AGENCIA ESPAÑOLA DE PROTECCIÓN DE DATOS

**Legal Department**

**No./REF: 143318/2016**

Having examined your application for a report, sent to this Legal Department concerning the enquiry raised by Farmaindustria, please allow me to inform you of the following:

The enquiry raises if it is pursuant to Organic Law 15/1999, of 13th December, for Personal Data Protection and its implementing Regulation approved by Royal Decree 1726/2007, of 21st December, that entities belonging to the requesting Association should publish on their web sites and without seeking the prior consent of the parties concerned, individual information related to value transfers carried out by those entities for the benefit of healthcare organisations and professionals, under the terms that shall be introduced in the Code of Practice for the Pharmaceutical Industry with the amendments that are appended to the enquiry.

For this purpose, the enquiry refers to possibly applying to the case the rule of balance of rights and interests laid down by Article 7 (f) of Directive 95/46/EC, under which "Member States shall provide that personal data may be processed only if: (…)(f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests for fundamental rights and freedoms of the data subject which require protection under paragraph 1 of Article 1. In this regard, the enquiry reminds us that the Judgement of the Court of Justice of the European Union of 24th November 2011 has come to recognise the direct effect of the above-mentioned provision of the Directive, which, if applicable to the case, would allow the aforementioned publication to be carried out without the consent of those affected.

As a preliminary matter, and as is clear from the actual text of Article 18 of the Code of Practice for the Pharmaceutical Industry subjected to report, it is necessary to emphasise that this report shall be confined to assessing the appropriateness or inappropriateness of the publication of the transfers of value made to healthcare professionals, whenever regarding organizations pursuant to the the first paragraph of Article 2.2 of the implementing Regulation of Organic Law 15/1999, , which confirms that the data protection rules do not apply to legal entities.

Having said this, and focusing on the publication of the transfers of value to individuals and in the application of Article 7 (f) of Directive

95/46/EC, the Judgement of the Court of Justice has expressly declared the direct effect of the aforementioned provision, as indicated in the enquiry. For this reason, this article should be taken directly into account in the application of the regulations on the personal data protection by the Member States, and accordingly by this Spanish Data Protection Agency, because, as pointed out by the Supreme Court in its judgement of 8th February 2012 "it produces immediate legal effects without the need of national standards for its implementation, and that therefore can be invoked before the administrative and judicial authorities when a transgression is observed".

As recalled by the Judgement of the Court of Justice of the European Union in its paragraph 38, Article 7 (f) of the Directive " sets out two cumulative conditions that must be fulfilled in order for the processing of personal data to be lawful: firstly, the processing of the personal data must be necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed; and, secondly, such interests must not be overridden by the fundamental rights and freedoms of the data subject , and in connection with the said balancing, paragraph 40 recalls that this "shall depend, in principle, of the individual circumstances of the particular case in question and in the context of which the person or the institution which carries out the balancing must take i account of the significance of the data subject's rights arising from Articles 7 and 8 of the Charter of Fundamental Rights of the European Union give the interested party".

For this reason, the Judgement points out in its paragraph 46 (corrigendum 43) that Member States, must, when transposing Directive 95/46, "take care to rely on an interpretation of that directive which allows a fair balance to be struck between the various fundamental rights and freedoms protected by the European Union legal order, therefore, in accordance with paragraph 47 (corrigendum 46) that " there is nothing to preclude Member States, in the exercise of their discretion laid down in Article 5 of Directive 95/46, from establishing guidelines in respect of that balancing. ".

Therefore, to determine if the application of the aforementioned provision is appropriate the rule of balancing laid down therein should be applied; that is to say, it shall be necessary to assess whether in the specific case subject to analysis there is a legitimate interest pursued by the data controller or by the third party or third parties to which the data is to be communicated that prevails over the interest or the fundamental rights and freedoms of the person concerned who require protection in accordance with the provisions of Article 1 of the Organic Law 15/1999, according to which "this Organic Law aims to ensure and protect, all that concerning personal data processing, public freedoms and fundamental rights of individuals, and especially of their honour and personal and family privacy" or if, on the contrary, these fundamental rights or interests of the people concerned which relate to the data processing have to override the legitimate interest in

which the controller aims to base the personal data processing.

