

## Advocate General's Opinion from the ECJ Finds Public Bodies' Prescribing Incentive Schemes to be Unlawful

*Maria Isabel Manley and Marina Barnden* examine the advocate general's opinion from the European Court of Justice that could prevent governments from managing their public health systems freely.

The Association of the British Pharmaceutical Industry has won the first round in its battle against the UK Medicines Healthcare products Regulatory Agency regarding the legality of prescribing incentive schemes.

On 11 February, European Court of Justice advocate general Niilo Jääskinen in *Association of the British Pharmaceutical Industry v Medicines and Healthcare products Regulatory Agency* issued an opinion that puts the brakes on UK national health service schemes that seek to control healthcare expenditure by providing prescribing incentives in respect of specific named medicines<sup>1,2</sup>. The case raises important questions as to the nature and scope of the right of member states to manage their public health systems freely.

AG Jääskinen concluded that public bodies forming part of the National Health Service are precluded under European legislation from implementing a scheme that offers financial incentives to medical practices (which may in turn provide a financial benefit to the prescribing doctor) to prescribe a specific named medicine that is either different to that which might otherwise have been prescribed, or different to that which the patient has been previously prescribed. The applicable legislation is Article 94(1) of Directive 2001/83/EC, as amended (referred to hereafter as the Medicinal Code).

The advocate general reached his opinion despite the fact that such schemes have as their ultimate objective the reduction of national expenditure on medicines. If his opinion is followed by the ECJ, the case will represent a landmark dent to the right of member states to manage their public health systems freely and will provide a salutary reminder that the interests of patients must always prevail.

### Background

Primary Care Trusts in England (and Local Health Boards in Wales) use financial incentives to influence the prescribing habits of general practitioners in order to control overall healthcare expenditure. Such schemes essentially reward doctors for prescribing specific named medicinal products.

In 2006, the ABPI – the trade association representing over 90 companies in the UK that produce prescription medicines for human use – raised concerns about the prescribing incentive schemes with the MHRA. The complaint focused on Article 94(1), which deals with prohibiting inducements to prescribe. Article 94(1) provides:

*Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.*

The MHRA expressed its view that Article 94(1) covered only incentive schemes of a commercial nature. The ABPI disputed this interpretation and brought the case before the High Court of Justice of England and Wales, which subsequently referred questions to the ECJ.

In referring to the ECJ the question of whether Article 94(1) precludes a public body within the national health system from implementing a prescribing incentive scheme, the High Court is essentially asking the ECJ to reconcile two colliding spheres of power: the power of member states to regulate pricing and reimbursement and the power of the European Union to regulate advertising. Because the determination of a medicinal product's price and its inclusion in the scope of the national health insurance system is under the prerogative of the member states, the field is non-harmonised. This leaves room for national policy, so long as the transparency requirements of the Transparency Directive (Directive 89/105/EEC) are satisfied and the general principles of EU law are complied with.

In contrast, the field of advertising does not leave room for national policy, except where this is expressly provided for (for example, in relation to industry self regulation). In the words of

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*Prescribing incentive schemes reward doctors for prescribing specific named medicines*

*The ABPI disputed the MHRA's interpretation that Article 94(1) covered only incentive schemes of a commercial nature*

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AG Ruíz-Jarabo Colomer in Gintec (regarding the use of prize draws and the results from consumer surveys)<sup>3</sup>:

*...a careful analysis of Title VIII of Directive 2001/83 [on information and advertising] reveals an exhaustive system, leaving no autonomy to the Member States except where this is expressly allowed.*

*The reason for harmonisation in the field of advertising is to ensure the free movement of goods throughout the EU*

The reason for harmonisation in the field of advertising is to ensure the free movement of goods throughout the EU. This is recognised by the European Commission in its proposal for a Council directive on advertising of medicinal products for human use<sup>4</sup>:

