# Romania - Decision No. 15 as of 12.03.2008 issued by the Romanian Competition Council Bid-rigging on the insulin market

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*The present case analysis examines the Romanian's Competition Council's decision no. 15 as of 12.03.2008, which established: (i) breach of Art. 5(1) (c) of the Romanian Competition Law no. 21/1996 by Eli Lilly Export S.A., A&A Medical S.R.L., Mediplus Exim S.R.L. and Relad Pharma S.R.L. through the establishment and implementation of an agreement and/or concerted practice on the insulin market and (ii) breach of Art. 9 of the Romanian Competition Law no. 21/1996 by the Romanian Public Health Minister through the avoidance of organising annual bids for the National Diabetes Program between 2004-2006.*

## 1. BACKGROUND

As a result of the investigation conducted[1] by the Romanian Competition Council (hereafter **CC**) on the Romanian insulin market, in July 2005, it was established that the joint stock company Eli Lilly Export S.A. (hereafter **Eli Lilly**) and its distributors: the limited liability company A&A Medical S.R.L. (hereafter **A&A**), the limited liability company Mediplus Exim S.R.L. (hereafter **Mediplus**) and the limited liability company Relad Pharma S.R.L. (hereafter **Relad**) had concluded an anti-competitive agreement and/or a concerted practice[2], by sharing Eli Lilly's diabetes portfolio of products and by eliminating intra-brand competition among them.

It was considered that the agreement and/or concerted practice lasted from April/ May 2003 to May 2005.

The anti-competitive behaviour of the undertakings on the insulin market was discovered at the national bid organised by the Romanian Public Health Minister (hereafter **RPHM**) and by the National Health Insurance Authority (hereafter **NHIA**) in 2003.

Pursuant to the applicable Romanian legislation, as part of the national diabetes program, auctions should have been organised annually for the acquisition of insulin products. The year 2003 was the first and the last year when such an electronic bid (hereafter the **Bid**) was organised by the Romanian public health authorities[3] as: *(i)* between 2001-2002 the market was a decentralised one: each health unit had to acquire its necessary medicinal products through its own auctions, by respecting the applicable legislation for public acquisitions and *(ii)* between 2003-2005 RPHM and NHIA did not pursue the bidding procedures and, as a result, they amended the agreements concluded with the distributors in 2003; moreover, during this period, hospitals organised their own electronic bids.

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[1] The investigation was initiated by Order no. 157/07.07.2005, issued by the President of the Romanian Competition Council

[2] The term *„agreement and/or concerted practice"* shall be used for the anti-competitive behaviour of the undertakings, as the Decision makes reference to „agreements" and „concerted practice" without any consistency. In *Van Landewyck v Commission,* cases 209/78 [1980] ECR 3125, [1981] 3 CMLR 134, Advocate General Reischl stated that the point where an agreement ends and where a concerted practice begins, is of no importance. In complex European cases (e.g. *Cimenteries CBR SA v Commission*, cases T-25/95 etc, [2000] ECR II-491, [2000] 5 CMLR 204), the anti-competitive behaviour is referred to as the *„single, overall agreement"*.

[3] The measure was implemented through the Common Order no. 172/113/2004 regarding the approval of health programs in 2003, issued by Health Ministry and the President of NHIA.



### 1.1 Agreement and/or concerted practice concluded between Eli Lilly and its distributors

Eli Lilly is part of Lilly Group and is one of the biggest worldwide manufacturers of medicinal products. A&A, Relad and Mediplus are limited liability Romanian companies and they operate especially at the wholesale level in the medicinal products' market. All these three distributors had concluded non-exclusive distribution agreements with Eli Lilly.

In accordance with RPHM's specifications, the Bid comprised the request of 36 lots of human insulin products (these lots comprised all the insulin products on the Romanian market) and 27 oral anti-diabetes products. Eli Lilly participated in the Bid through its distributors in the following way: *(i)* A&A with the human insulin entitled Humulin, *(ii)* Relad with analogous human insulin product entitled Humalog and *(iii)* Mediplus with oral anti-diabetes products entitled Actos. Each of the distributors was authorised by Eli Lilly to offer in the Bid different human insulin products; therefore, the parties did not compete with each other.

Considering that for each of the above-mentioned products there was only one bidder, the auction should have been repeated. However, each of the distributors requested the Evaluation Committee for the National Diabetes Program of RPHM to conclude direct negotiations. Distributors invoked that they were the only distributors having authorisations issued by Eli Lilly for taking part in the Bid for the mentioned products and that Eli Lilly was the only producer of these medicinal products. As a result, supply agreements were concluded between the distributors and public bodies.

