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Case No.: 090-161/2009, January 22, 2010

**Applicant's request:**

Making reference to the Media Act and Access to Public Information Act, the applicant filed a request with the Ministry of health (hereinafter: the body) on October 12, 2009. The applicant wanted to inspect the agreement(s) between the body and pharmaceutical companies, the suppliers of vaccine against the swine flu, saying that if the body wished not to disclose the whole agreement they would like to have access to the information which is not confidential. The applicant wished to acquire the following information:

- Which pharmaceutical companies were parties to the agreement?
- What conditions were set out and whether the agreement conditions equally applied to all pharmaceutical companies,
- What responsibilities did the state take related to the vaccine/vaccination and what are the responsibilities of pharmaceutical companies?

**The exemption the body referred to:**

The body referred to the exemptions for accessing information, i.e. Subpara 2, Par 1, Art 6 of ZDIJZ according to which the body may refuse the request if the information has been defined as a business secret.

**Commissioner's decision:**

The appeal is founded.

**Grounds:**

1. **The concept and existence of Public Information**

The ZDIJZ (Slovenia's Access to Public Information Act) makes manifest the constitutional right of access to public information (as per the second paragraph of Article 39 of the Constitution of the Republic of Slovenia) and hence in the first paragraph of Article 1 ensures everyone free access to public information held by organs of the state, public agencies, public funds and other entities under public law, as well as holders of public power and contracted providers of public services. In including a massive swathe of public sector bodies within its embrace, the ZDIJZ encompasses a broad spectrum of public sector operations.

The scope of the ZDIJZ's domain is also manifested in the definition of that which constitutes public information. Public information, according to Paragraph 1 of Article 4 of the ZDIJZ is deemed to be information pertaining to the field and scope of work of public sector bodies and may occur in the form of a document, a case, a dossier, a register, a record, or other documentary material, drawn up by the body, by the body in co-operation with another body, or acquired from other persons. The above provision defines three basic criteria according to which public information can be defined:

- the information must stem from the field of work of the body;

- the body must possess the information;

- the information must exist in a material form, as a document and/or documentary material.

This means that the body needs to produce such public information within the scope and procedures of its work for which the body is liable to general regulations. The information does not have to be produced by the body but it must be related to its work. Such information can be obtained from other persons, even from persons under private law, which are not bodies in terms of the provisions of Art 1 of ZDIJZ. What is important is that the body has obtained such information within the scope of its competencies (for more information see doctoral dissertation by Urška Prepeluh, The right of access to public information, Ljubljana 2004, p. 148).

The body is a ministry, meaning that it represents executive branch of government. It is therefore a state body, which is liable to providing public information. The same derives from Art. 14 of the Public Administration Act (Official Gazette RS, No. 52/02, with amendments, hereinafter: ZDU-1), by which the ministries are administrative bodies, performing administrative functions. In this particular case there is no doubt that the agreement in question derives from the field of work of the body and that the document exists in a material form. Also, the third criterion is met, namely the information was produced by the body, or acquired from other persons.

Therefore, the Commissioner had to appraise whether this information should be freely accessible, or whether there might be an exemption to free access (such exemptions are listed in Par 1, Art 6 of ZDIJZ).

**2. Exemptions under Subpara 2, Par 1, Art 6 of ZDIJZ**

The body may deny access to the information if it falls under one of the exemptions defined in Par 1, Art 6 of ZDIJZ. In the contested decision the body did make reference to the exemption under subpara 2, Par 1, Art 6 of ZDIJZ, which stipulates that a business secret, which has been determined as such according to the Companies act, can be an exemption.

According to Art. 39 of ZGD-1 a business secret is defined as a data which has been determined as such by a written decision of a company. This means that all partners, employees, members of the bodies and other persons are obliged to treat such information as a business secret (Par 1, Art 39 of ZGD-1). Notwithstanding this, business secret is deemed to be the information which has not been determined as such by the decision of the company, however, it is evident that a significant damage could be made if the information was disclosed to an unauthorised person (Par 2, Art 39 of ZGD-1). The Commissioner notes that in ZGD-1, Par 3, Art. 39, there is an explicit provision by which the information, which is public by law, or the data on violations of the law or fair trade practices, cannot be deemed as business secret.

