



EUROPEAN COMMISSION

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Rome, 00198
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DECISION OF THE EUROPEAN COMMISSION PURSUANT TO ARTICLE 4 OF THE IMPLEMENTING RULES TO REGULATION (EC) No 1049/2001¹

**Subject: Your request for access to documents under Regulation (EC) No
1049/2001 - GESTDEM 2018/6670**

Dear [REDACTED],

I refer to your letter of 12 September 2016, registered on 14 September 2016, in which you submitted, on behalf of [REDACTED] (hereafter ‘[REDACTED]’), a confirmatory application in accordance with Article 7(2) of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents² (hereafter ‘Regulation (EC) No 1049/2001’).

1. BACKGROUND AND SCOPE OF YOUR REQUEST

In your initial application of 21 July 2016, registered under reference GESTDEM 2016/4100 and addressed to the Directorate-General for Health and Food Safety, you requested access to the ‘final report of an assessment of ICIM (0425) carried out in the framework of the joint assessment process for notified bodies (DG(SANTE) 2015-7552 – MR / 16.2.2016 [...]’.

The European Commission identified the following document as falling under the scope of your request:

- ‘Final report of an assessment of ICIM (NB 0425) carried out in the framework of the joint assessment process for notified bodies designated under the Medical Devices Directives’, European Commission, 16

¹ Official Journal L 345 of 29.12.2001, p. 94.

² Official Journal L 145 of 31.5.2001, p. 43.

February 2016, reference Ares(2016)808430 (hereafter ‘the requested document’), which includes the following annexes:

- Annex I ‘Legal references’ (hereafter ‘Annex I’);
- Annex II ‘Application for renewal of authorisation’, ICIM S.P.A., Italian Ministry of Health (*Ministero Della Salute*), 29 July 2015 (hereafter ‘Annex II’);
- Annex III ‘On-site assessment plan for ICIM’ (hereafter ‘Annex III’).

In its initial reply of 5 September 2016, the Directorate-General for Health and Food Safety refused access to the requested document based on the exception of Article 4(2), first indent (protection of commercial interests) of Regulation (EC) No 1049/2001. In your confirmatory application of 14 September 2016, you requested a review of this position.

On 14 October 2016, the European Commission adopted a confirmatory decision (hereafter ‘the first confirmatory decision’), confirming the initial reply of Directorate-General for Health and Food Safety to refuse access, based on the exception of Article 4(2), first indent (protection of commercial interests) of Regulation (EC) No 1049/2001.

On 12 December 2016, Falcon Technologies International LLC lodged before the General Court an action for annulment of the European Commission’s first confirmatory decision refusing access to the requested document.

In its judgment of 5 December 2018 in Case T-875/16 P (*Falcon Technologies v European Commission*)³, the General Court annulled the European Commission’s first confirmatory decision, insofar as it refused to grant partial access to the requested document.

Pursuant to Article 266 of the Treaty on the Functioning of the European Union, the European Commission is required to take the necessary measures to comply with the above-mentioned judgment of the General Court. By adopting a new confirmatory decision regarding your request for access to documents, the European Commission herewith gives effect to the judgment in question.

2. ASSESSMENT AND CONCLUSIONS UNDER REGULATION (EC) NO 1049/2001

Following a new assessment of your confirmatory application, I can inform you that partial access is granted to the requested document on the basis of the exceptions of Article 4(2), first indent (protection of commercial interests) and Article 4(1)(b)

³ Judgment of the General Court of 5 December 2018, *Falcon Technologies International LLC v European Commission* (hereafter referred to as ‘*Falcon Technologies v European Commission* judgment’), T-875/16, EU:T:2018:877.

(protection of privacy and the integrity of the individual) of Regulation (EC) No 1049/2001, for the reasons set out below.

2.1. Protection of commercial interests of a natural or legal person

Article 4(2), first indent of Regulation (EC) No 1049/2001 provides that ‘[t]he institutions shall refuse access to a document where disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property, [...] unless there is an overriding public interest in disclosure’.

