



## **Enforcement Decision Series (ED/01/008)**

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### **Competition Act 2002**

### **Enforcement Decision of Competition Authority investigation**

### **Alleged anticompetitive conduct by the Health Service Executive relating to the administration of the Community Drugs Schemes**

**10 October 2008**

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#### **EXECUTIVE SUMMARY**

The Competition Authority has received several complaints alleging that the Health Service Executive ("HSE") has violated sections 4 and 5 of the Competition Act 2002 ("Competition Act") in relation to the various schemes it administers for the provision of prescription drugs to the general public. The threshold question for the application of sections 4 and 5 of the Competition Act is whether the HSE acts an undertaking for the purposes of competition law. The Competition Authority has therefore considered whether the HSE is an undertaking for the purpose of applying the Competition Act. To the extent that the activities under consideration may affect trade between Member States, the Competition Authority has assessed the status of the HSE for the purpose of applying EC competition law. Similarly, Articles 81 and 82 EC apply only to undertakings.

According to established case law, it is possible for an entity to be an undertaking when engaged in certain activities and to not be an undertaking when engaged in other activities. This enforcement decision considers only two specific activities of the HSE: negotiating with the representative bodies of the pharmaceutical industry in Ireland to reduce the ex factory price of certain pharmaceutical drugs; and purchasing community pharmacy services from private sector pharmacy undertakings under various schemes for the provision of prescription drugs to the general public.

For the purposes of the Competition Act, an undertaking is any individual, body corporate or unincorporated body of persons engaged for gain in the provision, supply or distribution of goods or the provision of a service. In light of this statutory definition and its interpretation by the Irish courts, the Competition Authority is of the opinion that the HSE is not an undertaking for the purposes of the Competition Act when engaging in either of the activities under consideration.

Furthermore, to the extent that the activities may affect trade between Member States, the Competition Authority is of the opinion that the HSE is not an undertaking for the purposes of EC competition law when engaging in these activities. In arriving at this view, the Competition Authority has

considered and applied both the public authority and the solidarity exceptions to the concept of undertaking that have been developed in EC law.

Therefore, in the opinion of the Competition Authority, the two activities of the HSE in question are outside the purview of sections 4 and 5 of the Competition Act and Articles 81 and 82 EC. Accordingly, the Competition Authority has determined that it will take no further action in respect of the complaints it has received alleging breaches of competition law by the HSE.

## 1. THE ISSUES

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- 1.1 This enforcement decision sets out the views of the Competition Authority regarding the status of the Health Services Executive ("HSE") for competition law purposes, in relation to various activities carried out by the HSE. Under Irish law, the courts, and not the Competition Authority, are the decision-making body with regard to the enforcement of competition law in the State. Therefore, this enforcement decision should not be considered a legally enforceable decision as to whether a breach of either Irish or EC competition law has occurred. Nevertheless, the Competition Authority has chosen to publish this enforcement decision to explain its approach and reasoning to practitioners, those in the health sector and interested members of the public.
- 1.2 The Competition Authority has received a number of complaints against the HSE, which is the State body responsible for the provision of health services to the general public. Established pursuant to section 6(1) of the Health Act 2004 ("2004 Act"), the HSE largely fulfils those functions previously performed in the State by the regional Health Boards and the Eastern Regional Health Authority. In 2007, the HSE had an income of about €13.5 billion, and was the largest employer in the State, with 111,505 employees.<sup>1</sup>
- 1.3 Pursuant to section 7(1) of the 2004 Act, the object of the HSE is "*to use the resources available to it in the most beneficial, effective and efficient manner to improve, promote and protect the health and welfare of the public.*" The HSE is required to "*manage and...deliver, or arrange to be delivered on its behalf, health and personal social services*".<sup>2</sup> Its mandate encompasses responsibility for the provision of *inter alia* acute hospital and ambulance services, care in the community services and general public health services. One component of this duty is the administration of a variety of schemes for the provision of prescription drugs to the general public, known as the Community Drugs Schemes.
- 1.4 The complainants in this instance are various parties involved in the delivery of services to the general public in connection with the Community Drugs Schemes.<sup>3</sup> Broadly, the complaints allege that the HSE has breached sections 4 and/or 5 of the Competition Act 2002 ("Competition Act") when engaging in two activities:
- 1) Negotiating with the representative bodies of the pharmaceutical industry in Ireland to reduce the ex factory prices of certain drugs, resulting in a "landed price" for these drugs; and
  - 2) Purchasing community pharmacy services from private sector pharmacy undertakings under the various schemes, known as the Community Drugs Schemes,

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<sup>1</sup> These figures are taken from *Health Service Executive, Annual Report and Financial States 2007*.

<sup>2</sup> 2004 Act, section 7(4).

<sup>3</sup> The complainants have not been named for confidentiality reasons. In any event, the identity of the complainants does not affect the Competition Authority's analysis of the issues involved.

administered by the HSE for the provision of prescription drugs to the general public.

## 2. ASSESSMENT

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### The applicable law

2.1 Pursuant to the Competition Act, the Competition Authority is responsible for the enforcement of Irish and EC competition law in the State. It undertakes, *inter alia*, investigations of alleged breaches of competition law either on its own initiative or on foot of complaints submitted by third parties.

2.2 The Competition Authority assesses alleged anticompetitive conduct for compliance with sections 4 and 5 of the Competition Act and Articles 81 and 82 EC. Sections 4 and 5 of the Competition Act are based on the equivalent competition provisions of the Treaty establishing the European Community ("Treaty"), viz. Articles 81 and 82 EC, respectively.

2.3 Section 4(1) of the Competition Act provides:

Subject to the provisions of this section, all agreements between undertakings, decisions by associations of undertakings and concerted practices which have as their object or effect the prevention, restriction or distortion of competition in trade in any goods or services in the State or in any part of the State are prohibited and void, including in particular, without prejudice to the generality of this subsection, those which

(a) directly or indirectly fix purchase or selling prices or any other trading conditions,

(b) limit or control production, markets, technical development or investment,

(c) share markets or sources of supply,

(d) apply dissimilar conditions to equivalent transactions with other trading parties thereby placing them at a competitive disadvantage,

(e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which by their nature or according to commercial usage have no connection with the subject of such contracts.

2.4 Section 4(2) qualifies the prohibition contained in section 4(1), providing that where an agreement, decision or concerted practices complies with four cumulative criteria set out in section 4(5), or falls within a category of agreements, decisions, or concerted practices declared by the Competition Authority in writing to satisfy the section 4(5) criteria, pursuant to section 4(3), it is not prohibited by section 4(1). Section 4(5) provides:

The conditions mentioned in subsections (2) and (3) are that the agreement, decision or concerted practice or category of

agreement, decision or concerted practice, having regard to all relevant market conditions, contributes to improving the production or distribution of goods or provision of services or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit and does not—

(a) impose on the undertakings concerned terms which are not indispensable to the attainment of those objectives,

(b) afford undertakings the possibility of eliminating competition in respect of a substantial part of the products or services in question.

2.5 Whereas section 4 of the Competition Act addresses anticompetitive collusive conduct, section 5 of Competition Act concerns unilateral conduct. The relevant portions of section 5 provide:

(1) Any abuse by one or more undertakings of a dominant position in trade for any goods or services in the State or in any part of the State is prohibited.

(2) Without prejudice to the generality of subsection (1), such abuse may, in particular, consist in—

(a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions,

(b) limiting production, markets or technical development to the prejudice of consumers,

(c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage,

(d) making the conclusion of contracts subject to the acceptance by other parties of supplementary obligations which by their nature or according to commercial usage have no connection with the subject of such contracts.