Having said that, it is appropriate to examine whether in this case the publication raised, under the terms indicated in the enquiry and in Article 18 of the Code of Practice for the Pharmaceutical Industry that is attached herein shall be deemed to be covered by the widely quoted Article 7 (f) of Directive 95/46/EC.

Paragraph 3 of Article 18 states that "In each applicable period, companies shall disclose on an individual basis for each clearly identifiable Recipient Transfers of Value to such Recipient in each reporting period which can be reasonably allocated to one of the categories set out below. Such Transfers of Value must be aggregated on a category-by-category basis, provided that itemised disclosure shall be made available upon request to (i) the relevant Recipient, and/or (ii) the relevant authorities. ".

At the same time, with regard to the professionals, the second sub-paragraph of this article stipulates that the publishing shall relate to the following concepts:

- *" **(a)(**corrigendum **b)** **Contribution to Costs Related to Events.***

  *Contribution to the costs related with Events such as:*
  ***(i)** registration fees; and*
  ***(ii) (**corrigendum **iii)** travel and accommodation (governed by Article 11 of the Code).*

- ***b) (**corrigendum **c) Fees for Service** Transfers of Value related to or made under contracts between laboratories and Healthcare Professionals, from which there is a provision of a service or a value transfer not covered by the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts."*

The information " disclosed shall be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed, unless, in each case, a shorter period is required under applicable national law ", according to paragraph 2 of the article, and published within the first six months of the financial year following that in which the transfer of value took place, including it on the company´s web page. Transfers of Value related to research and development shall be disclosed only on an aggregate basis, according to paragraph 5 of Article 18.

With regards to the delimitation of legitimate interest invoked by the requesting party, the letter sent to the Agency indicates that “the disclosure of transfers of value on an individual basis pursues, to decrease the perception risk on the influence that the healthcare professional might have received,

it promotes a culture of integrity in transactions with healthcare professionals and the confidence of the public and patients in the integrity and independence of the healthcare professional, something essential for generating confidence in such relations and for their proper functioning". It also indicates that the aim is to "ensure that the pharmaceutical companies comply with the strict limits that are set by both the legislation (national and Community) and the own self-regulation system in the field of promotion of medicines", avoiding "that interactions of the pharmaceutical industry with the healthcare professionals may constitute an infringement of Directive 2001/83/EC on the Community Code relating to medicinal products for human use and Royal Legislative Decree 1/2015, of 24th July, approving the Consolidated Law on Guarantees and rational use of medicines and medical devices".

This all means that the aim pursued by the disclosure of the information would be to ensure the adequate knowledge by the general population, and in particular by the patients of a specific health care professional, that the latter's action is not tampered with in any way as a result of the intervention of the laboratories linked to the requesting party and, ultimately reveal the integrity and independence of those professionals to carry out a specific prescription, dispensing and administration of medicines.

In this regard, it should be recalled that Article 4.6 of the Consolidated Law on guarantees and rational use of medicines and medical devices, approved by Royal Legislative Decree 1/2015, of 24th July, in the wording given to it by the final disposition 20.1 of Law 48/2015, of 29th October, establishes in its first two sub-paragraphs that "in order to ensure the independence of decisions related to the prescription, dispensing and administration of medicines in respect of commercial interests, the direct or indirect offer of any type of inducements is prohibited, together with rebates, discounts, premiums or gifts, by those who have direct or indirect interests in the production, manufacture and marketing of medicines to the health professionals involved in the cycle of prescribing and dispensing and administration of medicines or to their relatives and persons with whom they live. This prohibition shall also apply when the offer is made to healthcare professionals that prescribe medical devices".

Equally, Article 78.4 of the Consolidated Law establishes that "the offers of awards, grants and contributions and subsidies to meetings, conferences, study tours and similar acts by any natural or legal person, related to the manufacture, processing, distribution, prescribing and dispensing medicines and healthcare products, shall be made public in a manner to be determined by regulations and shall apply only to activities of a scientific nature when their recipients are healthcare professionals

or the entities to which they are associated. The source of financing and the funds obtained from each source must be recorded in the programmes, publications of work and papers of meetings, congresses and similar acts. The same obligation would be applicable to the media through which this work is made public and funds are obtained by or for its publication".