By virtue of Art. 5(1)(c) of the Romanian Competition Law no. 21/1996[4] (hereafter **Law 21/1996**), the correspondent of Art. 101(1)(c) of the Treaty on the Functioning of the European Union (hereafter the **TFEU**), *„any express or tacit agreements between undertakings or associations of undertakings, any decisions by associations of undertakings and any concerted practices, which have as their object or may have as their effect the restriction, prevention or distortion of competition on the Romanian market or on a part of it, shall be prohibited, especially those aimed at: […] allocating distribution markets or supply sources according to territorial criteria, sales and purchase volume or other criteria"*.

CC considered that the four undertakings breached Art. 5 (1) c) of Law 21/1996 by way of concluding and implementing different agreements and/or concerted practices, which had the same anti-competitive object of sharing the markets concerning Eli Lilly's portfolio of diabetes products.

[4] As this law was re-published in the Official Gazette Part I, no. 742/16.08.2005. It should be noted that the present case analysis is made under the provisions of Law 21/1996, in the form this law was in force on the date when the present Decision was issued and prior to its latest amendment from 2010. Law 21/1996 was modified by Emergency Governmental Ordinance no. 75/2010, published in the Official Gazette no. 459/06.07.2010.

The undertakings were fined as follows: *(i)* Eli Lilly approximately EUR 1,040,000[5] *(ii)* A&A approximately EUR 1,180,000, *(iii)* Relad approximately EUR 7,150,000 and *(iv)* Mediplus approximately EUR 13,379,000.

1.2 Romanian Public Health Minister's breach of competition provisions

As a public authority, one of the main responsibilities of the RPHM is to organise, implement and coordinate the national health programs with the NHIA. The national health programmes are regulated[6] with the purpose of preventing and treating diseases that may have significant negative effects upon population (e.g. AIDS, heart diseases, diabetes).They are financed from the state budget and the social insurance fund, in the limits established by virtue of the state budget law issued annually.

Pursuant to Art. 9 (1) a) of Law 21/1996 *„any actions by the central or local public administrative body which have as an object of may have as an effect the restriction, prevention or distortion of competition are prohibited, especially by: a) making decisions that limit the freedom of trade of undertakings' autonomy, which are being exercised under law"* (hereafter **Art. 9**).

The CC investigation revealed that from 2003 to 2006 the RPHM did not conduct annual auctions for the acquisition of medicinal products in the national diabetes program. Instead, the acquisition agreements concluded in 2003 were prolonged *"artificially"*[7] (in the terms of the CC) by monthly addenda and through governmental decisions. The distributors' offers were not modified since 2003.

Moreover, after 2003 the effective supply of insulin products through the national diabetes program represented 99% of supply of these products on the market. As stated at para. 507 of decision no. 15/12.03.2008 (hereafter the **Decision**), this situation may be considered to be a *de facto* monopsony held by RPHM, where the RPHM is the acquirer of the medicinal products from the distributors and the NHIA is the public body responsible for the payment from the national state budget. One should note that the insulin market is a regulated one, where the supply and acquisition is organised by auctions; hence, it can be said that competition on this market „happens" only when the bids are held.

Considering the above-mentioned statements, the CC concluded that RPHM prevented the existence of competition on the Romanian insulin market by restricting the distributors which had not won the Bid to access the market (by limiting the number of distributors to those which had won the auction in 2003) and by constraining the commercialisation of new insulin products which appeared on the market meanwhile. Actions which prevent entry on the market have the nature of restraining or even eliminating the competitive constraints between competitors and have negative effects on prices and/or quality of products.

[5] The amounts of the fines were converted into EUR at the medium ROL/EUR exchange rate for 2008: 1 EUR=3.6827 ROL, as this exchange rate is posted on the National Bank of Romania's website: http://www.bnr.ro/Cursuri-medii-3544.aspx

[6] RPHM is entitled to project, implement and coordinate the national health programmes, as per art. 34 of Law no. 145/1997 regarding social health insurance, which was repealed by the Governmental Emergency Ordinance no. 150/2002 regarding the organisation and functioning of health social insurance system

[7] As the CC evidenced, pursuant to the applicable legislation the auctions may be extended only expressly and in exemptional circumstances, until the auctions for the following year are organised.