2.6 Considering these provisions, it is apparent that sections 4(1) and 5(1) apply only where the relevant conduct or agreement involves undertakings, or for the purposes of section 4(1), an association of undertakings. The term undertaking as defined by the Competition Act is not synonymous with company law concepts of corporate bodies. Section 3(1) defines an undertaking for the purposes of the Competition Act as "*a person being an individual, a body corporate or an unincorporated body of persons engaged for gain in the production, supply or distribution of goods or the provision of a service.*"

- 2.7 Pursuant to Article 3 of Council Regulation (EC) No 1/2003,<sup>4</sup> when the Competition Authority applies domestic competition law to behaviour which may affect trade between Member States within the meaning of the Community competition rules, it must also apply Articles 81 and/or 82 EC. Community case law establishes that an agreement, decision or concerted practice that extends over the whole of the territory of a Member State has, by its very nature, the effect of reinforcing the partitioning of markets on a national basis. As this holds up the economic interpenetration that the Treaty is designed to bring about, this triggers the application of Community law.<sup>5</sup> To the extent that the activities of the HSE under review may affect trade between Member States, the Competition Authority must apply the relevant Community competition rules in conjunction with the provisions of the Competition Act.
- 2.8 In any event, Community case law is persuasive authority informing the development of Irish competition law.<sup>6</sup> Consequently, when applying national law provisions, the Competition Authority has regard not only to the interpretation by the Irish Courts, but also to the interpretations of Articles 81 and 82 EC by the European Commission

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<sup>4</sup> Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Article 81 and 82 of the Treaty. The full text of Article 3 provides as follows:

***Relationship between Articles 81 and 82 of the Treaty and national competition laws***

1. *Where the competition authorities of the Member States or national courts apply national competition law to agreements, decisions by associations of undertakings or concerted practices within the meaning of Article 81(1) of the Treaty which may affect trade between Member States within the meaning of that provision, they shall also apply Article 81 of the Treaty to such agreements, decisions or concerted practices. Where the competition authorities of the Member States or national courts apply national competition law to any abuse prohibited by Article 82 of the Treaty, they shall also apply Article 82 of the Treaty.*
2. *The application of national competition law may not lead to the prohibition of agreements, decisions by associations of undertakings or concerted practices which may affect trade between Member States but which do not restrict competition within the meaning of Article 81(1) of the Treaty, or which fulfil the conditions of Article 81(3) of the Treaty or which are covered by a Regulation for the application of Article 81(3) of the Treaty. Member States shall not under this Regulation be precluded from adopting and applying on their territory stricter national laws which prohibit or sanction unilateral conduct engaged in by undertakings.*
3. *Without prejudice to general principles and other provisions of Community law, paragraphs 1 and 2 do not apply when the competition authorities and the courts of the Member States apply national merger control laws nor do they preclude the application of provisions of national law that predominantly pursue an objective different from that pursued by Articles 81 and 82 of the Treaty.*

As a result of Article 3, a Member State can apply its domestic competition law even in situations where Community law also applies. National law provisions governing abuse of dominance can impose more onerous obligations than Article 82 EC; however, in situations falling within the provisions of Article 81 EC, the national law applied cannot prohibit conduct not caught by that article.

<sup>5</sup> Case C-309/99 *Wouters v. Algemene van de Nederlandsche Orde van Advocaten* [2002] ECR I-1577, hereafter "Wouters", at para 95; Case C-35/99 *Arduino* [2002] ECR I-1529, hereafter "Arduino", at para 33.

<sup>6</sup> It can be inferred from the judgment of the Supreme Court in the *The Competition Authority v. O'Regan and Others* [2007] IESC 22 (hereafter "ILCU") at para 86 that the approach of the Irish courts to the definition of undertaking will be broadly in line with that of the European courts. To an extent, therefore, the status of the HSE under the Irish competition rules is influenced by its status in EC law.

("Commission"), the Court of First Instance ("CFI") and the European Court of Justice ("ECJ").

2.9 Article 81 EC, on which section 4 of the Competition Act is based, provides:

1. The following shall be prohibited as incompatible with the common market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market, and in particular those which:

- (a) directly or indirectly fix purchase or selling prices or any other trading conditions;
- (b) limit or control production, markets, technical development, or investment;
- (c) share markets or sources of supply;
- (d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

2. Any agreements or decisions prohibited pursuant to this Article shall be automatically void.

3. The provisions of paragraph 1 may, however, be declared inapplicable in the case of:

- any agreement or category of agreements between undertakings,
- any decision or category of decisions by associations of undertakings,
- any concerted practice or category of concerted practices,

which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not:

- (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;
- (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

2.10 Article 82 EC, on which section 5 of the Competition Act is based, provides:

Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States.



Such abuse may, in particular, consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- (b) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

2.11 Like sections 4 and 5 of the Competition Act, Articles 81 and 82 EC apply only to the behaviour of undertakings, and for the purpose of Article 81 EC, to a decision taken by an association of undertakings. Although the term undertaking is not defined by the Treaty, Community case law has established that "*...the concept of an undertaking encompasses every entity engaged in an economic activity, regardless of the legal status of the entity and the way in which it is financed...*"<sup>7</sup> This definition is broader than that found in the Competition Act, and its application is considered in greater detail below.

2.12 Accordingly, it is a precondition for the application both of Irish and of EC competition rules to the behaviour of an entity that the entity constitutes an undertaking or association of undertakings. This enforcement decision refers to the question of whether the HSE is an undertaking, for the purposes of Irish and/or EC competition law, when administering or participating in the activities at issue. It is important to note that the concept of undertaking found in Irish competition law is not coextensive with the concept in EC competition law, insofar as an entity may be an undertaking for the purposes of one body of law and not the other.

2.13 As noted above, since an entity may act as an undertaking when it conducts certain of its activities and not as an undertaking with respect to other activities, each activity in issue must be considered separately.<sup>8</sup>

2.14 This enforcement decision does not consider the question of whether the HSE constitutes an association of undertakings for the purposes of section 4 of the Competition Act and/or Article 81 EC. In his Opinion in *Wouters*, Advocate General Léger stated that as "*...a general rule, an association [of undertakings] consists of undertakings of the same general type and makes itself responsible for representing and defending their common interests vis-à-vis other economic operators, government bodies and the public in general.*"<sup>9</sup> Although the HSE performs more than one function, it is a single State entity. This

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<sup>7</sup> Case C-41/90 *Hofner and Elser v. Macrotron GmbH* [1991] ECR I-1979, hereafter "*Hofner*", at para 21.

<sup>8</sup> Case C-49/07 *Motosykletistiki Omospondia Ellados NPID v Elliniko Dimosio* (Judgment of 1 July 2008) at para 25.

<sup>9</sup> Opinion in *Wouters*, delivered by Attorney General Léger on 11 July 2001.

contrasts with the decentralised structure of regional health boards that existed prior to the 2004 Act.

2.15 Moreover, even if one argues that it is possible to fragment the HSE such that its activities can be attributed to several constituent entities, the jurisprudence on the concept of undertaking applies equally to each of these entities. Self-evidently, an association of undertakings must be composed of entities that constitute undertakings in their own right.<sup>10</sup> As set out in detail below, the Competition Authority is of the view that the HSE is not an undertaking in either Irish or EC competition law when engaged in any of the activities under consideration. The same reasoning would apply to a fragmented HSE, none of the constituent entities of which would be undertakings under either Irish or EC competition rules. Consequently, the matter of an association of undertakings does not arise.