*...the divergence in national laws restricting or prohibiting certain forms of advertising is capable of hindering the free movement of goods, by affecting the access of goods to the market. Harmonisation of national laws concerning pharmaceutical advertising is therefore necessary in so far as differences in the specific rules relating to this form of advertising limit the free movement of pharmaceuticals.*

This proposal resulted in Directive 92/28/EEC, which was subsequently codified (by the Medicinal Code) with other directives relating to medicinal products for human use. The Medicinal Code was adopted as an internal market measure with Article 95 EC as its legal basis. In making proposals under Article 95 concerning health, safety and consumer protection, the commission is to take as its basis a high level of protection. The very clear intention behind Article 94(1) of the Medicinal Code prohibiting inducements to prescribe is to maintain independence and objectivity in prescribing. Indeed, the precursor to Article 94(1) in Directive 92/28/EEC was explained as follows by the commission in its proposal for the directive on advertising<sup>5</sup>:

*...the objective information of doctors and pharmacists is incompatible with financial inducements of whatever nature, and as such should be prohibited.*

This is echoed by Recitals 47 and 50 of the Medicinal Code concerning, respectively, advertising generally and financial inducements:

*(47) The advertising of medicinal products to persons qualified to prescribe or supply them contributes to the information available to such persons. Nevertheless, this advertising should be subject to strict conditions and effective monitoring, referring in particular to the work carried out within the framework of the Council of Europe.*

*(50) Persons qualified to prescribe medicinal products must be able to carry out these functions objectively without being influenced by direct or indirect financial inducements.*

*AG Jääskinen recognised that the MHRA and ABPI were arguing the case on different foundations*

Against this background, AG Jääskinen recognised that the MHRA and ABPI were arguing the case on different foundations; the one on the basis of policy, the other on the basis of legal principle. The UK, adopting a position based on policy, argued that measures taken by public authorities in the context of limiting the increase in medicinal expenditure did not fall within the scope of the prohibition on inducements to prescribe. The ABPI, on the other hand, argued that as a matter of legal principle the primary obligation of medical professionals is to act in patients' best interests and, from this perspective, economic incentives provided by public authorities may be as harmful as those offered by pharmaceutical companies.

AG Jääskinen, finding in favour of the ABPI, was of the view that the aim of Article 94(1) – to maintain objectivity and independence in prescribing – would be compromised if public bodies were exempted from the prohibition relating to inducements to prescribe. His reasoning was, therefore, closely allied with Damgaard, which concerned the application of the advertising legislation to an article published by an independent journalist referring to an unlicensed medicinal product<sup>6</sup>. In Damgaard, the ECJ gave “advertising” a broad meaning in light of the essential aim of the Medicinal Code to safeguard public health<sup>7</sup>:

*...the wording of Directive 2001/83 does not rule out the possibility that a message originating from an independent third party may constitute advertising. Nor does the directive require a message to be disseminated in the context of commercial or industrial activity in order for it to be held to be advertising.*

*In that regard, it must be stated that, even where it is carried out by an independent third party outside any commercial or industrial activity, advertising of medicinal products is liable to harm public health...*

*“Advertising” appears to include any communication regarding medicinal products that may be liable to harm public health*

Therefore, for the purposes of Article 86(1) of the Medicinal Code, “advertising” appears to include any communication regarding medicinal products that may be liable to harm public health. The MHRA did not contest this broad definition of advertising. However, as explained below, AG Jääskinen considered that the MHRA misinterpreted Damgaard because the defining factor for determining whether an activity constitutes advertising is the party’s “deliberate and direct intention” (para 75), not its underlying goal.

Interestingly, AG Jääskinen noted that even though some kind of financial incentive schemes exist in other member states, the UK appears to be the only member state that has prescribing incentive schemes involving the substitution of specifically named medicines (with different active ingredients). PCTs also reward GP practices for prescribing generic medicinal products, although generic substitution was not at issue in the case.