ZGD-1 makes distinction between two criteria, based on which a business secret can not be disclosed. The subjective criterion means that the body alone, by its own will and by its own act, can define a particular data to be confidential and thus prohibits its further distribution. According to this criterion it is irrelevant what significance such confidential data has for the company. The holder of such information is also free to define other, less relevant pieces of information as a business secret, To meet this criterion, a special and explicit order must be provided, stating, which data are deemed to be a business secret. Such order can be issued as a special act (e.g. rules on business secret) or individually. For the purpose of clarity and in order to avoid ambiguity, the order must be made in writing, and should be made available to all persons responsible to protect the confidential data. However, a third requirement, which in fact applies to all regulatory acts, can be added to this, namely that the order should not have retroactive effect and that violations of a business secret are only the actions which were made during the time when the order was already in force (for more information: Commentary to the Companies Act, second edition, Vol. 1, Editor: Prof. Dr. Marijan Kocbek, GV Založba, d.o.o., Ljubljana, 2002, pp. 195-196).

Further on the Commissioner had to establish, whether the agreement in question represented a business secret according to the subjective criterion. The Commissioner inspected the agreement concluded between Glaxo Group Limited, the National Stock-holding Institute and the body on supplying the vaccine for pandemic flu (hereinafter: agreement) to find out that the agreement (indent 15. 1, subheading »Confidentiality«), determines that parties to this agreement will treat the agreement as confidential and shall not disclose it to third persons. Other details on communication are mentioned in Appendix D – Publicity measures. This appendix includes a list of information marked red which has been determined as confidential by the agreement, and a list of information marked green which was defined as non-confidential, and the procedures for communicating the information to the public. This means that the parties to this agreement have explicitly marked the agreement as a business secret, binding each partner not to disclose any part of the agreement to third persons. Another fact showing that the agreement has been marked as confidential according to the subjective criterion derives from the Decision on the protection of confidentiality of the agreement related to the supply of the vaccine against pandemic flu/Slovenia, delivered by the accessory intervenor on July 15, 2009, and received by the Commissioner on Jan 14, 2010. From all the above it derives that in this case all statutory conditions have been met for the existence of a business secret by using the

subjective criterion according to Par 1, Art. 39 of ZGD-1 which requires that all three criteria need to be met: firstly, the document must be determined as a business secret by a written order (Decision on the protection of confidentiality of the agreement related to the supply of the vaccine against pandemic flu/Slovenia of Jul 15, 2009), secondly, this decision was made available to all person responsible to protect such confidential information (provision under indent 15. 1 of the agreement), and thirdly, the information had already been classified as business secret prior to signing the agreement (the agreement was signed on Aug 20, 2009, while the Decision on the protection of confidentiality was signed on July 15, 2009).

According to the wording of Art. 39 of ZGD-1, only one of the two conditions (subjective or objective criterion) needs to be met for defining a business secret. After the Commissioner established that statutory conditions have been met for the existence of business secret by subjective criterion (Par 1, Art. 39 of ZGD-1), a further assessment on the existence of a business secret using objective criterion was unnecessary in spite of the arguments of the accessory intervenor for a possible damage which might be caused by the disclosure of the agreement.

The Commissioner believes that the accessory intervenor has done everything possible to protect the data by marking them as business secret, however, in this case it was necessary to find out whether the agreement contained the data which could not be treated as business secret according Par 3, Art. 39 of ZGD-1.