### **The activities at issue**

2.16 The notion of undertaking is relative; whether an entity is an undertaking depends on the specific activity under scrutiny.<sup>11</sup> As stated above, this enforcement decision relates to two particular activities of the HSE:

- 1) Negotiating with the representative bodies of the pharmaceutical industry in Ireland to reduce the ex factory prices of certain drugs, resulting in a "landed price" for these drugs; and
- 2) Purchasing community pharmacy services from private sector pharmacy undertakings under the various schemes, known as the Community Drugs Schemes, administered by the HSE for the provision of prescription drugs to the general public.

2.17 The status of the HSE for the purpose of applying competition law must be considered separately for each of these activities. In the interests of clarity, the specific elements of each activity will be examined in detail.

2.18 Pursuant to section 59 of the Health Act 1970 ("1970 Act"), the HSE has a statutory obligation to make arrangements for the supply of drugs, medicines and medical and surgical appliances to the general public.<sup>12</sup> Differing levels of provision are mandated for persons of "full eligibility" and "limited eligibility".<sup>13</sup>

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<sup>10</sup> See *Ramadan Hemat v The Medical Council* [2006] IEHC 187 at para 59.

<sup>11</sup> See the Opinion of Advocate General Jacobs in Case C-67/96 *Albany International BV v Stichting Bedrijfspensioenfonds Textielindustrie*, delivered on 28 January 1999, at para 207, and *Eco-Emballages* OJ [2001] L233/37 at para 70. See also Faull & Nikpay (2007) *The EC Law of Competition*, 2nd ed., Oxford University Press at paras 3.29-3.30. The judgment of Fennelly J in *ILCU* at paras 84-87 appears to acknowledge this possibility.

<sup>12</sup> The full text of section 59 of the 1970 Act is as follows:

- (1) A health board shall make arrangements for the supply without charge of drugs, medicines and medical and surgical appliances to persons with full eligibility.
- (2) When a person with limited eligibility, or a person with full eligibility who does not avail himself of the service under subsection (1), satisfies the chief effective officer of the health board that, in respect of a period and to an amount determined by regulations made by the Minister, he has incurred expenditure on drugs, medicines and medical and

- 2.19 The HSE has negotiated agreements (“manufacturer agreements”) with the Irish Pharmaceutical Healthcare Association (“IPHA”) and the Association of Pharmaceutical Manufacturers of Ireland (“APMI”), organisations representing manufacturers of brand-name and generic drugs in the State, respectively. The current manufacturer agreements were concluded in September 2006. Under their terms, phased decreases in the ex factory or “landed” price of each of more than 800 of the most commonly used products covered by the Community Drugs Schemes were introduced from 1 March 2007.<sup>14</sup> The landed price of a drug functions as the reference price by which the HSE administers the reimbursement of pharmacies for drugs dispensed under the Community Drugs Schemes.
- 2.20 The HSE attempted to negotiate a reduction in the wholesale cost of delivering drugs from pharmaceutical manufacturers to retail pharmacies. The representative body of pharmaceutical wholesalers in the State, the Pharmaceutical Distributors Federation (“PDF”), refused to negotiate with the HSE, arguing that to do so would involve a breach of the competition rules.<sup>15</sup> Based on legal advice, the HSE concluded that it could not negotiate directly with the PDF.<sup>16</sup> The Competition Authority understands that the HSE has not entered into any agreements with pharmaceutical wholesalers for the purposes of administering the Community Drugs Schemes.
- 2.21 At the retail pharmacy level, the HSE has entered into an individual Community Pharmacy Contractor Agreement (“Contractor Agreement”) with each pharmacy contractor in the State.<sup>17</sup> A pharmacy contractor is the proprietor of a retail pharmacy that acquires the designation “community pharmacy” when the Contractor Agreement is signed with the HSE. Community pharmacies provide what the Contractor Agreement calls “community pharmacy services” to HSE patients, namely the provision of prescription drugs to eligible persons pursuant to the various Community Drugs Schemes.

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surgical appliances which were obtained on the prescription of a registered medical practitioner and were for the treatment of that person or his dependants, the health board shall make arrangements to meet the balance of the cost, or a proportion thereof (as may be prescribed) of the person’s being supplied in respect of that period with such drugs, medicines and medical and surgical appliances.

(3) A health board may make arrangements for the supply without charge of drugs, medicines or medical and surgical appliances to persons suffering from a prescribed disease or disability of a permanent or long-term nature.

(4) Regulations relating to the service under this section shall be made with the consent of the Minister for Finance.

<sup>13</sup> These terms are defined by sections 45 and 46 of the 1970 Act, respectively.

<sup>14</sup> See HSE press release of 28 February 2007, *HSE to save over €250m in drug costs*, at [http://www.hse.ie/eng/newsmedia/2007\\_Archive/February\\_2007/HSE\\_to\\_save\\_over\\_E250m\\_in\\_drug\\_costs.html](http://www.hse.ie/eng/newsmedia/2007_Archive/February_2007/HSE_to_save_over_E250m_in_drug_costs.html).

<sup>15</sup> See *A Fair Price for Wholesale Services Means Lower Medicine Prices*, released 25 February 2008, found on the HSE’s website at: [http://www.hse.ie/eng/newsmedia/A\\_Fair\\_Price\\_for\\_Wholesale\\_Services\\_Means\\_Lower\\_Medicine\\_Prices.html](http://www.hse.ie/eng/newsmedia/A_Fair_Price_for_Wholesale_Services_Means_Lower_Medicine_Prices.html).

<sup>16</sup> See the Report of the Independent Body on Pharmacy Contract Pricing, published June 2008, hereafter “Dorgan Report”, at para 2.16.

<sup>17</sup> The full text of the *pro forma* Contractor Agreement is found at: [http://www.dohc.ie/publications/pdf/community\\_pharmacy\\_services.pdf?direct=1](http://www.dohc.ie/publications/pdf/community_pharmacy_services.pdf?direct=1).

- 2.22 The transactions that occur between the HSE and each pharmacy contractor are governed by the Contractor Agreement. Thus, the HSE is purchasing community pharmacy services from undertakings involved in the provision of goods and services on the market. In this manner, the HSE utilises services provided by private sector undertakings in order to discharge its statutory duty. Nevertheless, from the perspective of the HSE, the underlying impetus for the activities at issue is, in the opinion of the Competition Authority, the obligation imposed on the HSE by section 59 of the 1970 Act.
- 2.23 In consideration of the provision of community pharmacy services, the HSE makes payment to the pharmacy contractor.<sup>18</sup> Remuneration consists of several components, which vary for each of the different Community Drugs Schemes.
- 2.24 Drugs schemes covered by the Contractor Agreement include the General Medical Services scheme ("GMS"), which, among other benefits, provides GMS card holders with prescription drugs free of charge. For this service, the community pharmacy receives from the HSE a fee of €3.59 upwards for each drug dispensed.<sup>19</sup> The HSE also reimburses the community pharmacy the "ex wholesaler price" of the drug dispensed, which consists of the landed price<sup>20</sup> plus an additional 15 percent to cover the presumed mark-up imposed by the wholesaler on the landed price.<sup>21</sup>
- 2.25 The Drugs Payment Scheme ("DPS") is another scheme covered by the Contractor Agreement. The DPS covers the cost of prescription drugs for non-medical card holders, in excess of a threshold of €90 per household per month. For the dispensing of drugs covered by the DPS, community pharmacies receive a slightly lower dispensing fee of €3.16 upwards for each drug dispensed, plus the ex-wholesaler price, plus a 50 percent mark up on the ex-wholesaler price.<sup>22</sup> Other schemes under the Contractor Agreement cover, *inter alia*, patients suffering from long-term illness, and patients prescribed "high-tech" (i.e. high value) medication.