1.3 "Overview" document

During the dawn-raids conducted by the CC in Eli Lilly's headquarters, a document entitled „Overview" was found (hereafter the **Document**). The Document included the following: a list of the sales from that moment, especially with regard to its 3 distributors; references made to the diabetes health program (e.g. maximum product quantities, proposal of price for the Bid), the market before the Bid and the scenarios willing to be followed during the Bid. Particular importance should be given to these scenarios, as they revealed an intention to collude and were considered to be at the heart of the agreement and/or concerted practice on the insulin market.

The first scenario consisted in offering all portfolio of insulin products by one distributor; the second scenario (which was considered by the CC to be the anti-competitive one and which was implemented) consisted in the share of the portfolio of products among distributors; the third scenario permitted each distributor to participate in the Bid with all its products and the fourth scenario comprised a consortium concluded between Eli Lilly and one distributor. Each scenario had its own advantages and disadvantages mentioned. The means of presenting the products and the possible sales made by its distributors were also set forth. Interestingly, scenario no. 2 evidenced the following disadvantage (from Eli Lilly's perspective): the possibility of internal competition with regard to Eli Lilly portfolio of products.

**2. LEGAL ASSESSMENT**

*2.1* Definition of relevant markets in the pharmaceutical sector

In its assessment to this effect, CC by reference to the *Romanian Guidelines regarding the definition of the relevant market*[8] *and the Commission Notice on the definition of relevant market for the purposes of Community competition law.*considered the following criteria:

*(i) Characteristics of the pharmaceutical market*

The medicinal products are generally classified by their therapeutic indications (so called functional substitutability). The market is highly regulated (e.g. the establishment of maximum prices entitled „CANAMED prices", a product shall be authorised by the Medicinal Products National Agency before being released on the market). Furthermore, from the demand point of view, patients have little influence on the market, as medicinal products are prescribed by doctors.

*(ii) ATC (Anatomical Therapeutic Classification) system*

The ATC system classifies medicinal products in 5 groups according to their therapeutic, chemical and pharmaceutical properties[9]. The level considered by CC in its analysis is the 3rd level of ATC, which groups medicinal products considering their therapeutic indications. The European case-law[10] usually uses this level of ATC as an upfront point in defining the relevant pharmaceutical product markets. Other levels may be used, if further competitive constraints exist among the undertakings active on the market.

[8] Published in the Official Gazette Part I, no. 288/2004

[9] The World Health Organisation and the European Pharmaceutical Marketing Research Association use the therapeutic indications criteria when classifying medicinal products.

[10] E.g.: *Sanofi/Synthelabo case COMP/M.1397, Astra/Zeneca case COMP/M.1403, Pfizer/Pharmacia* case COMP/M.2922

Other factors considered by CC were: the prescription of medicinal products, their discounts, the way the human insulin and analogous human insulin products act, duration of action and their establishment in human body.

In analysing the substitutability between *human insulin products and analogous human insulin products,* CC asked the advice (*i.e.* whether products from the same group would have close properties, their mixture would lead to new properties) of the Diabetes and Endocrinology Committee of RPHM. Additionally, the Medicinal Products' National Agency stated that the replacement of the type, trade mark and concentration of these medicinal products should be done only by the endocrinologist. Furthermore, the surveys conducted in different hospitals concluded that these 2 types of medicinal products are not substitutable and that the analogous human insulin products would have better results and that they are superior in quality.

*(iii) Definition of relevant product markets*
The CC defined the relevant product markets by taking year 2003 as a reference. The relevant product markets for 2002-2003 before the Bid[11], comprised the following relevant product markets: *(i)* the relevant product market for human insulin products with rapid action, *(ii)* the relevant product market for analogous human insulin products with rapid action, *(iii)* the relevant product market for human insulin products with intermediate action, *(iv)* the relevant product market for human insulin products with rapid and intermediate action, *(v)* the relevant product market for analogous human insulin products with rapid and intermediate action, *(vi)* the relevant product market for analogous human insulin products with prolonged action.

The relevant product markets for 2003-2006: each lot of products (which corresponded to a single product) represented a relevant product market. Considering the composition of the medicinal product, the concentration and its packaging, it was quite easy for one to recognise the producer of the medicinal products in question and therefore which company offered in the Bid.

2.2 "Overview" document – the most important proof of the agreement and/or concerted practice

The Document represents the main proof of the breach of competition law provisions committed by CC. The finding was supported by the fact that Eli Lilly tried to modify the original version of the Document which was taken/copied? by the competition inspectors during the dawn-raids, when it was asked to provide it. Eli Lilly incurred a fine for this illegal behaviour.

