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# Developments in the online sale of pharmaceuticals in the EU

In this article, Gustaf Duhs, Partner and Head of Competition and Regulatory Law at Stevens & Bolton LLP, sets out a brief summary of the recent case before the CJEU relating to fixed pharmacy prices involving online pharmacy DocMorris and what this ruling means for the online sale of pharmaceuticals in Europe; further, Gustaf considers the latest developments in Germany and more generally in the EU following the CJEU's decision on the matter.

## Summary of the *Deutsche Parkinson Vereinigung* ('DPV') case

In short, the *DPV* case was one of several cases that originated in Germany and concerned restrictions placed by the German Government on the sale of pharmaceuticals. In that case an organisation supporting Parkinson's sufferers (DPV) offered a bonus scheme to members who purchased products from an online reseller (DocMorris). DPV was therefore accused of breaching German rules fixing the prices at which pharmaceutical products could be sold. DPV alleged that the rule on fixed prices breached the free movement provisions of the Treaty on the Functioning of the European Union ('TFEU').

This resulted in a reference for a preliminary ruling from the German Court to the Court of Justice of the European Union ('CJEU'). In October last year, the CJEU found that German rules applying fixed prices to pharmaceutical products were unlawful.

More specifically, the CJEU concluded that the fixed price measures amounted to a quantitative restriction on the free movement of goods in breach of Article 34 of the TFEU. This was because the measure had a disproportionate impact on online pharmacists, including those abroad. The CJEU found that online pharmacists were more reliant than bricks and mortar pharmacists on price competition, rather than, for example, competition based on physical location or pre and after sales advice. As the rules requiring fixed prices prevented pharmacists from competing on price,

the ability of online pharmacists to compete was more affected than that of bricks and mortar pharmacists.

The German Government's side put forward a number of arguments in favour of maintaining the fixed price rule. For example, it was argued that the fixed price rule ensured that there was an even spread of pharmacies across Germany and that it prevented free riding by online pharmacies on the sale efforts of bricks and mortar pharmacies. These arguments were not accepted by the Court. The Court held that any justification for restrictions on the grounds of protection of health and life of humans under Article 36 TFEU must be advanced by reference to appropriate evidence, which had not been provided. It was not clear, as the German Government contended, that allowing price competition from mail order pharmacists would prevent German bricks and mortar pharmacies from remaining competitive or that patients in poor health should not be required to carry out price comparisons.

## Developments since the *DPV* case in Germany

In Germany there has been vigorous debate following the judgment of the CJEU. German pharmacies and the Christian Democratic Union ('CDU')/Christian Social Union ('CSU') party have said that in light of the *DPV* case they can see no alternative to the reintroduction of an absolute prohibition of mail order pharmacies, and they maintain that such a prohibition would be necessary to protect human health. They suggest that a prohibition

would protect the independence of German health policies and ensure the survival of traditional pharmacies.

In late 2016, the German Bundesrat decided in favour of a proposal to once again prohibit the mail order sale of prescription only medical products. However, this proposal ground to a halt on 30 March 2017 when the coalition Government failed to reach an agreed position on the detail of the proposal. For example, there was some discussion around having the ban include exceptions in rural areas or for special circumstances, and also whether there would need to be additional requirements on bricks and mortar pharmacies in light of any such ban.

With the upcoming national elections in Germany (on 24 September 2017), it is reported that the outcome of the debate on the ban of online sales of medicines will not be clear until after the election. If the outcome is to move towards a ban, further legal objections are likely to be raised by online pharmacists that are now benefiting from the CJEU's judgment. Objections may be raised again on free movement grounds, for example on the basis that this ban is merely an attempt to circumvent the effects of the previous judgments, or that these restrictions might fall foul of other provisions of the TFEU like Article 106. Assuming the ban is introduced, and its legality is challenged in the courts, it will be interesting to see whether the German Government will learn from the *DPV* case and provide a much fuller case with extensive evidence to support its policy on public health grounds.

## The inexorable rise of the online sales model is likely to continue, and as it does, as Germany may find, it is very difficult to put the genie back in the bottle.