### **Application of the Competition Act to the activities at issue**

- 2.26 The Competition Authority is of the view that the HSE is not an undertaking for the purposes of Irish competition law when performing either of the activities under consideration.

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<sup>18</sup> Clause 12(1) of the Contractor Agreement provides:

The board shall in consideration of the service provided by the pharmacy contractor in accordance with these terms and conditions and on foot of claims made in the form and at the times directed by the Minister, make payments or arrange for payments to be made to the pharmacy contractor for prescriptions dispensed at his/her contracted community pharmacy in accordance with such rates as may be approved or directed by the Minister from time to time after consultation with the Pharmaceutical Contractors' Committee.

<sup>19</sup> Rate effective from 1 March 2008. See the Dorgan Report at para 2.6.

<sup>20</sup> Community pharmacies receive the benefit of these landed prices for all drugs purchased from pharmaceutical wholesalers in the State, whether or not they are supplied under the Community Drugs Schemes.

<sup>21</sup> As a result of competition between pharmaceutical wholesalers, community pharmacies receive *ex post* loyalty discounts of 7-8 percent on drugs dispensed under the GMS.

<sup>22</sup> Rate effective from 1 March 2008. See the Dorgan Report at paras 2.7-2.8.

- 2.27 Section 3(1) of the Competition Act defines undertaking as “a person being an individual, a body corporate or an unincorporated body of persons engaged for gain in the production, supply or distribution of goods or the provision of a service.” The form of the entity in law is irrelevant to the question of whether it is an undertaking. Consequently, the HSE would be an undertaking under Irish competition law if it were engaged for gain in the production, supply or distribution of goods or the provision of a service.
- 2.28 The Irish courts have considered the meaning of the phrase “for gain” for the purposes of the section 3(1) definition of undertaking. In *Deane and Others v. VHI*, the Supreme Court held that “the words ‘for gain’ connote merely an activity carried on or a service supplied...which is done in return for a charge or payment”.<sup>23</sup> Finlay C.J suggested a charitable association spending money and supplying goods or services free of any charge would fall outside the definition of undertaking in Irish law.
- 2.29 In *Greally v Minister for Education*,<sup>24</sup> the High Court considered the status of a trade union and of the Minister for Education pursuant to the Competition Act of 1991, which contained an identical definition of undertaking as that contained in section 3(1). Costello J in the High Court, relying on the long title of the Competition Act of 1991, interpreted acting “for gain” as meaning “any commercial activity”. He consequently held that the ASTI, a trade union, was not an undertaking as it was providing a service to its members for a common purpose. Such activity was not commercial in nature, despite the fact the service at issue resulted in improved employment opportunities for those qualifying members. Nor was the Minister an undertaking when it entered into an agreement with the ASTI to employ secondary school teachers in State schools on the basis of a panel scheme which gave priority in relation to vacancies to teachers on the panel. Costello J acknowledged that possibility that “there may be circumstance in which the Minister is engaged in activities which would constitute her an “undertaking””, but held that in the instant case, the Minister was not party to a commercial activity of any sort and so was not an undertaking.
- 2.30 By contrast, in the *ILCU* case, the Supreme Court accepted the factual position that individual credit unions operated on the basis of “mutuality, volunteerism, self help and a ‘not-for-profit’ philosophy”.<sup>25</sup> Nevertheless, it went on to find that such entities were engaged in activities “for gain” for the purposes of the Competition Act. Credit unions supply services to their members in return for a charge. In addition, the Supreme Court held that the representative body of credit unions in Ireland, the ILCU, was itself involved in the provision of services for gain. Its activities could be distinguished from “the sort of uneconomic activity identified in some of the cases.”<sup>26</sup>

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<sup>23</sup> [1992] 2 IR 319.

<sup>24</sup> [1995] 3 IR 481, hereafter “*Greally*”.

<sup>25</sup> *ILCU* at para 9.

<sup>26</sup> *ILCU* at para 87. On the facts of the case, the Supreme Court ultimately held that not all of the services provided by the ILCU constituted separate and distinct product markets.

- 2.31 Applying this case law, the Competition Authority is of the view that the HSE does not act “for gain” when it engages in either of the activities at issue. The HSE receives no form of payment from patients for drugs dispensed to eligible persons under the Community Drugs Schemes. When the HSE negotiates drugs prices with pharmaceutical manufacturers, it does not do so for gain. The predominant motivation of the HSE in so doing is to secure reduced prices for the drugs supplied to patients, in accordance with its statutory duties.<sup>27</sup>
- 2.32 It is well established in law that the fact that one party to a commercial transaction acts as an undertaking does not determine the status of other parties to the transaction. The sale of goods and services for gain by pharmaceutical manufacturers and community pharmacies is clearly “commercial activity”, and so fits within the *Greally* interpretation of section 3(1) of the Competition Act.
- 2.33 However, when the HSE performs the activities under consideration, it is engaged in the provision of a public service benefiting the public as a whole, by reason of what in Community law is regarded as the principle of “solidarity”.<sup>28</sup> It is possible to distinguish the *ILCU* case on the basis that the financial services at issue in that case were of a distinctly commercial nature, whereas the activities of the HSE in this instance are intrinsically linked to social welfare considerations. It follows that the HSE’s activities in the relevant instances fall outside the ambit of Irish competition law.
- 2.34 Thus, the Competition Authority is of the opinion that, with respect to the HSE activities in issue, the HSE is not an undertaking for the purposes of the Competition Act and therefore these activities are outside the ambit of the Competition Act.

### **Application of EC competition law to the activities at issue**

- 2.35 To the extent that the activities of the HSE at issue may affect trade between Member States, the Competition Authority has considered whether the HSE acts as an undertaking under Community competition law.
- 2.36 For the purposes of the EC competition rules, “...*the concept of an undertaking encompasses every entity engaged in an economic activity, regardless of the legal status of the entity and the way in which it is financed...*”<sup>29</sup> The characteristic feature of an economic

<sup>27</sup> Drug prices in Ireland have, until recently, been among the highest ex factory prices in the EU. See L. Tilson *et al*, “The High Cost of Medicines in Ireland: Is It Time to Change the Pricing Mechanism?” (2004) *Eur J Health Econ* 4, pp. 341-344. The HSE claims that the purpose of the manufacturer agreements is to reduce the cost of prescription drugs in the State, describing the agreements as “*ambitious agreements [that] will deliver significant value for money for the [HSE] once they are all fully implemented*” (HSE press release of 28 February 2007, *HSE to save over €250m in drug costs*, [http://www.hse.ie/eng/newsmedia/2007\\_Archive/February\\_2007/HSE\\_to\\_save\\_over\\_E250m\\_in\\_drug\\_costs.html](http://www.hse.ie/eng/newsmedia/2007_Archive/February_2007/HSE_to_save_over_E250m_in_drug_costs.html)). Nevertheless, the HSE has faced repeated criticism over the low rate of generic substitution of drugs in Ireland, which it is claimed would result in significant cost savings for the State. See, in this regard, M. Barry & L. Tilson, “Recent developments in pricing and reimbursement of medicines in Ireland” (2007) *Expert Review of Pharmacoeconomics and Outcomes Review* 7(6) pp. 605-611 and Irish Pharmacy Union press release of 3 January 2008, *Major survey highlights public support to allow pharmacists to provide additional services*, [http://www.ipu.ie/index.php?option=com\\_content&task=view&id=200&Itemid=221](http://www.ipu.ie/index.php?option=com_content&task=view&id=200&Itemid=221).