Why the specific circumstances at stake are unique to the UK is perhaps a consequence of its particular national health system, which is based on a very different model from that of any other EU member state. In England, GP practices providing medical services are contracted to PCTs, which are responsible for the funding of those services locally.

The PCTs, in turn, are effectively under the control of the National Institute for Health and Clinical Excellence, whose function is to assess the cost-effectiveness of drugs and to issue guidance recommending the most cost-effective product(s). In issuing prescriptions to be funded by the NHS, prescribers must comply with NHS rules and prescription controls. GPs will be aware that if their practice runs up a significant drug bill as a consequence of not following PCT prescribing guidance, the PCT may decide not to increase the practice's annual budget.

Arguably, prescribing practice under the English health system is inherently open to manipulation. This is because GPs – who are ultimately paid by the Department of Health – may find their prescribing discretion compromised by pressure from the PCTs to make decisions based on cost, which are not necessarily consistent with the best interests of the patient. Indeed, the prescribing incentive schemes implemented by PCTs exploit this chink in the system because any payment made to a GP practice by way of financial incentive will increase the profits of the practice – which ultimately benefits the individual practitioners who share in those profits (GP partners versus salaried partners). Therefore, although the Department of Health's guidance on Strategies to Achieve Cost-Effective Prescribing states that<sup>8</sup>: “[a]ll payments under a scheme should go into practice funds and not to individuals” and further that “[i]t is good practice to specify appropriate use of the money, eg, for the benefit of patients of the practice”, it would appear that GPs may nevertheless benefit financially from such schemes.

The English court found it necessary to refer to the ECJ on the interpretation of Article 94 because the application of the provision to the non-commercial activities of public bodies is not explicit from its wording. Indeed, considering that the Medicinal Code is silent on the point (as is the commission's proposal on the original Directive 92/28/EEC), it is perhaps reasonable to surmise that the legislature had not contemplated the possibility that public bodies forming part of the national health service would – or would be in a position to – offer/give financial inducements to prescribe particular medicines. It is arguably the peculiar nature of the English health system that is the cause of such practices. The fact that PCTs wield direct control over GP practices at a local level means that, in some respects, they operate more like pharmaceutical companies than public bodies; the prescribing incentive schemes at stake being one manifestation of this. What enabled AG Jääskinen to find that such schemes are precluded by the Medicinal Code is the very clear intention behind Article 94(1) prohibiting inducements to prescribe.

It is, therefore, acknowledged by the legislation that certain forms of promotion may have the adverse effect of compromising the standards that doctors agree to abide by (as set out in the professional codes of conduct issued by the General Medical Council, reflecting the Hippocratic Oath). As explained in this article, the factor underlying AG Jääskinen's approach was that financial inducements of “whatever nature” (to echo the wording of the commission's proposal above) are liable to violate prescribers' professional standards, irrespective of the identity and ultimate objective of the inducing party. Any other conclusion would be inconsistent with the essential aim of the Medicinal Code to safeguard public health.

## Analysis of the opinion

### The scope of the prerogative of member states

The MHRA's primary argument was that if Article 94(1) is held to apply to public authorities, it would restrict the discretion that member states have under Article 152 of the EC Treaty to adopt national provisions relating to the organisation and delivery of health services and medical care, of which the engagement of doctors, the prescription of medicines and the level of public expenditure are important features. Article 152(5) of the Treaty provides that:

*Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.*

AG Jääskinen disposed of the MHRA's argument swiftly, stating that member states are not exonerated from complying with the law in exercising the power conferred by Article 152.