According to the wording of the Regulation (EC) No. 726/2004 of the European Parliament and the Council, Art. 13 of March 31, 2004 on the procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, the marketing authorisation needs to be published in the Official Journal of the European Union with the following data: date of authorisation with registration number in the Community register, any international non-proprietary name (INN), active substances contained in the product, pharmaceutical form of the product, and any Anatomical Therapeutic Chemical Classification (ATC). The European Medicines Agency publishes the assessment report of the medicinal product for human use, which is made by the Committee for medicinal products for human use, and contains a justification of the reasons for issuing marketing authorisation after erasing all data of commercially confidential character. The European Public Assessment Report (EPAR) includes a summary, written in a simple way to be understood by the general public. The summary needs to contain the information on the conditions for product use. According to the European legislation, the components of the medicinal product, which has received marketing authorisation by the European Medicines Agency and has obtained the EPAR, cannot represent a business secret, since the Regulation (EC) No. 726/2004 stipulates that the information must be made public. The Commissioner found out on the web page of the Agency at:
(http://www.emea.europa.eu/humandocs/Humans/EPAR/pandemrix/pandemrix.htm, that the EPAR report was published for the vaccine which was the subject of the agreement between Glaxo Group Limited, National Stock-holding Institute and the body. This report is also accessible in Slovene language at http://www.ema.europa.eu/humandocs/PDFs/EPAR/pandemrix/H-832-sl2.pdf, and also contains the information included in indent 1.1. and indent 1.2 of the appendix A to the agreement. Considering the fact that this part contains the data, which have already been defined as public by the EU Regulation – which according to the Slovenian legal order is directly applicable and is binding -- this information can not be considered as business secret according to the provision under Par 3, Art. 39 of ZGD-1.

The Commissioner gives an additional argument speaking in favour of free access, namely that the information on the ingredients of the vaccine, which is the subject of the contract between Glaxo Group Limited, National Stock-holding Institute and the body, had also been published on the Internet and is therefore publicly available. This particular information gives instructions for the use of the vaccine, describes its main characteristics and instructions on labelling the vaccine. The document can be accessed at :
http://www.ema.europa.eu/humandocs/PDFs/EPAR/pandemrix/DH1N1%20single%20PDFs/PackageLeaflet/emea-pl-h832pu17sl.pdf,
http://www.ema.europa.eu/humandocs/PDFs/EPAR/pandemrix/D-H1N1%20single%20PDFs/SPC/emea-spc-h832pu17sl.pdf and
http://www.ema.europa.eu/humandocs/PDFs/EPAR/pandemrix/DH1N1%20single%20PDFs/Labelling/emea-lab-h832pu17sl.pdf).

It needs to be taken into account that the same information which has already been made public can not later be defined as a protected business secret. It needs to be emphasized that by nature, a business secret can only be data, known to a limited number of people. On the other hand, information which is available to a larger public audience, can not be considered as business secret. However, a question remains whether every information could represent a business secret. Considering that it is not possible to give a precise definition of a business secret, theory provides six elements which need to be taken into account when assessing if a particular information is a business secret:

1. to what extent the information is known to persons outside the company circle;
2. to what extent the information has been made available to the employees and other persons involved in business activities of the company:
3. what measures have been taken by the company to protect the confidentiality of their information; 4. how valuable the information is for the company and for its competitors;
5. how much effort and money has been put into developing such information;
6. how difficult or easy it would be for others to acquire, or duplicate such information.

The data, contained in the agreement on page 22, Appendix A, indent 1.1. (Antigen component), and indent 1.2 (Adjuvant component), have already been published, i.e. on the Internet which means outside the company circle, and therefore the Commissioner believes that the disclosure could have no negative effects on the competitive position of the accessory intervenor. Also, this is the information which, even by the statute, must be public, and can therefore not be exempted from free access as stipulated under Subpara 2, Par 1, Art. 6 of ZDIJZ.