<sup>28</sup> This point is considered in greater detail at paragraphs 2.50-2.52 below.

<sup>29</sup> *Hofner* at para 21.

activity is the offering of goods and services on a given market.<sup>30</sup> This definition is not coextensive with the definition contained in section 3(1) of the Competition Act, which requires that the entity act “for gain”. Under EC law, pursuit of profit is not essential for an entity to constitute an undertaking.<sup>31</sup> Therefore, the HSE’s non-profit-making status does not shield it from the application of Community competition rules.

- 2.37 The issue is, therefore, whether in carrying out the activities under examination, the HSE engages in economic activity. There is no doubt that pharmaceutical manufacturers and community pharmacies are undertakings under Community law. Applying the definition developed in Community law, the sale of drugs by pharmaceutical manufacturers and community pharmacy services by community pharmacies both clearly amount to economic activities. However, as noted at paragraph 2.16 above, the status of the HSE under competition law requires a separate examination.
- 2.38 EC competition law does not apply to any activity which is connected with the exercise of powers which are exclusively those of a “public authority”; nor does it apply to any activity which, due to its nature and purpose, is founded on “solidarity”.<sup>32</sup> If the activities of the HSE fall under either exception its behaviour will not be classified as “economic activity” as that concept has been developed in EC competition law. Each of these concepts will now be considered in turn, with respect to the activities of the HSE at issue.

#### **(i) Official Authority Exception**

- 2.39 The State may act in the exercise of official authority either directly through a body forming part of the State administration or by way of a body on which it has conferred special or exclusive rights. An entity acts in the exercise of official authority when it performs “*a task in the public interest which forms part of the essential functions of the State*”.<sup>33</sup> A public interest task for these purposes is one which “*is connected by its nature, its aims and the rules to which it is subject with the exercise of powers ... which are typically those of a public authority*.”<sup>34</sup> The dichotomy is between “*economic activities of an industrial or commercial nature [consisting of] offering goods or services on the market*”,<sup>35</sup> which cannot benefit from the official authority exception, and activities “*not of an economic nature*”, which may fall within the exception.<sup>36</sup>

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<sup>30</sup> Case 205/03P *FENIN v. Commission* [2006] ECR I-6295.

<sup>31</sup> Case 7/82 *GVL v. Commission* [1983] ECR 483.

<sup>32</sup> *Wouters* at para 57.

<sup>33</sup> Case C-343/95 *Cali e Figli* [1997] ECR I-1547, hereafter “*Cali e Figli*”, at para 22.

<sup>34</sup> *Cali e Figli* at para 23.

<sup>35</sup> *Cali e Figli* at para 16.

<sup>36</sup> *Cali e Figli* at para 23.

- 2.40 In *SELEX*,<sup>37</sup> the CFI confirmed that the nature of an activity is not determined by the fact that it is *normally* entrusted to public offices. It is only if an activity, which appears to be economic in nature, has always been and is *necessarily* carried out by public entities that it loses its economic character. The fact that the services at issue in *SELEX* were not at that time being offered by private undertakings did not prevent their being described as an economic activity, insofar as it remained possible for these services to be carried out by private entities.<sup>38</sup>
- 2.41 The issue, therefore, is whether the activities of the HSE under consideration can be carried out only by a public body.
- 2.42 Pursuant to section 59 of the 1970 Act, the HSE is the State body responsible for the administration of drugs schemes for the benefit of the general public. More generally, the 1970 Act makes provision for the administration of a public health service in the State. Moreover, pursuant to the 2004 Act, the HSE has the responsibilities imposed on the health authorities, and latterly the health boards, by the Health Act 1947 ("1947 Act"), the long title of which refers to "*further and better provision in relation to the health of the people*".<sup>39</sup>
- 2.43 In certain contexts, the provision of medical services by self-employed individuals constitutes "economic activity" for the purposes of the Community competition rules.<sup>40</sup> The activities of health insurance companies, which cover (some of) the costs of medical expenses incurred by their members, may also constitute economic activity for competition law purposes.<sup>41</sup> This is the case regardless of whether the insurance company is privately or publicly owned, at least where the entities compete with other privately owned undertakings active in the market.<sup>42</sup>
- 2.44 Yet, the Competition Authority takes the view that the provision of a general health care system is an activity in the public interest that can be performed only by the State. Clearly, the HSE's obligations in this instance derive from the Health Acts, including the 1947 and 1970 Acts. Specifically, applying the principles set out in *Cali e Figli* and paragraph 2.39 above, the Competition Authority believes that there is a compelling argument that the administration of the Community Drugs Schemes is "*a task in the public interest which forms part of the*

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<sup>37</sup> Case T-155/04 *SELEX Sistemi Integrati SpA v. Commission* (Judgment of 12 December 2006), hereafter "*SELEX*".

<sup>38</sup> *SELEX* at para 89.

<sup>39</sup> The concept of "the people" is a foundational principle of Irish constitutional law. Note, for example, the Preamble to Bunreacht na hÉireann, which reads "*We, the people of Éire...[d]o hereby adopt, enact, and give to ourselves this Constitution*" and Article 6.1, which states "*All powers of government, legislative, executive and judicial, derive, under God, from the people...*" In particular, the long title of the 1947 Act echoes Article 45.1, which establishes as a directive principle of social policy the requirement that "*[t]he State shall strive to promote the welfare of the whole people...*"

<sup>40</sup> Case C-180/98 etc *Pavel Pavlov v. Stichting* [2000] ECR I-6451.

<sup>41</sup> See Case T-289/03 *BUPA v Commission* (Judgment of 12 February 2008), hereafter "*BUPA*".

<sup>42</sup> Case C-67/96 *Albany International v Stichting Bedrijfspensioenfonds Textielindustrie* [1999] ECR I-5751.



*essential functions of the State*”, such as to bring it within the official authority exception.

- 2.45 As noted above, the activities of the HSE are premised on a perceived duty of the State to provide care for the health of “the people”. Coverage extends to every resident in the State with a Personal Public Service Number (PPSN), with every person falling below the income threshold or above the age threshold entitled to full medical card privileges, and all persons outside this category entitled to a reduced level of coverage.<sup>43</sup> In the context of the Community Drugs Schemes, a contingent liability falls on the HSE for every prescription drug purchased from a community pharmacy in the State, insofar as the HSE may potentially be required to pay for every drug dispensed.<sup>44</sup> In reality, this type of obligation is undertaken only by a public entity, and accordingly, the services provided to the general public by the HSE (directly or indirectly through the use of private operators such as community pharmacies) are fundamentally different from the services that are provided by, for example, a private health insurance company, or a public health insurance company operating on a selective or a for-profit basis. Consequently, the HSE falls outside the definition of undertaking found in Community law with respect to both of the activities under consideration.
- 2.46 In essence, only the State can and would provide a Community Drugs Scheme for the benefit of “the people”.<sup>45</sup> The State has delegated responsibility for the administration of health services in the State to the HSE, which is accountable to the Minister for Health and Children. The HSE, on behalf of the State, has a unique statutory duty to put in place and run a public health system, which is available to all persons ordinarily resident in the State (although coverage is bifurcated between persons of full and limited eligibility). The State is the ultimate payer in this instance. This is an activity exclusively in the public interest, which would only be performed (and funded) by the State. Accordingly, the Competition Authority takes the view that this is an essential function of the State. That the administration of the Community Drugs Schemes may be considered an essential function of the State colours both of the activities of the HSE under consideration.
- 2.47 Only the State, through the HSE, has the authority and capacity to negotiate drugs prices with manufacturers in relation to drugs to be provided by and on behalf of the public health service. To the extent that lower, landed drugs prices are necessary for the “*effective and*

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<sup>43</sup> In *BUPA*, the CFI found that the Irish health system consists of two “pillars”: a public health insurance system and a system of private medical insurance. In spite of the ostensibly unequal nature of this arrangement, however, the CFI accepted that the health system functioned on the basis of the principle of universality, as the private component helps to ensure the effectiveness and profitability of the public component by reducing pressure on the costs which it would otherwise bear. See *BUPA*, at paras 203-205.

