

# German fixed price system infringes EU law

With today's judgment the European Court of Justice ("ECJ") has ruled that the German fixed price system for prescription-only medicinal products ("Rx products") is incompatible with the principle of the free movement of goods under European law. Although, consequences of the judgment will have to be assessed in more detail, to avoid disadvantages for German dispensing pharmacies, a more radical change of the current legal framework may be required.

## Background of the case

In the case referred to the ECJ for a preliminary ruling, an organisation of Parkinson's patients has established and promoted a bonus system for its members ordering their medication at the Dutch mail-order pharmacy Doc Morris.

An association for the protection against unfair competition has taken the view that this bonus system infringes the German fixed price system for Rx products and has initiated civil court proceedings to stop this practice.

In the first instance, the Regional Court of Düsseldorf has ordered the self-help organisation to stop promoting the bonus systems among its members.

According to the German Regulation on the pricing of medicinal products, the manufacturer of Rx products must establish a uniform price for its products to which the wholesaler and the pharmacy may add a certain amount (*Aufschlag*). In addition to this, the German Health Advertising Act (*Heilmittelwerbegesetz*) prohibits the

grant of discounts in violation of this fixed price system.

The patient organisation has appealed to the Higher Regional Court of Düsseldorf arguing that the German fixed price system is incompatible with European law.

## The Preliminary Ruling

Against this background, the Higher Regional Court of Düsseldorf has referred three questions to the ECJ:

1. Must Article 34 of the Treaty on the Functioning of the European Union ("TFEU") be interpreted as meaning that a system of fixed prices laid down by national law applicable to Rx products constitutes a measure having equivalent effect within the meaning of Article 34 TFEU?
2. Is the system of fixed prices for Rx products justified under Article 36 TFEU on grounds of the protection of health and life of humans if that system is the only means of ensuring a consistent supply of medicinal products to the population across the whole

of Germany, in particular in rural areas?

3. What is the degree of judicial scrutiny required when determining whether the condition mentioned in Question 2 is in fact satisfied?

Confirming the Opinion of Advocate General Szpunar delivered on 2 June 2016, the ECJ has ruled that the German fixed price system for Rx products constitutes an unjustified restriction of the free movement of goods. In particular, this decision is based on the following considerations:

- The German pricing rules have a greater impact on pharmacies established in other Member States and, thus, could impede access to the German market for products from other Member States more than it impedes access for domestic products. The reason for this is that sale by mail order is by far the most important means of accessing the market and the price is a very important competition factor for this distribution channel.
- The restriction of the free movement of goods is not justified on grounds of protection of the

health and life of humans pursuant to Article 36 TFEU because it has not been demonstrated how the current pricing system would ensure a better geographical distribution of traditional pharmacies in Germany. Moreover, the ECJ does not see a risk to ensure the continuation of essential services, such as emergency care due to a consequential fall in the number of dispensing pharmacies because of the price competition by mail order pharmacies.

## Consequences

For the immediate future this judgment does not change the legal framework in Germany. However, with regard to mail order pharmacies based in other Member States the German pricing rules will no longer be applicable.

The German legislator has different options to react to this judgment:

- Without significantly changing the legal framework, mail order pharmacies in other Member States could be exempted from the German pricing rules.

- However the judgment may also set in motion a more radical change of the legal framework resulting in either a ban on the sale of Rx products by mail order or the abolition of the current German pricing rules in order to avoid disadvantages for German dispensing pharmacies.

As of today, there has been no official announcement by the Federal Ministry of Health with regard to the options outlined above. However, first statements indicate that the legislator recognises the need to avoid disadvantages for German dispensing pharmacies.

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