The CC based its conclusions on the anti-competitiveness of the arrangements at stake on the *Adalat case*[12] , where Bayer AG implemented a unilateral commercial strategy with the scope of preventing parallel imports. However, the European Commission did not prove adequately that Bayer France and Bayer Spain imposed their distributors a restriction to export the Adalat product, established a systematic monitoring of Adalat sale, imposed a sanctioning or threatening policy towards their distributors etc.

[11] The CC considered that the relevant market shall be defined differently before 2003 and after 2003, as the means of acquisition of the medicinal products has changed.
[12] *Bayer AG v Commission*, cases T-41/96 [2000] ECR II-3383 and Cases C-2/01 P and C-3/01 P *Bundesverband der Arzneimittel-Importeure eV v Bayer AG*



CC states at para. 283 of the Decision that Eli Lilly was not in the same situation as Bayer, as the manufacturer could not implement by itself the unilateral policy, considering that it had to participate in the Bid through its' distributors (Eli Lilly did not meet the eligibility criteria to participate itself in the Bid).

The Document was the first indication that the unilateral behaviour implemented by Bayer in the European case corresponded with the behaviour of Eli Lilly. The Decision is very interesting from this point onwards, as it reveals the arguments of the distributors in evidencing that Eli Lilly's unilateral behaviour has not been tacitly or expressly accepted and implemented by them. Much debate is upon an address[13] issued by the commercial manager of Relad, Mr. Sorin Chiutu, and sent to Eli Lilly, in which he thanks for the decision of Eli Lilly to be represented in the Bid for the diabetes national program with the Humalog product by Relad and requests the re-analysis of the discounts mechanism for two products. The CC was of the opinion that this address represented the proof that Relad has accepted the 2nd scenario, which Eli Lilly intended to carry out. The distributors tried to rebut the CC's assumptions, by stating that each party conducted unilaterally and that they were not aware of the strategy that the manufacturer was willing to be implemented.

2.3 „Per se" restriction of competition

According to para. 425 of the Decision, the CC states that any agreements and/or concerted practices having the object of restricting competition cannot benefit from the exemption under art. 5 (2)[14] of Law 21/1996[15]. Moreover, art. 8 (1) of Law 21/1996 establishes a *de minimis* rule: if certain market share thresholds are met, the undertakings restricting competition would not be sanctioned. Art. 8(2) of Law 21/1996 provides that the *de minimis* rule would not be applied in the case of agreements and /or concerted practices with regard to prices, sharing markets or bid-rigging. Para. 426 of the Decision states that the case at hand falls under art. 8(2) and it is a restriction of competition by object. It can be concluded therefore that the case at hand could not be analysed under art. 5(2) of Law 21/1996 and constitutes a per se restriction of competition[16].

Pursuant to para. 41, point 2 of *the Guidelines regarding the application of article 5 of Law 21/1996 with regard to vertical agreements*[17], in case of restrictions by object, as those mentioned at art. 5 of the Block Exemption Regulation, it is unnecessary to prove the effect of the agreement and/or concerted practice.This provision was invoked by the CC when it assessed the restriction of competition of the undertakings' agreement and/or concerted practice.

[13] Document no. 44 from the minutes no. 789/03.05.2006, 790/03.05.2006, respectively, concluded on 03.05.2006, at Relad headquarters and discovered in Mr. George Darie PC (Relad's Manager with regard to relations with suppliers).
[14] the correspondent of art. 101(3) of the TFEU
[15] Another difference between the Romanian and the EU competition regime is that in Romania is maintained the individual notification for obtaining an exemption from the CC. Conversely, in practice few undertakings undertake this way, as the CC is not willing to use it. It is expected that the amendments of Law 21/1996 willing to be undertaken will repeal this provision.
[16] The expression *„per se"* is used in the present article in the sense that no exemption or defence in light of art 5(2) of Law 21/1996 could be raised by the undertakings.
[17] Adopted through Order no. 77/14.04.2004, published in the Official Gazette Part I no. 437/17.05.2004

