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National Agency for Medicines and Medical Devices

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REGULATION (EU) No 658/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use (Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and point (c) of Article 168(4) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) The revenue of the European Medicines Agency (the 'Agency') consists of a contribution from the Union and fees paid by undertakings for obtaining and maintaining Union marketing authorisations and for other services as referred to in Article 67(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council ([3]).

(2) The provisions on pharmacovigilance relating to medicinal products for human use ('medicinal products') laid down in Regulation (EC) No 726/2004 and in Directive 2001/83/EC of the European Parliament and of the Council ([4])were amended by Directive 2010/84/EU of the European Parliament and of the Council ([5]), Regulation (EU) No 1235/2010 of the European Parliament and of the Council ([6]), Directive 2012/26/EU of the European Parliament and of the Council ([7]) and Regulation (EU) No 1027/2012 of the European Parliament and of the Council ([8]). Those amendments provide for new pharmacovigilance tasks for the Agency, including pharmacovigilance procedures carried out at Union level, the monitoring of

([1]) JO C 67, 6.3.2014, p. 92.
([2]) Position of the European Parliament of 16 April 2014 (not yet published in the Official Journal) and decision of the Council of 8 May 2014.
([3]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).
([4]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).
([5]) Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 348, 31.12.2010, p. 74).
([6]) Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products (OJ L 348, 31.12.2010, p. 1).
([7]) Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ L 299, 27.10.2012, p. 1).
([8]) Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance (OJ L 316, 14.11.2012, p. 38).

literature cases and the improved use of information technology tools. Furthermore, those amendments provide that the Agency should be enabled to fund those activities from fees charged to marketing authorisation holders. New types of fees should therefore be created to cover the new and specific tasks of the Agency.

(3) In order to enable the Agency to charge fees for those new pharmacovigilance tasks, and pending an overall legislative revision of the fees regimes in the medicinal products sector, this Regulation should be adopted. The fees provided for in this Regulation should be applicable without prejudice to the fees laid down in Council Regulation (EC) No 297/95 ([1]).

(4) This Regulation should be based on the dual legal basis of Article 114 and point (c) of Article 168(4) of the Treaty on the Functioning of the European Union (TFEU). It is aimed at financing pharmacovigilance activities that contribute to achieving an internal market as regards medicinal products, taking as a basis a high level of protection of health. At the same time, this Regulation aims to ensure financial resources to support the activities addressing common safety concerns, in order to maintain high standards of quality, safety and efficacy of medicinal products. Both objectives are pursued simultaneously and are inseparably linked, so that one is not secondary to the other.

(5) The structure and amounts of the fees for pharmacovigilance collected by the Agency, as well as the rules for their payment, should be established. The structure of the fees should be as simple as possible to apply in order to minimise the related administrative burden.

(6) In line with the Joint Statement of the European Parliament, the Council of the EU and the European Commission of 19 July 2012 on decentralised agencies, for bodies for which the revenue is constituted by fees and charges in addition to the Union contribution, fees should be set at a level that avoids a deficit or a significant accumulation of surplus, and should be revised when this is not the case. Therefore, the fees set out in this Regulation should be based on an evaluation of the Agency's estimations and forecasts as regards its workload and related costs, and on the basis of an evaluation of the costs of the work carried out by the national competent authorities of the Member States which act as rapporteurs and, where applicable, co-rapporteurs in accordance with Articles 61(6) and 62(1) of Regulation (EC) No 726/2004 and Articles 107e, 107j and 107q of Directive 2001/83/EC.

(7) The fees established in this Regulation should be transparent, fair and proportionate to the work carried out. Information on those fees should be publicly available. Any future revisions of the pharmacovigilance fees or other fees levied by the Agency should be based on a transparent and independent evaluation of the costs of the Agency and the costs of the tasks carried out by the national competent authorities.

(8) This Regulation should only regulate fees which are to be levied by the Agency, whereas the competence to decide on possible fees levied by the national competent authorities should remain with the Member States, including in relation to signal detection tasks. Marketing authorisation holders should not be charged twice for the same pharmacovigilance activity. Member States should therefore not levy fees for the activities which are covered by this Regulation.

(9) For reasons of predictability and clarity, the amounts of the fees should be provided in euro.