<sup>44</sup> Participants in the DPS receive a card, which can only be used in any one community pharmacy during the course of a month. If the DPS cardholder wishes to purchase drugs from more than one community pharmacy during this month, he or she must send the receipts for the purchases from the second community pharmacy to the HSE, which refunds expenditure in excess of €90 directly to the cardholder. This procedure can also be used by cardholders who forget their DPS card while making eligible purchases at a community pharmacy and also by individuals who choose to join the DPS having already paid for private prescriptions that month for which they can be reimbursed by the HSE.

<sup>45</sup> *SELEX* at para 61.

*efficient*" administration of the public health system, section 7(1) of the 2004 Act may *oblige* the HSE to negotiate such prices. Although private health insurers can negotiate with manufacturers on drugs prices, such negotiations do not have the same *universal* scope in terms of persons covered nor are they in the nature of an essential State function.

- 2.48 Furthermore, only the State, through the HSE, is obliged by statute to put in place a comprehensive payment scheme for provision of prescription drugs, which provides complete subsidisation for some and at least partial subsidisation for all. Accordingly, only the State purchases community pharmacy services that cover every individual ordinarily resident in the State with a PPSN.
- 2.49 On this basis, the Competition Authority is of the view that the operation of the official authority exception shields the HSE from the application of EC competition rules with regard to the activities at issue.

## **(ii) Solidarity Exception**

- 2.50 In addition to the official authority exception, EC competition rules do not apply if it is established that the HSE operates on the basis of "solidarity". Advocate General Fennelly in *Sodemare* defined solidarity as "*the inherently uncommercial act of involuntary subsidisation of one social group by another*".<sup>46</sup> Where an entity pursues pure social policy considerations, it is not engaged in an economic activity.
- 2.51 The application of the solidarity exception is highly dependant on the facts at issue in a particular case. A number of Community cases considering the application of the competition rules to non-public pensions funds illustrates this point. In *Poucet*,<sup>47</sup> the ECJ concluded that a pension fund operator was not an undertakings because the fund was operating on the basis of what the Court described as "*national solidarity*". The benefits of the pension fund under consideration were identical for all recipients, contributions were proportionate to income, pension rights were not proportionate to contributions made and schemes that were in surplus helped to finance those that had financial difficulties. By contrast, in *Albany*, the ECJ held that a sectoral pension fund was engaged in an economic activity in spite of its social objectives. The fund could determine the levels of contribution required of and benefits paid to participants, and it operated in the same market as private insurance companies, in competition with private funds.
- 2.52 The Competition Authority takes the view that the Community Drugs Schemes operate on the basis of national solidarity. The underlying rationale of the Community Drugs Schemes as a whole is to ensure that all members of the public have access to necessary drugs. For medical card holders, typically being persons on low incomes and the

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<sup>46</sup> Opinion of Advocate General Fennelly in Case C-70/95 *Sodemare v. Regione Lombardia* [1997] ECR I-3395, hereafter "*Sodemare Opinion*", at para 29.

<sup>47</sup> Cases C-159/91 etc *Christian Poucet v. Assurances Générales de France and Caisse Mutuelle Régionale du Languedoc-Roussillon* [1993] ECR I-637.

elderly,<sup>48</sup> prescription drugs are provided free of charge under the GMS. For persons of higher incomes, for whom basic drugs costs do not present a significant financial burden, spending is capped at a maximum of €90 per household per month. Therefore, no household is required to spend more than €90 per month on prescription drugs, and where this threshold is itself considered too high (e.g. low-income households), the State covers the entire cost. Echoing Advocate General Fennelly's dictum on involuntary subsidisation across social groups, those individuals making the greatest contribution to the Exchequer in the form of taxes (i.e. with the highest incomes) typically receive the lowest benefits under the Community Drugs Schemes.

## **Application of ECJ case law to National Health Systems**

2.53 In assessing the status of the HSE under EC competition law with respect to the activities at issue, the Competition Authority has considered and contrasted two recent cases applying EC competition rules to a national health system: the judgment of the Competition Commission Appeal Tribunal for Northern Ireland ("CAT") in *Bettercare*,<sup>49</sup> and the judgments of the CFI<sup>50</sup> and ECJ<sup>51</sup> in *FENIN*. It is instructive to set out these cases in some detail in order to illustrate how they have informed the legal analysis of this enforcement decision. It should be emphasised that the *Bettercare* decision was handed down on 1 August 2002, almost a year before the CFI's decision in *FENIN*, and four years before the ECJ's *FENIN* judgment.

### ***Bettercare*: the facts**

2.54 In *Bettercare*, the CAT considered whether a statutory authority, the North and West Belfast Health and Social Services Trust ("North & West"), acted as an undertaking for the purposes of competition law when it contracted out the provision of residential and nursing accommodation for the elderly.<sup>52</sup>

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<sup>48</sup> The decision to extend eligibility for medical cards to all persons aged 70 years and over has been widely criticised, on the basis that it has greatly increased the total cost of the GMS and yet does not necessarily target those with the greatest need. See, for example, the *Report of the Commission on Financial Management and Control Systems in the Health Service*, published 31 January 2003, at pp. 28-30. However, insofar as the decision to extend eligibility can be seen as an attempt to achieve "solidarity between the generations", the pursuit of which was recognised in *BUPA* as a "mandatory objective" of the Irish health system, it fits within the solidarity exception for the purposes of Community competition law. See *BUPA* at para 204.

<sup>49</sup> *Bettercare Group Limited v The Director General of Fair Trading* [2003] E.C.C. 40, hereafter "*Bettercare*".

<sup>50</sup> Case T-319/99 *FENIN* [2003] ECR II-357, hereafter "*FENIN* (CFI)".

<sup>51</sup> Case C-205/03 *FENIN* (Judgment 11 July 2006), hereafter "*FENIN* (ECJ)".

<sup>52</sup> Technically, the CAT applied the domestic law prohibition of the abuse of a dominant position contained in section 18 of the Competition Act 1998, which applies to the entire United Kingdom and is modelled closely on the competition provisions of the Treaty. However, the CAT stressed its duty pursuant to section 60 of the 1998 Act, which requires that UK competition law be dealt with in a manner consistent with EC competition law, to the greatest extent possible. The CAT in *Bettercare* at para 32 stated:

[W]e conceive it our duty under s.60(1) to approach the "undertaking" issue in the manner in which we think the European Court would approach it, as regards the principles and reasoning likely to be followed by that Court. In addition, under s.60(2) we must seek to arrive at a result which is not inconsistent with Community law.

