

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 new Proposal for a Council Directive on a Common Corporate Tax Base intends to “attribute income to where the value is created”

The draft proposal of the Common Corporate Tax Base Directive was released on October 25.

Its objectives are to attenuate the distortions resulting from the current interaction of 28 national tax regimes and create more favorable conditions for cross-border investment in the single market that would be better achieved at Union level through a mandatory single set of corporate taxation rules.

Law 186/2016 regarding certain measures for some categories of individuals to enroll in the public insurance pension system has been adopted

Based on this law, individuals who are not retired can pay pension contributions for the period during which they were not insured within the public pension system or within a non-integrated pension insurance system.

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.

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The new Proposal for a Council Directive on a Common Corporate Tax Base intends to “attribute income to where the value is created”

The re-launched Directive brings some new key features to the 2011 CCCTB Directive:

- **Mandatory applicability for large multinationals**
- **Step by step approach:** consolidation is postponed, the current focus being to create the conditions for a smooth common corporate tax framework within the EU.

The two-step approach consists of the following:

- **Step One (Common Corporate Tax Base - CCTB):** Large multinational groups with global sales of at least EUR 750 million would be subject to a single set of rules to calculate their taxable profits in the EU.
- **Step Two (Common Consolidated Corporate Tax Base - CCCTB):** The CCCTB would introduce rules for consolidation, formulary apportionment and a “one-stop shop” for tax administration. Losses in one EU member state would be available for offset against profits in another member state.

To whom do the Directive’s provisions apply?

- To companies established in the EU, including their permanent establishments within the Member States, to third party country companies in respect to their permanent establishments in the EU, provided that certain conditions are met (e.g. group revenues exceeding EUR 750 mil., companies subject to corporate tax/similar tax etc.).

How will the tax treatment change?

- The Directive acts as a tool for attributing income to where the value is created, based on three equally weighted factors (i.e. assets, labour, and sales).
- From a corporate income tax perspective, the Directive proposes certain specific rules, such as: super deduction for R&D costs, an allowance for growth and investment, deductibility conditions for interest expenses, anti-avoidance measures, temporary loss relief with respect to losses incurred by an immediate subsidiary etc.
- Member States will continue to decide their own corporate tax rates.

When will the Directive become effective?

- At present moment, the proposal for a CCTB is still pending for Examination in Council until political agreement is reached.
- If unanimous approval by the Member States is obtained, the CCTB Directive would have to be implemented in the Member States legislation by 31 December 2018. The second step, involving the consolidation provisions (CCCTB) would have to be implemented in legislation by 31 December 2020.

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The law introduces changes for individuals who can contribute to the public pension system

For whom are the law's provisions applicable?

Law 186/2016 is applicable for those individuals who are not retired and want to complete their period of contributions to the public pension system for the previous periods when they did not qualify as insured individuals.

The periods for which individuals can pay pensions contribution are those prior to the date when standard retirement age conditions are met, as mentioned by the law, and represent the time between the signing date of the contract and the last five years prior to concluding the respective contract.

Insurance and payment rules

To benefit from the law's provisions, within 6 months from the law's entry into force (until 26 April 2017) any interested individual can conclude a social insurance contract with the Pension House from the jurisdiction of their domicile/residence, according to the model included in the appendix of the current law.

The social insurance contribution due will be computed by applying the quota of the social insurance contribution used for normal work conditions to the monthly taxable base. The monthly taxable base will be at least equivalent to the minimum gross national salary and it should not exceed the value of five average gross national salaries used for fundamenting the budget of the state social insurance.

Social contributions can be paid in a single trance, based on instalments, on a monthly basis, or six months from the law's entry into force.

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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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