Also, exemptions from business secret can not be made for the data on financial conditions, data on time schedule of payments, the price which the body will cover from public funds, since these are the data on the use of public funds, and are defined as public according to Par 3, Art. 6 of ZDIJZ. This provision, among other things, stipulates that irrespective of possible exemptions, access to the information is allowed if the data concerns the use of public funds, or if the data relate to performing a public function or employment relationship of a public officer. The position of the accessory intervenor can be argued in that the information on the use of public funds is only the information on the total contractual value the will pay. This information alone does not indicate whether the body acted cost-effectively in this case and under what conditions the body took financial obligations in the name and on account of the Republic of Slovenia. The Commissioner explains that the data on total contractual value alone can not ensure adequate public control, pursued by the institution of transparency, i.e. promotion and ensuring effective and fair competition and cost-effective use of public funds. The latter can be achieved only by allowing the public to access information on financial conditions, the information on time schedule of payments and data on the unit price for the vaccine. Only with complete information, it is possible to ensure an efficient control over the use of public funds, which is the purpose of the provision under Par 3, Art. 6 of ZDIJZ. The data on financial conditions, time schedule of payments and data on the unit price for the vaccine are in fact the data which indicate how public funds have been spent and therefore access to such information is free, as stipulated by Par 3, Art. 6 of ZDIJZ. With all the above, the data from the agreement: page 11. and 12., indent 6 – Financial conditions, on page 26, Appendix B, indent 3 (Compensation for the preparation) and indent 4 (Prices) and on page 28, indent 8 (Billing), do not represent a business secret since they are defined as public by the statute.

Concerning the claims of the accessory intervenor, in that the agreement on the supply of the vaccine against pandemic flu has only a civil-law effect and ensures the rights and responsibilities among contractual partners, and that the parties to the agreement are bound to protect business secret, whereby non-compliance with this provision can result in liability for damage, the Commissioner emphasizes that it is possible to acknowledge a possibility that a contractual relationship between private entities can entirely represent a business secret in terms of Art. 39 of ZGD, however, this does not apply to contractual relationships between private entities and public sector entities. Every person, entering a contract with the state, needs to be ready to become subjected to a special regime in concluding contracts. Thus, when entering a contract with the sate the suppliers need to be aware that according to statutory provisions, it is impossible to expect total protection of their business secrets.

Considering all the above the Commissioner concluded that the agreement on the purchase of vaccine against pandemic flu, concluded between Glaxo Group Limited, National Stock-holding Institute and the body, represents a

business secret according to subjective criterion, except pages 11 and 12, indent 6 – (Financial terms), page 22, Appendix A, intent 1.1. (Antigen component) and indent 1.2 (Adjuvant component), page 26, Appendix B, indent 3 (Compensation for the preparation) and indent 4 (Price) and page 28, indent 8 – (Billing), which need to be considered as public information.

**3. Overriding public interest test**

The overriding public interest test, according to Par 2, Art. 6 of ZDIJZ, stipulates that without prejudice to the provisions in the preceding paragraph (which defines the exceptions from free access -- the Commissioner's note) the access to the requested information is sustained, if public interest for disclosure prevails over the interest of other persons not to disclose the requested information, except in cases defined under the same article, however none of these cases refer to a business secret. In the given case the Commissioner found out that one part of the agreement on the purchase of vaccine against pandemic flu, concluded between Glaxo Group Limited, National Stock-holding Institute and the body, represents a business secret which is exempted from free access according to Par 2, Art. 6 of ZDIJZ, thus the implementation of the overriding public interest test is admissible.

What is important for the assessment of the overriding public interest is that it is possible to relativise an exemption. Relativisation needs to remain limited only to such cases where the interest of the public for the disclose of a document is stronger than the interest of others to protect the document and treat it as an exemption from free access. When using the overriding public interest test it is necessary to assess whether the public interest for disclosing public information is stronger than the potential damage which might be caused by disclosing the document. Theory emphasizes that the overriding public interest test needs to be used extremely cautiously and conscientiously since it requires higher level of decision making in weighing between two opposite rights or interests. Therefore, the overriding public interest test means an exemption among exemptions which needs to be taken with extreme caution and only when it is expected that the test might reveal something which would contribute to a broader discussion and understanding of an issue important for the broader public.