In the *Falcon Technologies v European Commission* judgment, the General Court considered that public access to a final report detailing possible instances of non-conformity, by a notified entity, with European Union law, can undermine the reputation of the entity concerned.⁴ According to the General Court, the exception relating to the protection of commercial interests can be invoked on that basis, unless the infringement is of particular gravity, such as in the case of competition rules.⁵

The requested document is a report concerning the outcome of a joint assessment of a notified body, ICIM S.P.A - NB 0425. The assessment was carried out by the Italian designating authority and a joint assessment team composed of representatives of the European Commission and designating authorities from two Member States in accordance with the rules laid down in Commission Implementing Regulation (EU) No 920/2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (hereafter ‘Regulation (EU) No 920/2013’)⁶.

As explained in the document itself, the report ‘lists the nonconformities in the notified body’s performance identified by [the joint assessment team] and designating authorities and makes a recommendation regarding the renewal of designation of the notified body in accordance with Article 3(2) of [Regulation (EU) No 920/2013]’. The report focuses mainly on nonconformities with Annex I of Regulation (EU) No 920/2013. It does not intend to identify a breach by the notified body of competition rules or a breach of a similar nature and gravity.⁷

Public release of the redacted parts of this document, which contain specifically the analysis of the notified body’s nonconformities, would result into a reputational damage for the notified body in question. It would undermine the confidence in this entity, as other operators and the public in general would learn about its nonconformities with Union law at a given point in time, whereas these nonconformities were corrected at a later stage in the context of the re-designation process of the notified body under assessment. Moreover, competitors would gain an unfair competitive advantage, as their respective joint assessment reports have not been made public.

⁴ *Falcon Technologies v European Commission* judgment, cited above, paragraph 52.

⁵ Ibid, paragraphs 53 and 54.

⁶ Official Journal L 253 of 25.9.2013, p. 8.

⁷ *Falcon Technologies v European Commission* judgment, cited above, paragraph 54.

Disclosure of the above-mentioned information would also have a negative impact on the notified body's commercial activities with manufacturers of medical devices and other relevant actors in the market, which could be prevented from doing business with this entity. This would, in turn, seriously undermine the commercial interests of the notified body under assessment.

Indeed, as acknowledged by the General Court in the *Falcon Technologies v European Commission* judgment, a reputational damage for a notified body clearly constitutes a damage to its commercial interests, since the reputation of any operator in a given market is essential for its economic activities in the market concerned.⁸

Hence, there is a risk that public access to the withheld parts of the requested document would undermine the commercial interests of the notified body concerned. Given the limited number of actors and the high degree of competition which characterises the market of notified bodies in the concrete field of medical devices, I consider this risk as reasonably foreseeable and not purely hypothetical.

Moreover, Annex II of the requested document contains commercially sensitive information concerning the business activities and competences of the third party concerned. This information is covered by the exception laid down in Article 4(2), first indent (protection of commercial interests) of Regulation (EC) No 1049/2001.

In light of the above, I conclude that the use of the exception under Article 4(2), first indent of Regulation (EC) No 1049/2001 based on the protection of commercial interests of a legal person is justified, and that access to the redacted parts of the requested document must be refused on that basis.

Please note that the information regarding the notified body's application for re-designation submitted under Council Directive 93/42/EEC concerning medical devices⁹, contained in the requested document including Annex II, is disclosed insofar as it coincides with the scope for which the notified body was designated. This information is publicly available in the database of the European Commission's New Approach Notified and Designated Organisations Information System (hereafter 'NANDO').¹⁰

Finally, I would like to underline that Annex II of the document originates from a third party and cannot be re-used without the agreement of its author.

2.2. Protection of privacy and the integrity of the individual

Article 4(1)(b) of Regulation (EC) No 1049/2001 provides that '[t]he institutions shall refuse access to a document where disclosure would undermine the protection of [...] privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data'.

⁸ Ibid, paragraph 51.

⁹ Official Journal L 169 of 12.7.1993, p. 1.

¹⁰ http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notification_html&ntf_id=274151&version_no=12%20

In its judgment in Case C-28/08 P (*Bavarian Lager*)¹¹, the Court of Justice ruled that when a request is made for access to documents containing personal data, Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data¹² (hereafter ‘Regulation (EC) No 45/2001’) becomes fully applicable.