(10) Two different types of fees should be levied under this Regulation in order to take account of the diversity of the tasks of the Agency and of the rapporteurs and, where applicable, co-rapporteurs. First, fees for the pharmacovigilance procedures carried out at Union level should be charged to those marketing authorisation holders whose medicinal products are part of the procedure. Those procedures relate to the assessment of periodic safety update reports, the assessment of post-authorisation safety studies and assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data. Second, an annual fee should be charged for other pharmacovigilance activities carried out by the Agency that benefit marketing authorisation holders overall. Those activities relate to information technology, in particular maintenance of the EudraVigilance database referred to in Article 24 of Regulation (EC) No 726/2004, and the monitoring of selected medical literature.

(11) Marketing authorisation holders for medicinal products authorised under Regulation (EC) No 726/2004 already pay an annual fee to the Agency for the maintenance of their authorisations, which includes

([1]) Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 35, 15.2.1995, p. 1).

pharmacovigilance activities that are covered by the annual fee established by this Regulation. In order to avoid double charging for those pharmacovigilance activities of the Agency, the annual fee established by this Regulation should not be charged for marketing authorisations granted under Regulation (EC) No 726/2004.

(12) The work carried out at Union level in respect of the assessment of non-interventional post-authorisation safety studies imposed by the Agency or the national competent authority to be conducted in more than one Member State and of which the protocol has to be endorsed by the Pharmacovigilance Risk Assessment Committee, involves the supervision of those studies, including the assessment of the draft protocol and the assessment of the final study reports. Therefore, the fee levied for that procedure should cover all the work relating to the study. As the legislation on pharmacovigilance encourages the conduct of joint post-authorisation safety studies, marketing authorisation holders should share the applicable fee in cases where a joint study is submitted. In order to avoid double charging, marketing authorisation holders who are charged the fee for the assessment of such post-authorisation safety studies should be exempted from any other fee charged by the Agency or a national competent authority for the submission of those studies.

(13) For their assessments, rapporteurs rely on the scientific evaluations and resources of national competent authorities, while it is the responsibility of the Agency to coordinate the existing scientific resources put at its disposal by the Member States. For that, and to ensure the existence of adequate resources for the scientific assessments relating to the pharmacovigilance procedures carried out at Union level, the Agency should remunerate the scientific assessment services provided by the rapporteurs and, where applicable, co-rapporteurs appointed by Member States as members of the Pharmacovigilance Risk Assessment Committee referred to in point (aa) of Article 56(1) of Regulation (EC) No 726/2004 or, where relevant, provided by rapporteurs and co-rapporteurs in the coordination group referred to in Article 27 of Directive 2001/83/EC. The amount of remuneration for the services provided by those rapporteurs and co-rapporteurs should be based exclusively on estimations of the workload involved and should be taken into account in setting the level of the fees for pharmacovigilance procedures carried out at Union level. It is recalled that as a matter of good practice, in the context of referrals initiated as a result of the evaluation of pharmacovigilance data, the Pharmacovigilance Risk Assessment Committee generally seeks to avoid appointing as rapporteur the member nominated by the Member State that initiated the referral procedure.

(14) Fees should be levied on all marketing authorisation holders on a fair basis. Therefore, a chargeable unit should be established, irrespective of the procedure under which the medicinal product has been authorised, either under Regulation (EC) No 726/2004 or under Directive 2001/83/EC, and of the way in which authorisation numbers are assigned by the Member States or the Commission. That objective is met by establishing the chargeable unit on the basis of the active substance(s) and the pharmaceutical form of the medicinal products that are subject to the obligation to be registered in the database referred to in point (l) of the second subparagraph of Article 57(1) of Regulation (EC) No 726/2004, based on information from the list of all medicinal products authorised in the Union referred to in Article 57(2) thereof. The active substance(s) should not be taken into account when establishing the chargeable unit in respect of authorised homeopathic medicinal products or authorised herbal medicinal products.

(15) In order to take into account the scope of the marketing authorisations of medicinal products granted to marketing authorisation holders, the number of chargeable units corresponding to those authorisations should take into account the number of Member States in which the marketing authorisation is valid.

(16) In line with the policy of the Union to support small and medium-sized enterprises, reduced fees should apply to small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC ([1]). Such fees should be established on a basis which takes due account of the ability of small and medium-sized enterprises to pay. Consistent with that policy, micro enterprises within the meaning of that Recommendation should be exempted from all fees under this Regulation.

