industrially or manufactured by a method involving an industrial process'. This extension has to be seen against the backdrop of the 2015 ECJ ruling in the Abcur cases (C-544/13 and C-545/13), where the ECJ found that the pharmacy exemptions in Article 3 are only applicable, if the product satisfies the conditions of Article 2, ie. if it is not an industrially prepared product. [para. 30]

According to the Court, an industrial process differs from an artisanal process in the means of production used and, consequently, in the quantities produced. An industrial process is characterised in general "*by a succession of operations, which may, in particular, be mechanical or chemical, in order to obtain a significant quantity of a standardised product*". The standardised production of significant quantities of a medicinal product to be stocked and sold wholesale and the large-scale or serial production of magistral formulae in batches are characteristic of industrial preparation or manufacture by a method involving an industrial process. [para. 32+33)

In the present case, the Court believed that the medicinal product at issue is not industrially produced, but in small quantities by artisanal methods by a brick and mortar

pharmacy (in the oral hearing it was said that only 213 packages of the capsules had been sold in 2015).

However, should the referring court take a different view and consider that they have been prepared industrially, the pharmacy may rely on the specific derogation in German law for officinal formula, even if the German provision is just paraphrasing Article 3(2) of Directive 2001/83 without fully reproducing its wording.

- **Case C-114/15 – Audace – Judgement of 27 October 2016**

Background: The case concerns the possibility of livestock farmers to (parallel) import for their own use veterinary medicinal products from other Member States. The national court referred certain questions to the Court regarding the compliance of certain provisions in French law with the Treaty provisions on free movement of goods and Directive 2001/82.

Main considerations of the Court

While the ECJ considered that some of the restrictions provided by French law go beyond what is necessary, the Court confirmed the applicability of some essential public health requirements in order to ensure that such activity is appropriately framed.

According to the Court importation of veterinary medicinal products by livestock farmers for the needs of their farms constitute parallel import and farmers must obtain an authorisation, even if by a simplified procedure (para. 53-54). In addition, other provisions under Directive 2001/82 continue to apply, including on possession, dispensing, labelling/information leaflet and pharmacovigilance – as "part of the coherent system of measures put in place by [Dir 2001/82] in order to ensure a high level of protection of public health, in cases of parallel imports" (para. 56). Moreover, livestock farmers holding a parallel import license need prescription in accordance with Article 67 of the Directive (para. 58).

- **Case T-295/16 – Symbioflor v EMA – Order of 7 March 2017**

Background: The Agency was taken to Court (T-295/16) by a pharmaceutical company regarding the 'decision' to initiate an EU review procedure ('Union interest referral' – Article 31 of Directive 2001/83) of the medicinal product Symbioflor 2 (Escherichia coli bacteria), which is authorised in some Member States of the European Union (EU) for treating diseases affecting the stomach and gut including irritable bowel syndrome. The company alleges that the conditions for launching the review procedure were not fulfilled

Order of the General Court: The General Court dismissed the action as inadmissible. According to constant case law, the initiation of a procedure does not affect the legal position of the company. Moreover, within a procedure consisting of several steps only the final decision can be challenged before the courts, not the interim steps.

- **Watch list - Interesting pending cases on regulatory issues**

Case **T-269/15** (Novartis v Commission), direct action seeking the annulment of the Commission decision to grant marketing authorisation to the medicinal product Vantobra;

Cases **T-235/15, T-718/15 and T-729/15**, series of access to document cases against EMA concerning the confidentiality of scientific opinions on similarity/clinical superiority under the Orphan Regulation and the confidentiality of clinical study reports;

Case **T-80/16** (Shire v EMA), direct action seeking the annulment of EMA's decision to refuse validation for an application for orphan designation;

Case **T-303/16** (Novartis v Commission), direct action against the Commission decision in an Article 29 referral on tobramycin-containing products;

Case **T-329/16** (BMS v Commission/EMA), direct action against the Commission/EMA challenging the decision to withdraw the orphan status of a product at the time of marketing authorisation;

Case **C-629/15P (**and **C-630/15P)**, appeal of a pharmaceutical company against the General Court ruling in case T-472/12 and T-67/13 (Global marketing authorisation concept) – AG Opinion issued on 23.12.2016;

Case **C-296/15**, preliminary reference concerning tendering practices of Slovenian hospitals with regard to the procurement of plasma products;

Case **C-621/15**, preliminary reference concerning the liability for medicinal products (Article 4 of Directive 85/374 - standard of proof) – AG Opinion issued on 7.3.2017;

Case **C-179/16**, preliminary reference – anticompetitive behaviour of a pharmaceutical company on the Italian market – Avastin;

Case **C-557/16**, preliminary reference concerning data protection periods in a decentralised procedure and the mutual reliance on information provided by the Member State that first authorised the product.

Case **C-29/17**, preliminary reference regarding compliance of national provisions regarding off-label use, including reimbursement decisions, with Directive 2001/83, Regulation 726/2004 and Council Directive 89/105. The case may potentially frame the legal understanding of off-label use for the years to come.

- **Watch list - Interesting pending cases on the SPC Regulation**

Case **C-567/16**: This reference for a preliminary ruling relates to national court proceedings dealing with an appeal of a pharmaceutical company against the rejection of an application for a supplementary protection certificate by the competent authority in the UK (UKIPO).

UKIPO argues that the application did not comply with Article 3(b) of the SPC Regulation, which provides under the heading 'conditions for obtaining a certificate':

> *"A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:*
>
> *[…]*
>
> *(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;"*

In the case under consideration the company filed in September 2013 a marketing authorisation application under the decentralised procedure in accordance with Article 28 of Directive 2001/83, with UK as one of the concerned Member States.

On 10 September 2014 the reference Member State issued a so-called End of Procedure notice under Article 28(4) of Directive 2001/83. In accordance with Article 28(5), each Member States involved in the procedure "shall adopt a decision in conformity with the approved assessment report, the summary of product characteristics and the labelling and package leaflet as approved, within 30 days after acknowledgement of the agreement."

On 12 September 2014 the company filed an application for a SPC in the UK. The next day the patent expired. At that time the UK had not yet issued a UK marketing authorisation for the product concerned pursuant to Article 28(5). Therefore, the company submitted the End of Procedure notice instead.

As part of the questions referred by the national court to the ECJ, the Court is asked whether the "End of Procedure notice" can be considered as a 'valid authorisation' in the sense of Article 3(b) of the SPC Regulation.

Action to be taken:
For information