

# Tax & Legal Weekly Alert

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### **New Methodology for the calculation of the maximum price for medicine for human use**

The Romanian Government has approved a new Methodology regarding the calculation method and the approval procedure of the maximum prices for medicine destined for human use with marketing authorization in Romania.

The new regulation repeals the Norms regarding the manner of calculating the prices for medicines for human use, approved through Order of the Ministry of Health no. 75/2009. The main modification include the introduction of an annual correction procedure for the prices of prescription medicine (Rx).

### **New mechanism for preventing conflict of interest**

Law 184/2016 on the establishment of a mechanism for preventing conflict of interest within the procedures for awarding public procurement contracts will enter into force starting with 20 June 2017.

### **The dismissal decision on reasons other than disciplinary will be considered valid communicated to the employee by email, the High Court of Cassation and Justice ruled**

According to a statement published on the Supreme Court's website on October 24, 2016, the High Court of Cassation and Justice (the Panel for ruling on legal matters) has ruled that individual dismissal decisions issued in accordance with Article 76 of the Labor Code can be communicated via e-mail.



## New Methodology for the calculation of the maximum price for medicine for human use

On October 26, the Romanian Government approved a Decision regarding the approval of the Methodology regarding the calculation method and the approval procedure of the maximum prices for medicine destined for human use having marketing authorization in Romania (the "**Methodology**").

According to the project of the Methodology published on the website of the Ministry of Health, the main new points introduced by the Methodology include:

- The introduction of new criteria for the approval of the maximum price for medicines. Thus, according to one such new criteria applicable for generic medicines that meet the following two cumulative conditions:
  - they have an international common name included on the list of essential medicines recommended by the International Health Organization; and
  - have an international common name included on the list of medicines with a compensation percentage of 100% from the reference price, if not found on other compensation lists,

the proposed price shall be the smallest prices between the prices approved through CANAMED and the average of the smallest 3 prices for the same medicine, practiced in the countries included in the comparison list.

For the rest of prescription medicine the price calculation procedure remains unchanged, being based on the lowest European price from a basket of 12 countries.

- Introducing of new threshold that must be observed when the increase of the medicines prices approved in CANAMED is requested, respectively:
  - the increased price must not exceed the average of the smallest 3 prices for the same medicine, practiced in the countries included in the comparison list; and
  - the increased price must not exceed, under any circumstance, the price approved in CANAMED for the innovative medicine of which generic is the medicine for which the price increase is requested.
- As opposed to the previous regulation, which included few references to annual reanalysis of the prices for authorized medicines, the Methodology provides a detailed annual correction procedure for medicines prices. In this manner, it is envisaged a constant alignment to the level of the minimum price from the compared countries, and also economies to the state budget.

According to the information available on the Romanian Government's website, the prices calculated according to the Norms regarding the manner of calculating the prices for medicines for human use, approved through Order of the Ministry of Health no. 75/2009 shall remain valid until the implementation of the price correction procedure according to the Methodology. In principle, the prices' prolongation may not exceed a period of 120 days from the date of entry into force of the Methodology.

For the purpose of implementing the correction procedure, the owners of marketing authorizations have the obligation to submit the files for the new prices within 30 days from the date on which the Methodology is approved. The price correction process shall be finalized on March 1, 2017 and the new medicine process shall enter in to force on April 1, 2017.

For further questions regarding the aspects mentioned in this alert,  
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## **Law no.184/2016 on the establishment of a mechanism for preventing conflict of interest within the procedures for awarding public procurement contracts, will enter into force starting with 20 June 2017**

On 20 October 2016, Law no.184/2016 on the establishment of a mechanism for preventing conflict of interest within the procedures for awarding public procurement contracts was published in the Official Gazette of Romania.

The Law will enter into force within eight months from its publication in the Official Gazette of Romania. The law aims to prevent conflict of interest within the procedures for awarding public procurement contracts that are initiated through the Electronic Public Procurement System. ("SEAP")

The regulation will apply to public procurement procedures regulated by Law no.98/2016 on public procurement as well as to the sectorial procurement procedures regulated by Law no.99/2016.

To safeguard public procurement procedures from any conflict of interest, the National Integrity Agency will employ an ex-ante control mechanism ensuring that public procurement procedures are not affected.

In order to prevent conflict of interest within the public procurement procedures, the law implements the following measures:

1. Establishment of a computer system within the National Integrity Agency, called the "Prevention System";
2. Introduction of an Integrity Form within the documentation for public procurement;
3. Contracting Authorities will be required to supplement and update the Integrity Form from the publication of the award documentation in SEAP and until the publication of the award notice;
4. Integrity Forms will be verified through the Prevention System and by the National Agency for Integrity inspectors;
5. In case the Prevention System or the integrity inspectors detect any potential conflict of interest, an integrity warning will be submitted through SEAP to the contracting authorities, the National Integrity Agency and to the authorities in charge of verification, control and monitoring of the public procurement procedures;
6. The management of the contracting authorities receiving integrity warnings will take all the necessary measures to avoid any conflict of interest. If such measures are not adopted, relevant provisions of Law no.176/2010 on integrity in the exercising of public functions and offices will apply.

Law no.184/2016 will exclusively apply to those procedures for awarding public procurement contracts that are initiated after its entry into force, namely after 20 June 2017.

For further questions regarding the aspects mentioned in this alert,  
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## The dismissal decision on reasons other than disciplinary will be considered validly communicated to the employee by email, the High Court of Cassation and Justice ruled

Starting with the publication of the Decision No. 34/2016 of the High Court of Cassation and Justice in the Official Gazette, individual dismissal decisions issued in accordance with Article 76 of the Labour Code can be communicated via e-mail; the time period within which an employee can appeal this decision in court starts once the decision is communicated via email.

### Implications of Decision no. 34/2016 of the High Court of Cassation and Justice

Starting with the publication of the Decision No. 34/2016 in the Official Gazette, employers will be able to communicate the dismissal decisions to the employees (excluding dismissal decisions on disciplinary grounds) via email, if the following conditions are met:

- Employees have notified the employer of the necessary contact details, i.e. e-mail address;
- There has been a practice between employees and their employers with regard to communication via e-mail.

In this case, the dismissal decision communicated by e-mail in PDF format, electronically accessible, must comply with the requirements under Article 76 of the Labor Code, but not those of Law no. 455/2001 on Electronic Signature.

The deadline for appealing the dismissal decision starts once the decision is communicated via e-mail to the employee.

The Decision of the High Court of Cassation and Justice shall have a major impact in practice, making the employer's burden on communicating the dismissal decision to employees significantly easier. The Decision is welcomed, especially in the context where practice has revealed a true challenge in communicating the dismissal decisions to employees.

The Decision will become binding following its publication in the Official Gazette.

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