*The UK appears to be the only member state that has prescribing incentive schemes involving the substitution of specifically named drugs*

*It is arguably the peculiar nature of the English health system that is the cause of such practices*

*The MHRA argued that applying Article 94(1) to public authorities would restrict the discretion that member states have under the EC Treaty*

*Article 4(3) of the Medicinal Code was also in issue*

As the practice of providing financial incentives to prescribe specific named medicines undeniably has as its goal the reduction of expenditure on healthcare, Article 4(3) of the Medicinal Code was also in issue. It provides that:

*The provisions of this Directive shall not affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.*

However, AG Jääskinen did not accept that Article 4(3) provides a general exemption for public health measures designed to reduce expenditure on medicinal products. Rather, it establishes two clear exceptions: the setting of prices for medicinal products and their inclusion in the scope of national health insurance schemes. He considered that neither exception applied on the facts because the PCTs are making a decision on the basis of the price that has already been set and influencing the use of medicines already included in the national health insurance system. The advocate general completed his thorough analysis on the point by arguing that, even if the prescribing incentive schemes could be considered to be an exempted measure under Article 4(3), they would fall foul of the Transparency Directive. He interpreted Article 4(3) to be a reference to the Transparency Directive – even though it is not explicitly mentioned – with the consequence that if member states take any of the measures regarding the setting of prices or their inclusion in the national health system, they must fulfil the requirements of the Transparency Directive.

*The requirements of the Transparency Directive have not been fulfilled in ABPI v MHRA*

In *ABPI v MHRA*, the requirements of the Transparency Directive have not been fulfilled. For example, the affected manufacturers are not informed of such schemes, the reasons for it and the remedies available to them.

AG Jääskinen's reasoning was, therefore, rooted in a careful analysis of the law; he did not accept that member states have a general right to decide freely on any matter relating to the reduction of expenditure on healthcare and he was unwilling to stretch the scope of the Article 4(3) exemption. If the ECJ disagrees, its reasoning will have to be robust, because AG Jääskinen's analysis leaves little room for manoeuvre.

### **Scope of Article 94(1)**

The MHRA's second line of defence was that non-commercial promotion is excluded from the scope of Article 94(1). AG Jääskinen acknowledged that the legislature probably had the commercial promotion of medicines in mind, but deliberately chose not to make such a restriction (hence its silence on the matter). Indeed, he followed the approach in *Damgaard* (on Article 86(1)), where AG Colomer stated that the crucial question in deciding whether a communication constitutes "advertising" is the objective pursued, rather than the identity of the party communicating the message. Aligning himself with this reasoning, AG Jääskinen in *ABPI v MHRA* argued that the aim of Article 94(1) – to preserve the independence and objectivity of a doctor's prescribing decisions and to protect the integrity between doctor and patient – can be undermined not only by economic operators with industrial or commercial interests in the pharmaceutical sector, but also by other parties. AG Jääskinen recognised that the aim of the provision would be negated if member states could be exempted from its application. Thus, he adopted a teleological approach, which is the preferred approach of the ECJ in interpreting the EU law.

Interestingly, the MHRA also relied on *Damgaard*, arguing that, as the underlying motivation of the prescribing incentive schemes is the lowering of expenditure on medicine, such schemes are not in the nature of advertising or promotion. In rejecting this argument, AG Jääskinen emphasised the need to consider the PCTs' "deliberate and direct intention" in operating such schemes, rather than just the underlying goal:

*...the prescribing incentive schemes have the deliberate and direct intention of promoting within the NHS certain medicinal products at the expense of others, even if their overall objective is to save budgetary resources and thus to improve the provision of public health services. (para 76)*

Thus, AG Jääskinen was not willing to accept the MHRA's approach of "the end justifies the means", emphasising that the legitimate goal of reducing expenditure on healthcare can be reached by different means that do not compromise the interests protected by the Medicinal Code (including state price-setting, state price freezes and reductions, reference price or fixed price systems, pharmaceutical budgets, positive and negative lists, non-prescription pharmaceuticals, exclusion of pharmaceuticals from reimbursement, greater contribution by the patient and promotion of generic drugs).