Moreover, CC's **White Charter of free competition in Romania**[18] (hereafter the **White Charter**) (a non-binding explanatory document providing guidance on the Romanian competition policy) states that a *per se* prohibition is reinforced by article 8(2) of Law 21/1996, according to which *"anti-competitive practices related to prices, tariffs, market division agreements or auctions are not subject to the limits imposed by the law concerning the turnover and market share level and consequently, are not exempted from the enforcement of the law" (the de minis rule)*. Additionally, it is mentioned that with regard to concerted practices at horizontal level, they are generally forbidden *"per se […] (as they are, by definition). […] this mean that their anti-competitive effects are so evident that they do not need to be demonstrated, the only proof necessary in these cases being the fact that they indeed occurred and had an anti-competitive object even if they did not produce effects"*.[19]

The European jurisprudence has clearly established that when applying Article 101(1) TFEU, if the agreement and/or concerted practice contains a restriction, prevention or distortion of competition by object, there is no need to further demonstrate its effect on competition[20]. Market - sharing agreements and/or concerted practices are considered to be anti-competitive as they isolate markets and prevent the single market integration - a primary aim of the TFEU.

Pursuant to para. 20 of the *European Commission's Guidelines on the application of article 101(3) of the Treaty* (hereafter the **Guidelines on 101(3)**), *„the distinctions between restrictions by object and restrictions by effect is important. [...] Article 101(3), on the other hand, does not distinguish between agreements that restrict competition by object and agreements that restrict competition by effect"*. Even though restrictions by object are considered to impede competition by their very nature (market sharing is mentioned expressly as an example of object restriction in para. 21 of the Guidelines on 101(3)) and even if, in practice, are considered not to fulfil conditions of Article 101(3) TFEU, they can still be assessed under the Guidelines on 101(3), in order to fall outside of Article 101(1) TFEU.

In light of the above, one should consider CC's approach towards market sharing as being a per se infringement (with the effect that no assessment can be made under art. 5(2) of Law 21/1996 and hence the agreement and/or concerted practice would not be able to fall outside art. 5(1) of Law 21/1996) too narrow. Even if the White Charter makes reference to horizontal agreements between undertakings as being per se infringements, one should note that even these types of agreements may theoretically fall under Article 101(3) TFEU. Even if, in the case at hand, the agreement and/or concerted practice was considered to be a vertical one, the per se approach is too restrictive. One may conclude that the CC -- the restriction, prevention and distortion of competition *by object* with the idea of *per se* infringement. One should emphasize that this matter should be addressed in CC's ?(future legislation amendments).

[18] http://www.competition.ro/documente/ro/carteaalba.pdf
[19] P. 24.
[20] *Volkswagen AG v Commission* [2000], ECR II – 2707, case T-62/98, para 178; *Societe Technique Miniere v Maschinenba Ulm,* Case 56/65 [1966] ECR 235, para. 249
[21] Issued by the CC, approved by Order no. 107/2004 and published in the Official Gazette Part I, no. 439/17.05.2004



2.4 Establishment of fines

In the assessment of fines, the CC considered art. 51 and 52 of Law 21/1996 and *the Guidelines for individualising the sanctions for infringements under art. 56 of Law 21/1996*[21] (hereafter the **Guidelines**).

The CC's analysis comprised: *(i)* the gravity of the breach (in the present case medium gravity anti-competitive actions, due to the significant effects on the market, even though the agreement was a vertical one), *(ii)* the duration (between 1-5 years) and *(iii)* the effects on competition. With regard to the last criterion, it was found that all supplies of human insulin products on the Romanian market were affected: those supplied through the national diabetes program and outside the program; moreover the undertakings offered maximum prices in the Bid.

The CC calculated fines by applying a basic amount (gravity plus duration) and adjusting it upwards or downwards, if there are any aggravating or mitigating circumstances. Pursuant to the Guidelines, when assessing the **gravity** of a competition law violation, the following shall be considered: the nature of the act, the impact of the act on the market and the extent of the geographical market. The acts were established to be medium-gravity ones, for which the sanction is usually between 2%-4% of the turnover of the undertaking in question. The parties argued that the acts were imposed by Eli Lilly individually and that they were not aware of the other distributors' allocations. However, the CC invoked repeatedly a provision from the Guidelines mentioning that undertakings of a certain magnitude have the knowledge and the legal and economic expertise to assess their anti-competitive behaviour. The **duration** was considered to be a medium one, as it lasted from 2003-2005 and hence an appraisal of 50% of the amount established by the gravity was applied.