- 2.55 The Department of Health, Social Services and Personal Safety had a statutory duty to provide personal social services, including accommodation for the elderly, in Northern Ireland. It delegated this function to North & West, a health trust established by secondary legislation. North & West owned and operated several care homes in Belfast, which provided part of the residential and nursing services required, and contracted out the remainder of its needs to private companies, including Bettercare. All members of the general public were entitled to access the services provided by or on behalf of North & West pursuant to its statutory duty. However, persons above a certain means threshold were required to make a contribution towards the funding of their accommodation, up to the full cost of the service.
- 2.56 The CAT held that North & West was an undertaking for the purposes of competition law both as a direct provider and when it contracted out to private companies.<sup>53</sup> For the purposes of this enforcement decision, the most significant aspect of the judgment is that, as regards the contracting out to independent providers, the CAT relied upon the fact that North & West was engaged, on a regular basis, in entering into commercial contracts. The CAT emphasised that this is the essence of most “economic” activities. It noted that the supply of residential care or nursing services in the UK was, from the perspective of service providers, “*in a real sense 'big business'*”,<sup>54</sup> and so transactions for the supply of these services constituted economic activity as a matter of common sense. As North & West necessarily engaged in commercial transactions, it was engaged in economic activity for the purposes of applying the competition rules.<sup>55</sup>
- 2.57 This portion of the *Bettercare* holding, establishing that where an entity enters into a commercial contract it is necessarily engaged in economic activity,<sup>56</sup> must now be considered in light of the more recent

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<sup>53</sup> The CAT noted that North & West itself provided some of the services on offer in the market for residential care services in Northern Ireland, by virtue of the eight care homes it directly ran. This aspect of the case is not relevant to the assessment of the administration of the Community Drugs Schemes. Nevertheless, the CAT also made stand-alone findings relating to the status of North & West for competition law purposes when engaged in contracting out, which are of application to the Community Drugs Schemes case. It is the findings of the CAT in relation to contracting out activity that must be contrasted with the decisions of the Community courts in *FENIN*.

<sup>54</sup> *Bettercare* at para 199.

<sup>55</sup> *Bettercare* at paras 191-193.

<sup>56</sup> The CAT found as a further factor supporting its contention that North & West was involved in economic activity the fact that North & West sought to recover as much as possible of the cost of the services it provided from the resident in question, whether in respect of accommodation services provided directly or contracted out. As the HSE does not make provision for all members of the general public to receive prescription drugs free of charge, this aspect of the *Bettercare* decision is of greater relevance. However, the Competition Authority is of the opinion that the “solidarity” exception to the economic activity concept governs in this instance. An entity does not act as an undertaking where it exercises an exclusively social function. In *Bettercare*, the CAT dismissed the solidarity argument on the basis that North & West’s activities had two dimensions: a social dimension (fulfilling the need for social care of the elderly population) and a business dimension. As North & West delivered its functions by using “*business methods*” (entering into commercial transactions with independent providers), its activities were not *exclusively* social in character and therefore fell outside the ambit of the solidarity exception.

The Competition Authority finds two difficulties with this analysis. Firstly, the CAT conflates the situation where an entity uses private undertakings to provide a public service with a situation where the entity itself acts as a private undertaking in providing an ostensibly ‘public’ service. As set out below, the judgment in *FENIN* does not support the view that entering into a commercial transaction to purchase goods or services constitutes economic activity, where the goods or services purchased are to be used for exclusively non-economic purposes.

decisions of the Community courts in *FENIN*. The *FENIN* decisions are outlined below, followed by an assessment of the impact of the *FENIN Bettercare* decision. To the extent that the judgments may be in conflict, the Competition Authority is obliged to follow the applicable Community law precedent in a case in which Article 81 EC is affected.

### **FENIN: the facts**

- 2.58 In *FENIN*, the CFI and ECJ considered the applicability of the term undertaking to the Spanish national health system ("SNS"). The SNS was managed by 26 public bodies, including three ministries. *FENIN*, an association of undertakings which sold medical goods and equipment used in Spanish hospitals, lodged a complaint against the SNS with the Commission, alleging the SNS acted as an undertaking in Community law when purchasing medical goods and equipment from private suppliers. *FENIN* argued that systematic delays in payment by the SNS management bodies constituted an abuse of a dominant position within the meaning of Article 82 EC.
- 2.59 The ECJ held that "*...there is no need to dissociate the activity of purchasing goods from the subsequent use to which they are put in order to determine the nature of that purchasing activity... the nature of the purchasing activity must be determined according to whether or not the subsequent use of the purchased goods amounts to an economic activity.*"<sup>57</sup> It therefore upheld the CFI's finding that the goods purchased by the SNS were to be used for the social purpose of providing health care and not for purposes of an economic activity. Consequently, the SNS was not an undertaking for the purposes of Community competition law when it purchased medical goods and equipment, and so Articles 81 and 82 EC did not apply to the entity.
- 2.60 In the context of the activities of the HSE under consideration, it is useful to note that the CFI went so far as to suggest that even if such a purchaser wielded monopsony power, it would not be acting as an undertaking for the purpose of the competition rules.<sup>58</sup>

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Secondly, the CAT had noted that self-funded residents to some extent cross-subsidised the services provided to State-funded residents (*Bettercare* at para 152). This fits neatly with Advocate General Fennelly's description of social solidarity as "*the inherently uncommercial act of involuntary subsidisation of one social group by another.*" (*Sodemare* opinion at para 29). Indeed, this statement is quoted in the *Bettercare* judgment at para 88. However, when considering the application of the solidarity principle, the CAT stressed that solidarity should "*not...be imposed externally on external trading parties such as independent providers.*" [Emphasis in the original.] The CAT appears to understand the concept of solidarity to require that care homes such as *Bettercare* engage in an uncommercial act of involuntary subsidisation, i.e. to sacrifice their profits for the benefit of society. However, this may confuse the threshold issue of whether North & West was an undertaking with the question of whether, if it was an undertaking, it abused its allegedly dominant position in the market place. The solidarity exception related to whether North & West could be said to have engaged in economic activity, not whether *Bettercare* had received a fair price.

<sup>57</sup> *FENIN* (ECJ) at para 26.

<sup>58</sup> "[A]n organisation which purchases goods - even in great quantity - not for the purpose of offering goods and services as part of an economic activity, but in order to use them in the context of a different activity, such as one of a purely social nature, does not act as an undertaking simply because it is a purchaser in a given market. Whilst an entity may wield very considerable economic power, even giving rise to a monopsony, it nevertheless remains the case that, if the activity for which that entity purchases goods is not an economic activity, it is not acting as an undertaking for the purposes of Community competition law and is therefore not subject to the prohibitions laid down in Articles 81(1) EC and 82 EC." *FENIN* (CFI) at para 37.