(17) Generic medicinal products, medicinal products authorised under the provisions relating to well-established medicinal use, authorised homeopathic medicinal products and authorised herbal medicinal products should be subject to a reduced annual fee, as those medicinal products generally have a well-established safety profile. However, in cases where those medicinal products are part of any of the pharmacovigilance procedures carried out at Union level, the full fee should be charged for the work involved.

([1]) Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

(18) Homeopathic and herbal medicinal products registered in accordance with, respectively, Article 14 and Article 16a of Directive 2001/83/EC should be excluded from the scope of this Regulation as the pharmacovigilance activities for those medicinal products are carried out by the Member States. Medicinal products which are authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC should also be excluded from the scope of this Regulation.

(19) In order to avoid a disproportionate administrative workload for the Agency, the fee reductions and the fee exemption provided for in this Regulation should be applied on the basis of a declaration of the marketing authorisation holder claiming to be entitled to such a fee reduction or exemption. The submission of incorrect information should be discouraged by means of the application of an increase in the amount of the applicable fee in such circumstances.

(20) For reasons of consistency, deadlines for the payment of fees levied under this Regulation should be established, taking due account of the deadlines of the procedures relating to pharmacovigilance provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC.

(21) The amounts of the fees and of the remuneration for the rapporteurs and co-rapporteurs provided for under this Regulation should be adjusted, where appropriate, to take account of inflation. For that purpose, the European Index of Consumer Prices published by Eurostat pursuant to Council Regulation (EC) No 2494/95 (1) should be used. For the purpose of such an adjustment, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(22) Since the objective of this Regulation, namely to ensure adequate funding of pharmacovigilance activities carried out at Union level, cannot sufficiently be achieved by the Member States but can rather, by reason of the scale of the measure, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(23) For reasons of predictability, legal certainty and proportionality, the annual fee for the information technology systems and literature monitoring should be levied for the first time on 1 July 2015,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

(1) This Regulation shall apply to fees for pharmacovigilance activities relating to medicinal products for human use (‘medicinal products’) authorised in the Union under Regulation (EC) No 726/2004 and Directive 2001/83/EC which shall be levied by the European Medicines Agency (the ‘Agency’) on marketing authorisation holders.

(2) Homeopathic and herbal medicinal products registered in accordance with, respectively, Article 14 and Article 16a of Directive 2001/83/EC, and medicinal products which are authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC, shall be excluded from the scope of this Regulation.

(3) This Regulation establishes the pharmacovigilance activities performed at Union level for which fees are due, the amounts and the rules of payment of those fees to the Agency, and the amounts of remuneration by the Agency for the services provided by the rapporteurs and, where applicable, the co-rapporteurs.

(4) Micro enterprises shall be exempted from the payment of any fee under this Regulation.

(5) The fees laid down in this Regulation shall apply without prejudice to the fees laid down in Regulation (EC) No 297/95.

Article 2

Definitions
For the purposes of this Regulation, the following definitions apply:

1. 'chargeable unit' means a unit defined by a unique combination of the following dataset derived from information on all medicinal products authorised in the Union held by the Agency, and consistent with the obligation of marketing authorisation holders referred to in points (b) and (c) of Article 57(2) of Regulation (EC) No 726/2004 to submit such information to the database referred to in point (l) of the second subparagraph of Article 57(1) of that Regulation:

(a) name of the medicinal product, as defined in point 20 of Article 1 of Directive 2001/83/EC;

(b) marketing authorisation holder;

(c) the Member State in which the marketing authorisation is valid;

(d) active substance or a combination of active substances; and

(e) pharmaceutical form.

Point (d) of the first subparagraph is not applicable in the case of authorised homeopathic medicinal products or authorised herbal medicinal products, as defined, respectively, in points 5 and 30 of Article 1 of Directive 2001/83/EC;

2. 'medium-sized enterprise' means a medium-sized enterprise within the meaning of Recommendation 2003/361/EC;

3. 'small enterprise' means a small enterprise within the meaning of Recommendation 2003/361/EC;

4. 'micro enterprise' means a micro enterprise within the meaning of Recommendation 2003/361/EC.

Article 3

Types of fees
(1) The fees for pharmacovigilance activities shall consist of the following:

(a) fees for procedures carried out at Union level as provided for in Articles 4, 5 and 6;

(b) an annual fee as provided for in Article 7.