**3. COMMENTS**

3.1. Breach of competition provisions by a public authority

*(i) Object or effect?*

In its analysis with regard to the breach of Article 9 by the public authority, the CC evidenced the two conditions that were met: *(i)* the action of breach should be performed by a central/local administrative body and *(ii)* the action should have the object/effect of restricting, preventing or distorting competition. The CC did not make any assertion whether the analysis is made in light of an object or an effect breach of the competition provision.

Interestingly, the breach found under Article 9 in the case at hand, can be compared with a similar previous one handled by the Romanian Competition Authority. In Order no. 131/2006 (hereafter the **Order**), by which the CC closed its investigation into the oncologic products[22] market,[23] when the activity of the RPHM is analysed, it is considered that the extensions of the agreements concluded after the auctions held in 2003 are only barriers to the market[24]. At the end of the Order, the CC issued the recommendations after the investigation, among which, the one for the RPHM was to pursue the auctions on a yearly-basis in order to "normalise" the competition environment[25].

[22] The case was closed as there was no breach of competition law provisions.
[23] The oncologic products were acquired by the RPHM through a National Health Program. The only auction held was in 2003 and afterwards the agreements were extended artificially on an annual basis.
[24] Point 4 letter c) of the Order
[25] Art 2 of the Order

Moreover, Article 9[26] provides that *"any **actions** […] which have as an object of may have as an effect the restriction, prevention or distortion of competition are prohibited"*. However, para. 515 of the Decision mentions about the passivity of the public authority with regard to organising the auctions, not about an "action". Could the artificial extensions of the concluded agreements be considered as the "actions", as this term is needed under Article 9, even if the breach is assessed more from the inactivity point of view? The answer might be found in CC's "discovery" that the provision encounters a lack, as in the proposed amendments of Law 21/1996[27], Article 9 comprises *"**actions and in-activities** […] which have as an object of may have as an effect the restriction, prevention or distortion of competition are prohibited"*.

*(ii) No fine imposed to the Romanian Public Health Minister*
Unlike the undertakings, the public authority was not fined for breaching Article 9. In Romania there are no sanctions to be applied to public authorities that do not respect the competition law provisions[28]. The fact the CC mentioned in the Decision that a public body breached Law no. 21/1996, might have relevance for the follow-on actions[29] by third parties or by the undertakings that incurred fines from the CC. Considering this and that actions in Romania are usually avoided because of the huge amount of time and costs that they imply, one should doubt the efficiency of the Article 9 in practice.

*(iii) Is Romanian competition law different?*
The way Article 9 is drafted evidences a unique approach of the Romanian competition law towards the infringements undertaken by public authorities.

Even if the European competition law provisions do not comprise such a straightforward approach towards the anti-competitive actions pursued by public authorities, through an express mentioning in article 101 of the TFEU, the European practice makes a distinction between: *(i)* the situation where state bodies qualify as an undertaking when they are engaged in economic activities and consequently can fall under Article 101 TFEU and *(ii)* the situation where their behaviour is connected to the exercise of powers of a public authority[30].

A very good example is the *Fenin case*[31], where the GCJ[32] asserted that when health care is provided to citizens, the public authorities act on the basis of solidarity[33] and therefore the act is not an economic one.

[26] The present case-analysis is made in light of the provisions of Law 21/1996, as this law was in force at the date when the Decision was issued and prior to its latest amendment from 2010. Law 21/1996 was modified by Emergency Governmental Ordinance no. 75/2010, published in the Official Gazette no.459/06.07.2010.
[27] The amendments of Law 21/1996 are found in the Emergency Governmental Ordinance no. 75/2010, published in the Official Gazette no.459/06.07.2010...
[28] It is questionable whether this approach will be changed with the amendments that are willing to be made on Law 21/1996. The amendments are currently being analised by the CC.
[29] Article 61 of Law no. 21/1996.
[31] Case T – 319/99 [2003] ECR II-357, [2003] 5 CMLR 34
[32] The decision was upheld by the ECJ.
[33] This term was defined by Advocate General Fennelly in the case Sodemare v Regione Lombardia [1997] ECR I-3395, [1997] 3 CMLR 591, para. 29, as being *„the inherently uncommercial act of involuntary subsidisation of one social group by another". If „social protection is provided on the basis on solidarity, it is not provided by an undertaking" – R. Whish in „Competition Law"*, 6th edition, page 86



It was concluded that the activity of purchasing goods should be analyzed in light of their purpose. As health care activities were not economic, the ancillary act of procurement was not as well. There is no distinction made between the purchase of goods offered in health-care sponsored programmes (like in the case at hand, where through the national diabetes programme, medicinal products are offered for free to patients) and purchase of goods offered by charging certain patients (the correspondent of the situation where the insulin products would be offered outside the national diabetes programme).