The above standards certainly do not establish a publication system for individual data related to transfers of value, submitting to the detail of the publicity to be given to a later regulatory development. However they do lay down the principle that the companies shall have to make public the information related with transfers of value carried out with the aim expressed in the enquiry, to ensure transparency in their work and the independence of the professionals at the time of prescribing, dispensing or administering medicines.

All this would help to consider that the measure at issue in the enquiry would have as its object that of meeting a legitimate interest, which the trials of suitability and need also indicated in that enquiry could not favourably rule on and that respond to the doctrine emanating from the Constitutional Court and the European Court of Human Rights.

However, to appreciate if the publishing could be based on this legitimate concern without requiring as a result, and unlike as was being carried out until now, the consent of those affected, it is necessary to assess whether this interest has to be regarded as prevalent over the rights and freedoms of health professionals with regard to the information to be published and in particular their right to personal data protection. This would also allow taking into account that in addition to the judgement of suitability and of need, the measure raised would exceed the judgement of strict proportionality mentioned by jurisprudence.

This Agency has been indicating that, in general, the prevalence of legitimate interest could occur in the event that measures are taken that would minimise the impact on those affected as a result of the personal data processing. In any case, and as has been demonstrated, we should not lose sight of the fact that the legitimate interest invoked has been expressly taken into consideration by the legislator:

In the enquiry raised it is noted that "in any case, these measures would be taken and would be put into practice ensuring respect for the general principles of Organic Law 15/1999 on data processing and comprehensively informing the healthcare professional. Healthcare professionals whose data are to be published would be informed of the adequacy and relevance; the purpose of the data collection and accuracy of the data and the possibility of exercising the rights of access, rectification, cancellation and

opposition (ARCO) by the healthcare professionals concerned".

At the same time, it is relevant to recall that Article 18.3 of the Code of Practice, in the version proposed, anticipates that the publication of the information is carried out in an aggregated manner for the categories referred to in Article 18.3.2, so that only the amount received due to the collaboration in scientific and professional meetings and for the provision of services would be made public, excluding value transfers related to research and development, in accordance with Article 18.5. In this way, only the cumulative data for the categories would be known and not the breakdown of the information from which this amount proceeds from.

Article 4.1 of Law 15/1999 enshrines the principle of proportionality in processing, so that the data that is adequate, relevant and not excessive for the purpose that justifies it. The inclusion of the aggregated amount, without incorporating any breakdown, allows the data object of publication to be the minimum necessary to ensure the objective pursued by this measure, in line with the legal regulations to which reference has been made earlier.

At the same time, the recognition to exercise one's rights makes it possible to take into consideration that in any event the exclusion of the data would be possible if the personal circumstances of the professional were to justify reversal of the rule of balancing that has been analysed through the right of opposition.

Whereas these circumstances would allow to consider that the balancing requested by article 7 f) of Directive 95/46/CE can be secured in favour of the publication, it would be convenient that additional measures were implemented preventing a further processing of data which might deviate from the original purpose, since access to this information might allow those getting to know it to undertake additional processing aimed not as much at the transparency objective linked to the transfers of value, but at the elaboration of profiles of healthcare professionals receiving those transfers.

To this effect, it would be convenient that protocols were applied to the website hosting the publication of the data, preventing its indexation through search engines. Likewise, it would be relevant that the website clearly states, in order to guarantee the proportionality of the measure, that the final purpose of the publication is the one indicated in this consultation, and that the publication does not grant a general permission for those accessing the website to undertake additional processing of the healthcare professionals' data, such as crossing the data with information published in other members' websites.

As a consequence, we consider that the publication to which the consultation is referred, and the corresponding amendment of article 18 of the Code of Practice for the Pharmaceutical Industry is compatible with article 7f) of Directive 95/46/CE, so that the healthcare professionals' consent is not necessary for this publication to be made. In addition, the adoption of measures to guarantee the privacy of the professionals mentioned herein would be convenient, with the aim of avoiding further processing which exceeds the objective justifying this publicity.