## Analysis of the *Bettercare* and *FENIN* case law

- 2.61 The *FENIN* decisions may cast some doubt on the findings of the CAT in *Bettercare* in relation to contracting out activity. The CAT appeared to hold that where an entity bought a service from a for-profit company that offered the service to the public, the transaction was intrinsically “economic” in nature and so the entity would invariably be involved in economic activity.
- 2.62 By contrast, the ECJ in *FENIN* emphasised that the mere fact that an entity enters into a contract of a commercial nature does not lead to the conclusion that the entity engages in economic activity. Where the ultimate purpose for which the entity transacts does not amount to an economic activity, then the transaction itself is not considered an economic activity from the perspective of that entity. Consequently, the entity is not an undertaking for the purposes of Community law.<sup>59</sup> This is without prejudice to the question of whether the transaction constitutes economic activity *vis-à-vis* the entity with which the non-undertaking transacts.
- 2.63 On the facts of *Bettercare*, for example, although North & West entered into commercial contracts with private care homes, it purchased the services of these care homes to fulfil its statutory obligation to provide social services in the community. Since the ultimate purpose of the transaction was not an economic activity, it is arguable that North & West’s actions in contracting with private care homes would not amount to economic activity.
- 2.64 On the basis of *FENIN*, the Competition Authority is of the view that the HSE falls outside the definition of undertaking for the purposes of EC competition law with regard to the activities under consideration. Although the *FENIN* case itself related to the purchasing of *goods* by State bodies, the legal principles set out in the judgment are broad enough to cover the purchasing of *services*. In particular, the Court makes reference to “*purchasing activity*”, a phrase which clearly captures the activities of the HSE in purchasing community pharmacy services. There is no principled reason why a different legal rule should apply depending on whether the product purchased is a good or a service.
- 2.65 The HSE purchases the dispensing services of community pharmacies for the sole purpose of providing prescription drugs to the public as part of the State health service. The HSE negotiates with pharmaceutical manufacturers in order to set the prices at which it reimburses community pharmacies for drugs dispensed to the public in fulfilment of the HSE’s statutory obligations. The HSE does not engage in these activities for any commercial purpose.
- 2.66 The Competition Authority acknowledges that the judgment of the ECJ in *FENIN* leaves unexplored some aspects of the application of the competition rules to the national health system. In particular, *FENIN* had argued that the fact that Spanish public hospitals provide care for patients not covered by the SNS, such as foreign visitors, amounted to an economic activity.<sup>60</sup> This claim was held inadmissible on procedural

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<sup>59</sup> *FENIN* in the ECJ at para 26.

<sup>60</sup> *FENIN* (ECJ) at para 9.

default grounds and so was not considered by the ECJ. A similar argument may be raised in the present context.

- 2.67 With regard to the purchasing of community pharmacy services from community pharmacies, the question of private patients can be answered briefly. All drugs dispensed by community pharmacies under the Community Drugs Schemes are provided to the public as an aspect of the HSE's statutory duty to deliver a health service within the State. The dispensing of drugs to private patients for a fee does not come within the ambit of the Community Drugs Schemes, although an undertaking designated a community pharmacy remains entitled to dispense private prescriptions outside of the Community Drugs Schemes.
- 2.68 The "private patients" argument may be more compelling in relation to negotiations between the HSE and pharmaceutical manufacturers to reduce drugs prices. The manufacturer agreements cover all drugs supplied to HSE entities and State-funded hospitals, in addition to drugs dispensed and reimbursed under the Community Drugs Schemes. As public hospitals treat private patients for a fee as well as public patients, some of the drugs procured by the HSE under the manufacturer agreements are used for what probably amounts to an "economic activity" for the purposes of the competition rules.
- 2.69 Nevertheless, the principal purpose of the manufacturer agreements is to set a reduced, landed price at which the HSE pays for drugs used in the public health service, including drugs dispensed by community pharmacies under the Community Drugs Schemes.<sup>61</sup> The principal task of the HSE is the management and delivery of the public health service; provision of health services to private patients for which the HSE gets payment from, for example, private health insurance companies, is merely ancillary to its purpose. The impact of the manufacturer agreements on the drug prices paid by private patients can properly be regarded as merely incidental and *de minimis* to the HSE's aims in negotiating the manufacturer agreements. Taken as a whole, the HSE is not engaging in economic activity when it negotiates with the representative bodies of pharmaceutical manufacturers in the State.<sup>62</sup>
- 2.70 The Competition Authority notes that when one party to a commercial transaction acts as an undertaking that does not affect the status, under the competition rules, of any other party to that transaction. Following *FENIN*, the determinative factor is whether the relevant undertaking enters the transaction in furtherance of economic activity. The Competition Authority therefore takes the view that none of the activities of the HSE under consideration are economic activities for the purposes of Community competition law.

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<sup>61</sup> As explained at footnote 27 above, the HSE claims that the manufacturer agreements also result in significant cost saving for the State.

<sup>62</sup> See Case C-364/92 *SAT Fluggesellschaft mbH v European Organisation for the Safety of Air Navigation* [1994] ECR I-43 on this point.

## **Application of Article 81 in conjunction with Articles 3(1)(g) and 10 EC**

2.71 Lastly, a further legal issue emerging from the Competition Authority's assessment of the status of the HSE is of note. As the HSE is not, in the opinion of the Competition Authority, an undertaking for the purposes of the activities at issue, it is not subject to the competition rules set out in sections 4 and 5 of the Competition Act and Articles 81 and 82 EC. However, this position does not immunise the State absolutely against liability potentially arising from a breach of the Community competition rules. In particular, the State may be liable if it adopts or maintains in force measures that are contrary to Articles 3(1)(g), 10 and 81 EC taken together.

2.72 Article 3(1)(g) EC states that the activities of the Community include a system ensuring that competition in the internal market is not distorted. Article 10 EC provides:

Member States shall take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Treaty or resulting from action taken by the institutions of the Community. They shall facilitate the achievement of the Community's tasks.

They shall abstain from any measure which could jeopardise the attainment of the objectives of this Treaty.

2.73 Applied in conjunction with Article 81 EC, these provisions have been interpreted to prohibit a Member State from introducing or maintaining in force measures that may render ineffective the competition rules applicable to undertakings. A Member State breaches the Treaty where it "*requires or favours the adoption of agreements, decisions or concerted practices contrary to Article [81 EC] or reinforces their effects*".<sup>63</sup> In such a situation, the Commission and other Member States may start infringement proceedings under Articles 226 and 227 EC against the offending Member State.<sup>64</sup>

2.74 This might be the case where, for example, the HSE engaged in negotiations with undertakings collectively, which involved a breach of Article 81 EC by the undertakings concerned. The State, in the guise of the HSE, may be found to have "required or favoured" this breach, and therefore would itself have breached Article 81 EC in conjunction with Articles 3(1)(g) and 10 EC.

2.75 Consequently, while the Competition Authority takes the view that the activities of the HSE under consideration do not fall within the purview of the direct application of Articles 81 and 82 EC, if the State fails to protect the Community competition rules and thus breaches its duty of loyalty to the Community, it may be liable for this breach by virtue of the indirect application of these rules. In such circumstances, the Commission could bring an action against the State in the Community courts, pursuant to Article 226 EC.

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<sup>63</sup> *Arduino* at paras 34-35.

<sup>64</sup> Communication from the Commission, *Report on Competition in Professional Services* (COM(2004) 83 final) at para 89.



### **3. CONCLUSION**

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3.1 On the basis of the facts and for the reasons set out above, the Competition Authority is of the view that the HSE does not constitute an undertaking for the purposes of the Competition Act and that the HSE does not constitute an undertaking for purposes of Articles 81 and 82 EC in respect of the following two activities:

- 1) Negotiating with the representative bodies of the pharmaceutical industry in Ireland to reduce the ex factory prices of certain drugs, resulting in a "landed price" for these drugs, and
- 2) Purchasing community pharmacy services from private sector pharmacy undertakings under the various schemes, known as the Community Drugs Schemes, administered by the HSE for the provision of prescription drugs to the general public.

3.2 Accordingly, the Competition Authority has determined that it will take no further action in respect of the complaints it has received alleging breaches of sections 4 and 5 of the Competition Act by the HSE. The view of the Competition Authority does not, however, affect the rights of private parties to take action under the Competition Act and/or the Treaty.

**For the Competition Authority**



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**Dr. Stanley Wong**  
**Member and Director, Monopolies Division**  
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