### Developments in relation to the online sale of pharmaceuticals across the EU

The treatment of online pharmaceutical sales is inconsistent across the EU. In an attempt in part to address these inconsistencies, in 2012 the European Commission launched Proposal 2012/0035 for a Directive 'relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems.' The aim of this proposal included an intention to ensure the transparency of measures established to control the pricing and reimbursement of medicinal products. The reason behind it was a perception that inconsistencies and opaqueness in the way that prices were regulated across the EU created barriers to cross border pharmaceutical trade. This Proposal was however withdrawn in 2015 on the stated basis of "no foreseeable agreement."

Interestingly the findings in the *DPV* case are consistent with those in the European Commission's Digital Single Market Study Preliminary Report. The wide ranging market study states its aim to be "better access for consumers to online goods and services." The Report found in respect of the (admittedly broad) category of Healthcare and Cosmetics: firstly that compared to other sectors studied, online retailers of cosmetics and healthcare as compared to bricks and mortar retailers found price competition particularly important, and secondly that manufacturers of cosmetics and healthcare viewed pure online sellers as particularly detrimental to their business. In light of this it might be anticipated that further cases might arise and that the European Commission might take further steps to seek to resolve the apparent tension in the sector between online resellers and manufacturers.

Certainly Member State governments are actively involved. The Netherlands, Sweden and Italy intervened in the *DPV* case alongside the German Government. In the UK, although online sales are not restricted, the

regulation of pharmaceutical prices is certainly a hot topic, with a wide array of enforcement cases under competition law and legislative changes to the regulation of generic medicine prices coming into effect.

### Wider implications for the online sale of pharmaceuticals

The *DPV* case and related developments highlight some common themes across many sectors:

- The ongoing (and perhaps never to be resolved) tension between bricks and mortar operations and the vigorous price competition offered by online resellers. This is typically characterised as a battle between online price discounters offering minimal levels of service and support and rock bottom prices pitched against traditional retail operations selling products using high levels of service and expertise.
- The tension (at times) between national government regulations and EU law provisions. Even governments that are broadly supportive of the EU (such as the German Government) can find themselves at odds with the free market structures of the EU.

The inexorable rise of the online sales model is likely to continue, and as it does, as Germany may find, it is very difficult to put the genie back in the bottle. The traditional distinctions between bricks and mortar and online sales are likely to decrease, and relationships change. Anecdotally at least we see that there are increasingly sophisticated models to ensure that service received online is at least on a par with that received in a bricks and mortar store, and the rise of apps, virtual reality and AI will only increase this trend. Bricks and mortar operations are in part seeking to compete by vigorously cutting costs and reducing service levels. Certainly the window for making arguments that online sales restrictions are justified may be narrowing with technology that increasingly makes a physical presence less relevant. Clearly if patients will in

the near future be able to be diagnosed and pharmaceuticals prescribed without needing to be present, it seems unlikely that a physical presence will be required to pick up such pharmaceuticals. In addition, at least one potential justification for online sales restrictions, which is perceived risks associated with the supply of false medicines, may be removed with the implementation across EU Member States of the Falsified Medicines Directive, which already applies in certain respects (for example requirements in relation to website logos for online pharmacies) and which will apply in full across the EU from February 2019. This wide ranging legislation ensures a central record and seeks to monitor supply of all medicines produced in the EU from the point of manufacture to final sale.

In relation to the tension between national government policies and the EU, this has always been a feature of EU law and policies, although perhaps it appears a more acute issue now in light of certain political developments (i.e. Brexit). Of course, that is not to say that the winds of change will only blow in one direction. The regulatory landscape is inevitably shaped by developments and politics, and perceived scandals with online sales have in the past slowed liberalisation or have been used as justifications for increased protections. As a UK lawyer it is inevitable to consider the impact of Brexit, and of course notwithstanding the outcomes of the Dutch and French elections it would be foolish to say that increased liberalisation in the field of online sales is inevitable even if for the reasons given above it appears likely. In relation to Brexit's impact on online sales in the UK it is very difficult to imagine that there will be significant changes resulting in this area. The UK was relatively quick to relax restrictions on online sales of pharmaceuticals. However, if there is an end to the free movement of EU goods to the UK one cannot entirely dismiss the possibility of online sales restrictions being more readily adopted.