Additionally, other Member States of the EU sustain the approach of the European practice with regard to the anti-competitive practices pursued by public authorities. For example, in **UK** the Competition Act 1998 does not make any reference to this matter in its statutory provisions. Section 2 of the act or the Chapter I Prohibition, how it is also entitled, mirrors nearly 100% article 101 of the TFEU. However, the UK seems to approach in the same manner this matter. For example in *OFT's Guideline on agreements and concerted practices*[34], it is mentioned that the *"key consideration in assessing whether an entity is an undertaking for the application for the article 102 and/or Chapter I Prohibition is whether it is engaged in an economic activity"*. Like one should observe, no distinction is made between public and private undertakings. Therefore, indirectly said, the UK is upholding EU's approach.

In **France**, art. L410-1 of the Commercial Code establishes that the competition law provisions apply to all production, distribution and services agreements, comprising also the ones pursued by public authorities[35]. In its 2008 Report, the Conseil de la Concurrence asserts that the practice established that it can sanction also the public authorities for anti-competitive behaviours[36]. Conversely, no assessment shall be made under the competition provisions for activities performed under public scope. It might be concluded that the French competition authority is in the same line as the UK and EU decisional practice.

Moreover, the German Act against Restrictions of Competition[37] in its Section 1 Prohibition of agreements restricting competition, specifies that *"agreements between undertakings, decisions by association of undertakings and concerted practices, which have as their object or effect the prevention, restriction or distortion of competition, shall be prohibited"*. Moreover, in Section 130 of the ARC entitled *"Public undertakings, scope of application"* provides that the act will also apply to undertakings *"which are entirely or partly in public ownership or are managed or operated by public authorities"*. Conversely, German practice makes the same distinction as in EU[38].

[34] Paras. 2.5-2.6 of the guideline
[35] http://www.legifrance.gouv.fr/affichCode.do;jsessionid=6ED45C13B0A612F0BAFEBE400919BF8C.tpdjo04v_2?idSectionTA=LEGISCTA000006133183&cidTexte=LEGITEXT000005634379&dateTexte=20100531
[36] http://www.autoritedelaconcurrence.fr/doc/pratique_decisionnelle_ra08.pdf, page 7
[37] The Act can be found at http://www.bundeskartellamt.de/wEnglisch/Legal_bases/Legal_basesW3DnavidW2625.php
[38] GWB § 130, Unternehmen der öffentlichen Hand; Geltungsbereich, Emmerich/Rehbinder/Markert, editors Immenga/Mestmäcker, "Wettbewerbsrecht: GWB" 4, edition Auflage 2007

The definition of the relevant product markets based on the reference period of 2003 and the moment of the Bid raises questions. Considering that, as mentioned above, before 2003, the auctions were organised by each health unit in a decentralised manner and seeing how the relevant product markets are defined for that period (*i.e.* by their way of action and divided in human insulin products and analogous human insulin products), one might question the definition of the relevant product markets after the Bid up to 2006. The definition of the markets during the Bid seems fair enough, however the extension of the supply agreements concluded with the distributors in 2003 should not be considered to be the starting point for defining the relevant product markets after the Bid. The de facto situation reveals that after the Bid until 2006, health units held individual bids and the distributors even made offers in some of them. If the automatic extension of the agreements concluded during the Bid was considered not to be in accordance with the relevant legal provisions, hence it means they were illegal. Is the CC's definition of the relevant product markets after the Bid up to 2006 appropriate, considering that it is based on non-valid agreements? And, should the individual bids held after 2003 up to 2006 and the automatic extension of the agreements after 2003 have any impact on the definition of the relevant markets?

In a public procurement procedure, the procurer determines the product; consequently there is no demand side substitution[39]. With regard to supply side substitution it should be analyzed how many undertakings can provide the same relevant product. If there are a few undertakings that are willing to submit an offer, they represent the supply side.