Please note that, as from 11 December 2018, Regulation (EC) No 45/2001 has been replaced by Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC¹³ (hereafter ‘Regulation (EU) 2018/1725’).

However, the case-law issued with regard to Regulation (EC) No 45/2001 remains relevant for the interpretation of Regulation (EU) 2018/1725.

In the above-mentioned judgment, the Court of Justice stated that Article 4(1)(b) of Regulation (EC) No 1049/2001 ‘requires that any undermining of privacy and the integrity of the individual must always be examined and assessed in conformity with the legislation of the Union concerning the protection of personal data, and in particular with [...] [the Data Protection] Regulation’.¹⁴

Article 3(1) of Regulation (EU) 2018/1725 provides that personal data ‘means any information relating to an identified or identifiable natural person [...]’.

As the Court of Justice confirmed in Case C-465/00 (*Rechnungshof*), ‘there is no reason of principle to justify excluding activities of a professional [...] nature from the notion of private life’.¹⁵

Annex II contains personal data from representatives of the notified body, such as names, surnames and other personal information. The names¹⁶ of the persons concerned as well as other data from which their identity can be deduced undoubtedly constitute personal data in the meaning of Article 3(1) of Regulation (EU) 2018/1725.

Pursuant to Article 9(1)(b) of Regulation (EU) 2018/1725, ‘personal data shall only be transmitted to recipients established in the Union other than Union institutions and bodies if [t]he recipient establishes that it is necessary to have the data transmitted for a specific purpose in the public interest and the controller, where there is any reason to assume that the data subject’s legitimate interests might be prejudiced, establishes that it is

¹¹ Judgment of the Court of Justice of 29 June 2010, *European Commission v The Bavarian Lager Co. Ltd* (hereafter referred to as ‘*European Commission v The Bavarian Lager* judgment’), C-28/08 P, EU:C:2010:378, paragraph 59.

¹² Official Journal L 8 of 12.1.2001, p. 1.

¹³ Official Journal L 205 of 21.11.2018, p. 39.

¹⁴ *European Commission v The Bavarian Lager* judgment, cited above, paragraph 59.

¹⁵ Judgment of the Court of Justice of 20 May 2003, *Rechnungshof and Others v Österreichischer Rundfunk*, Joint Cases C-465/00, C-138/01 and C-139/01, EU:C:2003:294, paragraph 73.

¹⁶ *European Commission v The Bavarian Lager* judgment, cited above, paragraph 68.

proportionate to transmit the personal data for that specific purpose after having demonstrably weighed the various competing interests’.

Only if these conditions are fulfilled and the processing constitutes lawful processing in accordance with the requirements of Article 5 of Regulation (EU) 2018/1725, can the transmission of personal data occur.

In Case C-615/13 P (*ClientEarth*), the Court of Justice ruled that the institution does not have to examine by itself the existence of a need for transferring personal data.¹⁷ This is also clear from Article 9(1)(b) of Regulation (EU) 2018/1725, which requires that the necessity to have the personal data transmitted must be established by the recipient.

According to Article 9(1)(b) of Regulation (EU) 2018/1725, the European Commission has to examine the further conditions for the lawful processing of personal data only if the first condition is fulfilled, namely if the recipient establishes that it is necessary to have the data transmitted for a specific purpose in the public interest. It is only in this case that the European Commission has to examine whether there is a reason to assume that the data subject’s legitimate interests might be prejudiced and, in the affirmative, establish the proportionality of the transmission of the personal data for that specific purpose after having demonstrably weighed the various competing interests.

In your confirmatory application of 14 September 2016, you did not put forward any arguments to establish the necessity to have the data transmitted for a specific purpose in the public interest. Therefore, the European Commission does not have to examine whether there is a reason to assume that the data subjects’ legitimate interests might be prejudiced.

Notwithstanding the above, there are reasons to assume that the legitimate interests of the data subjects concerned would be prejudiced by the disclosure of the personal data reflected in the document, as there is a real and non-hypothetical risk that such public disclosure would harm their privacy and subject them to unsolicited external contacts.