(2) Where a fee is levied by the Agency in accordance with point (a) of paragraph 1 of this Article, the Agency shall pay remuneration, in accordance with Article 9, to the national competent authorities:

(a) for the services provided by the rapporteurs and, where applicable, the co-rapporteurs in the Pharmacovigilance Risk Assessment Committee appointed as members of that Committee by Member States;

(b) for the work carried out by the Member States which act as the rapporteurs and, where applicable, co-rapporteurs in the coordination group.

Article 4

Fee for assessment of periodic safety update reports
(1) The Agency shall levy a fee for the assessment of periodic safety update reports referred to in Articles 107e and 107g of Directive 2001/83/EC and in Article 28 of Regulation (EC) No 726/2004.

(2) The amount of the fee and the corresponding amount of remuneration of the national competent authority in accordance with Article 3(2) are laid down in point 1 of Part I of the Annex.

(3) Where only one marketing authorisation holder is subject to the obligation to submit a periodic safety update report in the context of the procedures referred to in paragraph 1, the Agency shall levy the total amount of the applicable fee on that marketing authorisation holder.

(4) Where two or more marketing authorisation holders are subject to the obligation to submit periodic safety update reports in the context of the procedures referred to in paragraph 1, the Agency shall divide the total amount of the fee among those marketing authorisation holders in accordance with point 2 of Part I of the Annex.

(5) Where the marketing authorisation holder referred to in paragraphs 3 and 4 is a small or medium-sized enterprise, the amount payable by the marketing authorisation holder shall be reduced as laid down in point 3 of Part I of the Annex.

(6) The Agency shall levy the fee under this Article by issuing an invoice to each marketing authorisation holder concerned. The fee shall be due at the date of the start of the procedure for the assessment of the periodic safety update report. Fees due under this Article shall be paid to the Agency within 30 calendar days from the date of the invoice.

Article 5

Fee for assessment of post-authorisation safety studies

(1) The Agency shall levy a fee for the assessment carried out under Articles 107n to 107q of Directive 2001/83/EC and Article 28b of Regulation (EC) No 726/2004 of post-authorisation safety studies referred to in point (b) of Article 21a and point (a) of Article 22a(1) of Directive 2001/83/EC, and in point (cb) of Article 9(4) and point (a) of Article 10a(1) of Regulation (EC) No 726/2004 that are conducted in more than one Member State.

(2) The amount of the fee and the corresponding amount of remuneration of the national competent authority in accordance with Article 3(2) are laid down in point 1 of Part II of the Annex.

(3) Where the obligation to conduct a post-authorisation safety study is imposed on more than one marketing authorisation holder, the same concerns apply to more than one medicinal product and the marketing authorisation holders concerned conduct a joint post-authorisation safety study, the amount payable by each marketing authorisation holder shall be levied as laid down in point 2 of Part II of the Annex.

(4) Where the obligation to conduct a post-authorisation safety study is imposed on a marketing authorisation holder which is a small or medium-sized enterprise, the amount payable by the marketing authorisation holder shall be reduced as laid down in point 3 of Part II of the Annex.

(5) The Agency shall levy the fee by issuing two invoices to each marketing authorisation holder concerned, one for the assessment of the draft protocol and one for the assessment of the final study report. The relevant part of the fee shall be due at the start of the procedure for the assessment of the draft protocol and at the start of the procedure for the assessment of the final study report, and shall be paid to the Agency within 30 calendar days from the date of the respective invoice.

(6) Marketing authorisation holders who are charged the fee under this Article shall be exempted from the payment of any other fee charged by the Agency or a national competent authority for the submission of the studies referred to in paragraph 1.

Article 6

Fee for assessments in the context of referrals initiated as a result of the evaluation of pharmacovigilance data

(1) The Agency shall levy a fee for the assessment carried out in the context of a procedure initiated as a result of the evaluation of pharmacovigilance data under the second subparagraph of Article 31(1), Article 31(2) and Articles 107i to 107k of Directive 2001/83/EC or under Article 20(8) of Regulation (EC) No 726/2004.

(2) The amount of the fee and the corresponding amount of remuneration of the national competent authority in accordance with Article 3(2) are laid down in point 1 of Part III of the Annex.

(3) Where only one marketing authorisation holder is involved in the procedure referred to in paragraph 1 of this Article, the Agency shall levy the total amount of the fee on that marketing authorisation holder, as laid down in point 1 of Part III of the Annex, except in the cases specified in paragraph 5 of this Article.