Noting:

*(i)* how the relevant product markets were defined before 2003 - there was no separate market defined for the oral tablet Actos,

*(ii)* that despite the relevant product market definition before 2003, Actos was distributed prior to 2003, hence it should have been considered in the definition,

*(iii)* that there is a separate definition of Actos relevant market after 2003,

*(iv)* that the Decision makes reference to the agreement and/or concerted practice with regard to insulin products and analogous human insulin products, but when analyzing the allocation of products beside these two, also the Actos tablet is mentioned, one might presume that Actos is part of one of the following groups: the insulin products and the analogous human insulin products. This might represent that Actos is substitutable with one of these two. In the tender procedures, products are part of the same relevant product market if they are "reasonable interchangeable"[40]. If the CC considered that previous 2003 Actos was substitutable with one of the insulin groups, it means that it would be during the Bid as well. It is not clear how this product Actos was taken into consideration by the CC when it defined the relevant markets.

Should the CC have defined the relevant product markets for 2003-2006 as it has done it for 2002-2003? How would another definition of the relevant product markets have impacted the agreement and/or concerted practice?

[39] As this was decided in SAP v Gazdasagi Versenyhivatal Unreported November 5, 2008 (Hungary) – Pal Szilagyi "Case *Comment Hungary: antic-competitive agreements – bid-rigging"*, European Competition Law Review, 2009

[40] P. B. Work, *"Antitrust issues relating to arrangements and practices of government contractors and procuring agencies in markets for specialized government products"* (1988) 57 Antitrust Law Journal.543, 548



Would another definition of the relevant market have had an influence over the fine imposed to the undertakings, considering that, by virtue of the Guidelines, the relevant geographic market is one of the factors considered in the assessment of gravity of the infringement and that in many parts the Guidelines reference is made to the impact of the infringement on the market? The CC remained reluctant in its Decision towards this issue[41].

Additionally, the inclusion by a public body of medicinal products in a bid, in such a manner that would restrict competition on the market (by the elimination of the inter-brand competition, at the producers' level), do not change the characteristics and the prices of the medicinal products. Hence, should the interference of the RPHM, through an administrative act, have an economic and legal effect on the structure of the market (*i.e.* by defining it in another manner than based on the ATC level)[42]?

3.3. "Overview" document

The document issued by Relad's representative comprised the following assertion: *„we would like to thank very much for the decision to be represented by Relad to the tender for Diabetes Care"*.

Having in mind that the authorisation offered by Eli Lilly to its distributors, in order to allow them to participate to the Bid with specific medicinal products, was an unilateral document representing an unilateral decision, one may state that Relad's address may be a normal business answer that any distributor may give to its supplier, especially when its purpose is to obtain further discounts[43].

Furthermore, the distributors tried to evidence that they did not meet the transport and deposit capacities, thus they could not have participated in the Bid with offers for more medicinal products. Conversely, this argumentation was not sustained as the proof was contradictory.

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Whether the definition of the relevant product markets in the case at hand is correct and whether the proof on which the CC based the finding of an anti-competitive agreement and/or concerted practice on the Romanian insulin market is enough, is still left open for debate[44].

Conversely, one thing is for sure: the CC will pay further specific attention to the pharmaceutical market as *"there are some aspects of facilitating the anti-competitive practices with regard to the acquisitions of medicinal products by hospitals"*[45]. In this light, the CC requested the RPHM not to use the "dealer authorisations[46]" as a necessary document in a tender, as it is considered to restrict intra-brand competition.

[41] The definition of the relevant product markets based on the reference period when the Bid has been held was debated by Eli Lilly in para. 208 of the Decision. Conversely, the CC's answer is no more than a repetition of the facts already invoked when defining the relevant product markets.

[42] This issue was raised by Mediplus at para. 209 of the Decision

[43] Paras. 298 and 299 of the Decision

[44] The case is being appealed; the final judgement of the court might answer the debatable questions.

[45] http://www.consiliulconcurentei.ro/documente/Raport%20concurenta_18423ro.pdf

[46] The authorisation is usually issued by the manufacturer of medicinal products in order to grant distributors the opportunity to participate in tenders.

Generally speaking, about competition in the pharmaceutical market, after the investigations conducted on markets such as the insulin market or the dialysis market, currently the CC is addressing the problems that may exist in this sector and the artificial barriers that may have arisen over time.[47] It is expected that the CC will issue a report of its investigations at the end of 2010.[48] Sanctioning the anti-competitive behaviours on the pharmaceutical market is indeed a paramount and first step in solving the current issues; however, legislation in this area should be re-considered, as it encounters gaps where anti-competitive practices can easily find a warm blanket to develop.

[47] The CC opened a general investigation on the market for wholesale distribution of medicinal products and further individualized 4 investigations.
[48] http://www.consiliulconcurentei.ro/documente/Raport%20concurenta_18423ro.pdf