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New rules regarding the yearly visa applicable to environmental authorizations and integrated environmental authorizations

Order 1150/2020 brings, through the approval of the Procedure for the application of the yearly visa, new legal obligations with high impact on businesses that operate under environmental authorizations and integrated environmental authorizations.

CJEU clarifies the rules applicable to the distribution of samples free of charge to persons qualified to prescribe or supply them

The Court of Justice of the European Union ("**CJEU**") ruled under Decision C-786/18 ("the **Decision**") for a preliminary ruling, that in the matter of marketing of medicinal products, more specifically in the case of distribution of samples free of charge, pharmaceutical companies are not allowed to distribute free samples of prescription-only medicinal products to pharmacists.

New rules regarding the yearly visa applicable to environmental authorizations and integrated environmental authorizations

On **July 11, 2020** enters into force the Order of the ministry of environment, water and forests No. 1150/2020, which approves the new Procedure for applying the yearly visa to environmental authorizations and integrated environmental authorizations ("**the Procedure**").

The Procedure sets the rules applicable for applying for and obtaining the yearly visa (competences, time limits, documentation, steps to be followed and transitional provisions) and, extremely relevant, sets the measures which can be applied in case of non-conformity with the requirements of the Procedure, measures which can generate extremely harsh consequences for legal entities.

As a rule, the titleholder of the (integrated) environmental authorization has the obligation to apply for the annual visa within a time limit of maximum 90 days and minimum 60 days before the day and month corresponding to the day and month of issuance of the authorization held. Certain transitional provisions apply. The application for the visa must include:

- a standard application form based on the model available in Annex No. 1 to the Procedure;
- the annual environmental report and/ or reports mentioned in the authorization for which the annual visa is applied, as the case;
- the sworn declaration regarding the absence of relevant changes as compared to the conditions established through the existing authorization;
- proof of payment of the application assessment fee.

The Procedure is excessively strict for the cases when the minimum visa application deadline is not met, imposing the suspension of the authorization, starting with the day and month of issuance, for a period equal to the time of delay in the application for the annual visa. Operating during the period of suspension of the (integrated) environmental authorization is forbidden and, under certain circumstances, can be sanctioned even under criminal law. Moreover, the public authority for environmental protection (NEPA or the county EPA) has the obligation to notify the National Environmental Guard with regard to the delay in the application for the visa.

Considering the very strict provisions of the Procedure and the substantially negative consequences which can materialize in the case of failure to meet them, we recommend a strict monitoring of the compliance with the provisions of the (integrated) environmental authorizations as well as of the deadlines for applying for the yearly visa.

For further questions regarding the aspects mentioned in this alert, please contact us.

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CJEU clarifies the rules applicable to the distribution of samples free of charge to persons qualified to prescribe or supply them

According to the Decision, the Court construes necessary that the provisions regulating marketing activities of medicinal products, more specifically the distribution of samples free of charge, which are stipulated under Directive 2001/83/EC of the European Parliament and of the Council of November 6, 2001 on the establishment of a Community code relating to medicinal products for human use (the „**Community Code**") and by the harmonising norms adopted by each Member State, to be interpreted based on the following clarifications:

- The definition of „*qualified professionals*" as defined by the Community Code as well as by the harmonising norms, respectively Law no. 95/2006 on the public health reform („**Law 95/2006**") and the Order of the Ministry of Health no. 194/2015 on the Norms for assessment and approval of the advertising made to medicinal products of human use („MH **Order 194/2015**"), refers to both physicians and dental physicians, as well as to pharmacists and medical and pharmacy assistants.

- This notion is used to regulate the advertising actions that pharmaceutical companies can take to promote medicinal products for human use, including the provision of free samples.

- In the case of the provision of free samples, the legislation of the Member States and the Community Code does not make a clear distinction according to the legal regime applicable to the medicinal product, i.e. (i) prescription-only medicinal products (RX) and (ii) non-prescription medicinal products (OTC).

  This aspect would determine an interpretation according to which the activity of providing samples can be carried out by pharmaceutical companies without restriction to both physicians and pharmacists, under the same conditions.

- In this context, the Court has established the following rules:
  - In the case of RXs, the provision of free samples may be made solely to persons holding the power to prescribe a medical prescription, respectively physicians;
  - In the case of OTCs, the provision of free samples may be performed both to physicians as well as pharmacists.

- At national level, it is important to note that both Law 95/2006 as well as MH Order 194/2015 set out that the offering of free samples is made solely to persons qualified to prescribe or to distribute such products, within the provisions of the law. Given the manner in which the provision is regulated, the article refers to both physicians and to pharmacists.

  However, the conditions stipulated by Law 95/2006 are more restrictive than the Community Code (option that is given to Member States), in the sense that for the provision of free samples by pharmaceutical companies, the written request, dated and signed by a physician is required. Indirectly, it may be construed that there is a verification performed by a person qualified to prescribe a medicine both an RX as well as an OTC.

- The interpretation of the Court is mandatory to Member States.

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