(4) Where two or more marketing authorisation holders are involved in the procedure referred to in paragraph 1 of this Article, the Agency shall divide the total amount of the fee among those marketing authorisation holders in accordance with point 2 of Part III of the Annex.

(5) Where the procedure referred to in paragraph 1 of this Article involves one substance or one combination of substances and one marketing authorisation holder, the Agency shall levy a reduced amount of the fee on that marketing authorisation holder and shall remunerate the national competent authority for the services provided by the rapporteur or the co-rapporteur as laid down in point 3 of Part III of the Annex. Where that marketing authorisation holder is a small or medium-sized enterprise, the amount payable shall be reduced as laid down in point 3 of Part III of the Annex.

(6) Where the marketing authorisation holder referred to in paragraphs 3 and 4 of this Article is a small or medium-sized enterprise, the amount payable by that marketing authorisation holder shall be reduced as laid down in point 4 of Part III of the Annex.

(7) The Agency shall levy the fee by issuing a separate invoice to each marketing authorisation holder involved in the procedure. The fee shall be due at the date of the start of the procedure. Fees due under this Article shall be paid to the Agency within 30 calendar days from the date of the invoice.

Article 7

Annual fee for information technology systems and literature monitoring

(1) For its pharmacovigilance activities relating to information technology systems under Article 24, Article 25a, Article 26, point (l) of the second subparagraph of Article 57(1) and Article 57(2) of Regulation (EC) No 726/2004 and the monitoring of selected medical literature under Article 27 thereof, the Agency shall levy once per year a fee as laid down in point 1 of Part IV of the Annex (the 'annual fee').

(2) The annual fee shall be levied on holders of marketing authorisations for all medicinal products authorised in the Union in accordance with Directive 2001/83/EC, on the basis of the chargeable units corresponding to those medicinal products. Chargeable units corresponding to medicinal products authorised in accordance with Regulation (EC) No 726/2004 shall not be subject to the annual fee.
The total payable amount of the annual fee for each marketing authorisation holder shall be calculated by the Agency on the basis of the chargeable units which correspond to the information recorded on 1 July of each year. That amount shall cover the period from 1 January to 31 December of the year concerned.

(3) Where the marketing authorisation holder is a small or medium-sized enterprise, the amount of the annual fee payable by that marketing authorisation holder shall be reduced as laid down in point 2 of Part IV of the Annex.

(4) An annual fee which has been reduced as laid down in point 3 of Part IV of the Annex shall apply in respect of medicinal products referred to in Article 10(1) and Article 10a of Directive 2001/83/EC, and in respect of authorised homeopathic medicinal products and authorised herbal medicinal products.

(5) Where the marketing authorisation holder of medicinal products referred to in paragraph 4 is a small or medium-sized enterprise, only the fee reduction set out in paragraph 3 shall apply.

(6) The annual fee shall be due on 1 July of every year in respect of that calendar year.
The fees due under this Article shall be paid within 30 calendar days from the date of the invoice.

(7) The Agency shall retain the fee revenue from the annual fee.

Article 8

Fee reductions and fee exemption

(1) Any marketing authorisation holder claiming to be a small or medium-sized enterprise entitled to a fee reduction under Article 4(5), Article 5(4), Article 6(5), Article 6(6) or Article 7(3), shall make a declaration to that effect to the Agency within 30 calendar days from the date of the invoice from the Agency. The Agency shall apply the fee reduction on the basis of that declaration.

(2) Any marketing authorisation holder claiming to be a micro enterprise entitled to the fee exemption under Article 1(4) shall make a declaration to that effect to the Agency within 30 calendar days from the date of the invoice from the Agency. The Agency shall apply the exemption on the basis of that declaration.

(3) Any marketing authorisation holder claiming to be entitled to a reduced annual fee under Article 7(4) shall make a declaration to that effect to the Agency. The Agency shall publish guidance on how that declaration is to be formulated by the marketing authorisation holder. The Agency shall apply the fee reduction on the basis of that declaration. Where the declaration is made by the marketing authorisation holder after the receipt of the invoice from the Agency, the declaration shall be made within 30 calendar days from the date of that invoice.