*AG Jääskinen's conclusions do not come as a shock*

Arguably, in light of *Damgaard*, the conclusions reached by AG Jääskinen do not come as a shock. Indeed, in *Damgaard*, AG Colomer partially foreshadowed the situation at stake here, expressing the opinion that:

*...it is difficult to deny that the campaigns frequently launched by public authorities to encourage consumption or prescription of generic medicinal products are in the nature of advertising. (footnote 15)*

Further, as AG Jääskinen explained in *ABPI v MHRA*, restricting the meaning of promotion to commercial activities would create a logical absurdity:

*After Damgaard, such a conclusion would produce the absurd result that although it may be unlawful for someone in the position of an independent third party to advertise by means of a communication a medicinal product available on prescription only, it would be lawful for him to give money to induce doctors to prescribe that product. (para 79)*

*AG Jääskinen explained that restricting the meaning of promotion to commercial activities would create a logical absurdity*

## Implications for industry and prescribers

There is no doubt that AG Jääskinen's opinion will be welcomed by the innovative pharmaceutical industry, which has suffered the detrimental commercial effects of prescribing incentive schemes. It should be noted that even though generic substitution was not in issue, these schemes offer incentives for switching patients from a patented product to a non-patented/off-patent product, or prescribing a non-patented/off-patent product to new patients who would otherwise have been prescribed the patented product. On this basis, the MHRA accused the ABPI of bringing the case in order to maximise the sale of branded medicinal products manufactured and marketed by its members. However, AG Jääskinen's response on the point – which will be undoubtedly quoted by the industry – was fair and robust:

*In my view the self-regarding nature of the ABPI's motives is legally irrelevant. As a line of business the pharmaceutical industry is lawful, socially useful and even encouraged by the European Union legislature. It is also inherent in the economic order of the European Union, which aims for an open market with free competition, that private economic operators pursue lucrative purposes. This logic also applies to the pharmaceutical industry. (para 34)*

The above extract is indicative of the admirable balance struck by AG Jääskinen in recognising the commercial interests at stake – on the MHRA's side, reducing expenditure on medicine, and on the ABPI's side, ensuring an adequate return on the investment in bringing an innovative product to market – whilst nevertheless respecting the ultimate aim of the Medicinal Code to safeguard public health. This is a case where commercial considerations could very easily have clouded analysis of the fundamental questions as to whether prescribing incentive schemes constitute promotion and whether they are liable to compromise prescribers' discretion.

The opinion of AG Jääskinen hopefully will be endorsed by the ECJ. Nevertheless, it must be acknowledged as controversial. Bearing in mind that the UK's General Medical Council advises doctors that they have a responsibility to consider the impact of their actions (including prescribing) on resources available to other patients, it is understandable why many doctors will consider it unfair that their cost-effective prescribing will not be rewarded. However, the problem really lies with the system as a whole. Indeed, it is debateable whether doctors should be under an obligation to carry out any kind of cost-effectiveness analysis in the first place; arguably, cost considerations should be under the sole remit of the Department of Health.

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## Broader implications

It is notable that, in two *sui generis* situations – in *Damgaard*, the comments of a journalist, and in *ABPI v MHRA*, the activities of public bodies – the approach taken was based on what the Medicinal Code is trying to achieve by placing limitations on promotional material/advertising. Both cases embraced an interpretation of advertising/promotion that extends well beyond the commercial arena.

In addition, it will be particularly interesting to see whether the ECJ will take the opportunity to clarify the scope of the member states' prerogative to determine pricing and reimbursement policy, in particular in relation to the role played by national bodies such as NICE in the UK. As a preliminary point, it should be noted that NICE guidance is, in any event, inextricably linked with the prescribing incentive schemes under discussion. Indeed, the PCTs' decision in defining therapeutic equivalents within the same therapeutic class is based on NICE's instructions.