The overriding public interest test means weighing and assessing whether a certain right of the public to know prevails over another right, or exemption from ZDIJZ, and to establish what is better for public interest: to disclose or not to disclose the information. Public interest for disclosing information is, for example, very strong in situations which concern obtaining or spending public funds, public security, public health, responsibilities and transparency of decision making which trigger public or parliamentary debates.

In this case the Commissioner established that a particular part of the agreement on purchasing the vaccine against pandemic flu, concluded between Glaxo Group Limited, National Stock-holding Institute and the body, represents a business secret. Therefore, the Commissioner had to weigh between two interests and decide which is greater: the interest of the public to have this part of agreement disclosed, or the interest of those who protected their data as a business secret, i.e. the economic interest of the accessory intervenor to prevent the disclosure of information which represents its competitive advantage and which might cause damage to its competitive position should the information be disclosed.

The interest of the public is not as precise and defined as the interest for not disclosing the information; it is rather abstract and general. It is manifested as a demand for transparency of the activities of a public sector body to act conscientiously in decisions on public matters and in spending public funds. Public interest is also manifested by open discussion on important social issues. The concept of public interest is not the same in every case and cannot be defined in advance since it may appear in many different forms. Also, public interest may change over time and depends on numerous circumstances. Therefore, public interest is not something constant; it is changeable and depends on momentary situation. With this in mind, public interest test requires assessment case by case, considering different, variable factors which form public interest.

In Slovenia, as well as in Europe, the supply of the vaccine against pandemic flu H1N1 triggered numerous concerns and dilemmas. This issue was the subject of debate among professional institutions, the media, as well as among the broader public. Vaccination issues not only concern the question whether the purchase of the vaccine was transparent or cost-effective from the point of view of using public funds: all sorts of questions

emerged among the people about the vaccine and vaccination – is it safe, what are potential side effects, what is the responsibility of the state in terms of ensuring safety, etc. Public interest was manifested through extensive public debates on the question whether the World Health Organisation overstated the threat of swine flu H1N1. As a response to this, the Committee on health, family and social affairs of the Council of Europe proposed an urgent investigation of this case (ref: http://www.pharmatimes.com/WorldNews/article.aspx?id=17147, http://www.times.si/read/bde4944a5b/ba63a4d23a/index.html and http://www.times.si/read/bde4944a5b/910d1a0f1e/index.html).
As evident from the articles cited above, the Commission of inquiry of the European Parliament Commission unanimously passed a resolution demanding transparency in the investigation procedure on the suspicion of corruption of the World Health Organisation (WHO), pharmaceutical industries and researchers in declaring swine flue pandemic. This problem is an important social issue concerning people's health and touches upon every individual. Those who have already been vaccinated or are planning to do so, have the right to receive complete information whether the vaccine is safe and what responsibilities for the supply of this vaccine the state will take by this agreement, considering that the state will potentially take financial obligations which consequently means spending taxpayer's money. It also needs to be noted that a lot of opposing information about the safety of the vaccine emerged among the public (i.e. the article »Is the vaccine against new flu safe? », published on the web portal of 24ur.com on Nov 13, 2009, at http://24ur.com/specialno/nega_in_zdravje/je-cepivo-proti-novi-gripi-varno-za-nase-otroke.html or the article »Helsinki monitor calls for withdrawal of the vaccine against swine flu« of Oct 22, 2009, at: http://www.siol.net/slovenija/zdravje/2009/10/v_sloveniji_prva_posiljka_vaccine_.aspx). For example, the minister of health urged people to take the vaccine, warning them about the dangers of the new pandemic, claiming that vaccination was the only efficient preventive measure available (ref: mmc.info, »Miklavčič warning and urging people to take vaccination«, of Dec 1, 2009, at: http://mmc.info/zdravje/miklavcic-svari-in-poziva-k-cepljenju/218208). The public reacted with a question who would take responsibility in case of negative effects of vaccination, e.g. (ref: article in the journal Finance dated Jan 14, 2010 »What is Miklavčič trying to hide from us from the agreement on purchasing vaccine against swine flu?«, at: http://www.finance.si/268747/Kaj-vse-nam-Miklav%E8i%E8-prikriva-v-pogodbi-za-nakup-vaccine -proti-gripi). With all the above The Commissioner disagreed with the claims of the accessory intervenor in that all contractual provisions which refer to the liability for damage or limitations of liability, have only a bilateral effect, which means that public interest for the disclosure has not been given. The question about the responsibility of the state in such a delicate problem as public health can never be of no public interest, also for the reason that by taking such responsibility further financial consequences for the state budget can be expected, i.e. spending public funds. As already mentioned in this decision, contractual relationships between the state and legal persons governed by private law can not be treated as a general agreement under civil law because the body, when concluding agreements on behalf and in the name of the Republic of Slovenia, must always pursue public interest, while the party entering this agreement must submit itself to a special regime by entering such legal transaction. Particularly in contracts concluded between the public and private sector, it is not possible to avoid statutory provisions determined by the legal order of RS, namely the provisions of ZDIJZ. An important aspect of public interest is also to ensure transparency of work of the bodies and their responsibility, and hence reducing a chance of bringing bad political and professional decisions, since the transparency contributes to better and wiser decisions and better quality of work.