Consequently, I conclude that, pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access cannot be granted to the personal data, as the need to obtain access thereto for a purpose in the public interest has not been substantiated and there is no reason to think that the legitimate interests of the individuals concerned would not be prejudiced by the disclosure of the personal data in question.

3. OVERRIDING PUBLIC INTEREST IN DISCLOSURE

The exceptions laid down in Article 4(2), first indent of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosure. Such an interest must, firstly, be public and, secondly, outweigh the harm caused by disclosure.

¹⁷ Judgment of the Court of Justice of 16 July 2015, *ClientEarth v European Food Safety Agency*, C-615/13 P, EU:C:2015:489, paragraph 47.

According to settled case-law, it is for the applicant to put forward concrete elements to demonstrate the existence of an overriding public interest in the disclosure of the requested documents.¹⁸

In your confirmatory application of 14 September 2016, you argued that ‘the [requested document] should be disclosed [...] in order to enable [Falcon Technologies International] to exercise fully its fundamental right to defence’ in the context of an administrative procedure which concerned it. You also stated that ‘this is a key and essential element of [the administrative procedure], which clearly and undeniably prejudices [your client]’.

In the procedure before the General Court in Case T-875/16, Falcon Technologies International argued, in addition to the above, that there is an overriding public interest in the protection of competition, on the one hand, and in the protection of public health, on the other.

Please note that, in its judgment on the above-referred case, the General Court held that the essential nature of the final report in order to exercise the rights of defence before national courts does not establish the existence of a public interest. According to the General Court, such interest is, rather, of a private nature.¹⁹ Moreover, it considered that the existence of overriding public interests regarding the protection of competition and the public health had not been sufficiently demonstrated in the case at hand.²⁰

In light of the above, I must conclude that the arguments you put forward do not demonstrate the existence of an overriding public interest in disclosure. Nor have I been able to identify any public interest capable of overriding the private interest protected by Article 4(2), first indent (protection of commercial interests) of Regulation (EC) No 1049/2001.

The fact that the documents relate to an administrative procedure and not to any legislative act, for which the Court of Justice has acknowledged the existence of wider openness,²¹ provides further support to this conclusion.

Please also be informed that Article 4(1)(b) of Regulation (EC) No 1049/2001 does not include the possibility for the exception defined therein to be set aside by an overriding public interest.

¹⁸ Judgment of the Court of Justice of 29 June 2010, *Commission v Technische Glaswerke Ilmenau* (hereafter referred to as ‘*Commission v TGI* judgment’), C-139/07 P, EU:C:2010:376, paragraph 62, Judgment of the Court of Justice of 28 June 2012, *European Commission v Agrofert Holding*, C-477/10 P, EU:C:2012:394, paragraph 68; Judgment of the Court of Justice of 14 November 2013, *LPN and Finland v European Commission*, Joint Cases C-514/11 P and C-605/11 P, EU:C:2013:738, paragraphs 92 to 94; *Falcon Technologies v European Commission* judgment, cited above, paragraph 84.

¹⁹ *Falcon Technologies v European Commission* judgment, cited above, paragraph 89; Judgment of the General Court of 15 September 2016, *Herbert Smith Freehills LLP v European Commission*, T-755/14, EU:T:2016:482, paragraph 75.

²⁰ *Ibid*, *Falcon Technologies v European Commission*, paragraph 92.

²¹ *Commission v TGI* judgment, cited above, paragraphs 53-55 and 60; *Commission v Bavarian Lager* judgment, cited above, paragraphs 56-57 and 63.

4. PARTIAL ACCESS

In accordance with Article 4(6) of Regulation (EC) No 1049/2001, I have considered the possibility of granting partial access to the documents requested.

As stated above, partial access is herewith granted to the requested document.

As regards the undisclosed parts of these documents, I consider that further partial access cannot be granted as this would harm the interests referred to in Sections 2.1 and 2.2 of this decision for the reasons set out above.

5. MEANS OF REDRESS

Finally, I draw your attention to the means of redress available against this decision. You may either bring proceedings before the General Court or file a complaint with the European Ombudsman under the conditions specified respectively in Articles 263 and 228 of the Treaty on the Functioning of the European Union.

Yours sincerely,

*For the Commission
Martin SELMAYR
Secretary-General*

Enclosure: (1)