Further, the Department of Health's interim guidance specifically includes "offering incentives for the adoption of NICE guidance, including the appropriate use of medicines recommended by NICE" as an example of a practice that it considers acceptable (para 8). Therefore, in finding prescribing incentive schemes to be in contravention of the advertising legislation, AG Jääskinen is in effect condemning the use that PCTs are making of NICE guidance (as a basis for inducing prescriptions of specific named medicines). However, the question remains whether NICE itself may be considered to "advertise" medicinal products in so far as its guidance has the deliberate and direct

*AG Jääskinen is in effect condemning the use that PCTs are making of NICE guidance*

intention of promoting certain medicinal products at the expense of others. Following Damgaard and AG Jääskinen's opinion in *ABPI v MHRA*, the mere fact that NICE's motivation for recommending particular products is different from a pharmaceutical company's (cost saving as opposed to profit driven) does not take the activity outside the scope of promotion.

*There is perhaps an argument that NICE is inducing prescriptions of the treatments it recommends*

On the basis that NICE's guidance amounts to advertising/promotion, there is perhaps a further argument that it is inducing prescriptions of the treatments recommended therein – the financial incentive being cost-effectiveness. Indeed, even in the absence of prescribing incentive schemes implemented by PCTs, prescribers will be under significant pressure to comply with NICE guidance. Further, NICE's activity in issuing guidance would not necessarily fall within the scope of the Article 4(3) exemption because the price of a medicine and its inclusion for reimbursement are determined under the Pharmaceutical Price Regulation Scheme; the assessment undertaken by NICE is an additional step that has the objective of determining the medicinal product(s) that should be prescribed to treat a particular medical condition based on a clinical and cost-effectiveness analysis. However, on balance, AG Jääskinen's opinion probably does not go so far as to cover the activities of NICE. This is firstly because NICE's guidance does not, strictly speaking, amount to a prescribing incentive scheme, and secondly because NICE's activity does not fall clearly within the scope of Article 94 (which concerns the provision of financial incentives to individual members of the healthcare profession). Thus, whilst the activity of NICE arguably circumscribes the freedom of prescribers to an unreasonable degree, this may not be necessarily caught by the advertising legislation.

*The ECJ could hold that inducements offered by companies to NHS institutions are precluded by Article 94(1)*

It will be interesting to see the extent to which the provisions in the Medicinal Code might be extended still further to situations that are not obviously covered by the explicit wording of the legislation. It is conceivable that the ECJ will, in the future, hold that inducements offered by pharmaceutical companies to NHS institutions are precluded by Article 94(1), even though that provision explicitly concerns gifts, pecuniary advantages or benefits in kind to persons qualified to prescribe or supply. For example, it is not impossible to envisage a situation where a pharmaceutical company offers financial incentives to PCTs – intended for the benefit of patients – to prescribe its products. In that scenario, the question of interpretation arises from the identity of the party induced, namely whether Article 94 precludes inducements to NHS organisations, as well as inducements to individuals. This is in contrast to the present case, where the question of interpretation concerns the identity of the party providing the incentive. In the scenario envisaged, individual prescribers would not directly benefit from the inducement provided by the pharmaceutical company. However, such activity could ultimately influence prescribers through a domino effect if PCTs implement prescribing incentive schemes linked to the activity of the pharmaceutical company, which is exerting pressure from the top.

## **Conclusion**

*The ECJ's judgment in ABPI v MHRA is eagerly awaited by all industry stakeholders*

The ECJ's judgment in *ABPI v MHRA* is eagerly awaited by all pharmaceutical industry stakeholders. It will be particularly interesting to see whether the ECJ brings any further clarity on the scope of the powers of member states to regulate national pricing policy.

In the meantime, AG Jääskinen's recognition of the fact that even the activities of public bodies forming part of the national health system may compromise a doctor's independence and objectivity in prescribing raises broader questions about the English healthcare system, in particular whether it is proper for doctors to be placed in a position of conflict between the management of the NHS budget and the best interests of patients.

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