Weighing between all the factors and circumstances mentioned above, the Commissioner concluded that the interest of the public for disclosing the information, which directly concerns human health, risks of vaccination, guarantees, responsibilities for vaccination, claims for indemnification and limitation of liability, is stronger than the private-law interests of the company to protect the information and classify it as a business secret. The data contained in the agreement: page 13, indent 8 – Health risks and recall of the vaccine, pages 13 to 15, indent 10 – Guarantees (indents 10.1, 10.2, 10.3, 10.4), pages 15 to 16, indent 11 – Product liability and compensations (indents 11.1, 11.2, 11.3) and page 17, indent 13. 2 – Limitation of liability, need to be disclosed according to Par 2, Art. 6 of ZDIJZ.

As derives from the grounds of this decision, the applicant's appeal is founded, and for this reason the Commissioner annulled the contested decision and brought its own decision, referring to Par 1, Art. 252 of ZUP, on the grounds that the body misused the material law (Par 2. and 3. Art. 6 of ZDIJZ). The Commissioner granted the applicant's appeal for the part, in which it was established that the agreement does not represent a business secret because the information is considered public based on the statute, and because the information refers to the use of

public funds, as well as in the part where it was found out that the public interest is overriding, which means that the information needs to be disclosed according to Par 2, Art 6 of ZDIJZ. For the remaining part of the agreement, the Commissioner refused the applicant's request after establishing that this part represents a business secret which means that it is exempted from free access according to Subpara2, Par 1, Art. 6 of ZDIJZ, while public interest for the disclosure of this part of the agreement was not established.

**The body shall, within 30 (thirty) days after receiving this decision, allow access to the Slovenian version of the Agreement between Glaxo Group Limited, Ministry of Health of RS and National Stock-holding Institute, dated Aug 20, 2009 on supplying the vaccine against pandemic flu in the manner as derives from the operative part of this decision.**

**Instruction on legal remedy:** This decision cannot be appealed, but the applicant can initiate administrative dispute against the decision. The administrative dispute can be initiated by a lawsuit, which must be filed within 30 days after receiving this Decision with the Administrative Curt, Fajfarjeva 33, Ljubljana. The lawsuit can be sent by registered mail or filed directly with the Court. If the lawsuit is dispatched by registered mail, the date of delivery to the post office shall deem to be the day of delivery to the court. The lawsuit together with attachments must be filed in three copies. It must contain the attachment with this Decision in original, or in a copy form.

Procedure conducted by: Rosana Lemut Strle, LL.M.