(4) The Agency may at any time request evidence that the conditions for a fee reduction or fee exemption are fulfilled. In such a case, the marketing authorisation holder claiming or having claimed to be entitled to a fee reduction or fee exemption under this Regulation shall submit to the Agency, within 30 calendar days from receipt of the Agency's request, the information necessary to enable the Agency to verify that those conditions are fulfilled.

(5) Where a marketing authorisation holder claiming or having claimed to be entitled to a fee reduction or fee exemption under this Regulation fails to demonstrate that it is entitled to such a reduction or exemption, the amount of the fee laid down in the Annex shall be increased by 10 % and the Agency shall levy the resulting full applicable amount or, as appropriate, the balance of the resulting full applicable amount.

Article 9

Payment of remuneration by the Agency to national competent authorities

(1) The Agency shall remunerate the national competent authorities for the services provided by rapporteurs and, where applicable, co-rapporteurs in accordance with Article 3(2) in the following cases:

(a) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur and, where applicable, co-rapporteur for the assessment of the periodic safety update reports referred to in Article 4;

(b) where the coordination group has appointed a Member State which acts as rapporteur and, where applicable, corapporteur in the context of the assessment of the periodic safety update reports referred to in Article 4;

(c) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur and, where applicable, co-rapporteur for the assessment of the post-authorisation safety studies referred to in Article 5;

(d) where the Member State has appointed a member of the Pharmacovigilance Risk Assessment Committee who acts as rapporteur and, where applicable, co-rapporteur for the referrals referred to in Article 6.

Where the Pharmacovigilance Risk Assessment Committee or the coordination group decides to appoint a co-rapporteur, the remuneration for the rapporteur and the co-rapporteur shall be determined in accordance with Parts I, II and III of the Annex.

(2) The corresponding amounts of the remuneration for each of the activities listed in the first subparagraph of paragraph 1 of this Article are laid down in Parts I, II and III of the Annex.

(3) The remuneration provided for in points (a), (b) and (d) of the first subparagraph of paragraph 1 shall be paid only after the final assessment report for a recommendation, which is intended for adoption by the Pharmacovigilance Risk Assessment Committee, has been made available to the Agency. The remuneration for the assessment of post-authorisation safety studies referred to in point (c) of the first subparagraph of paragraph 1 shall be paid in two instalments. The first instalment, relating to the assessment of the draft protocol, and the second instalment, relating to the assessment of the final study report, shall be paid after the respective final assessment reports have been submitted to the Pharmacovigilance Risk Assessment Committee.

(4) The remuneration for the services provided by the rapporteur and the co-rapporteur and any related scientific and technical support shall be without prejudice to the obligation of Member States to refrain from giving the members and experts of the Pharmacovigilance Risk Assessment Committee instructions incompatible with the individual tasks of those members and experts in their capacity as rapporteur or co-rapporteur, or incompatible with the tasks and responsibilities of the Agency.

(5) The remuneration shall be paid in accordance with the written contract referred to in the first subparagraph of Article 62(3) of Regulation (EC) No 726/2004. Any bank charges related to the payment of that remuneration shall be borne by the Agency.

Article 10

Method of payment of the fee

(1) The fees shall be paid in euro.

(2) Payment of the fees shall be made only after the marketing authorisation holder has received an invoice issued by the Agency.

(3) Payment of the fees shall be made by means of a transfer to the bank account of the Agency. Any bank charges related to that payment shall be borne by the marketing authorisation holder.

Article 11

Identification of the payment of the fee

In every payment the marketing authorisation holder shall indicate the invoice reference number. For payments made via the on-line payment system, the reference number shall be the number automatically generated by the Agency's invoicing system.

Article 12

Date of payment of the fee

The date on which the full amount of the payment is received in the bank account held by the Agency shall be considered to be the date on which the payment has been made. A deadline for payment shall be considered to have been complied with only if the full amount of the fee due has been paid in time.

Article 13

Refund of fee amounts paid in excess

Any amount paid in excess of a fee amount due shall be refunded by the Agency to the marketing authorisation holder, unless otherwise explicitly agreed with the marketing authorisation holder. However, where such an excess amount is less than EUR 100 and the marketing authorisation holder concerned has not expressly requested a refund, the excess amount shall not be refunded.

Article 14

Provisional estimate of Agency budget

The Agency shall, when producing an estimate of revenue and expenditure for the following financial year in accordance with Article 67(6) of Regulation (EC) No 726/2004, include detailed information on income from fees relating to pharmacovigilance activities. That information shall distinguish between the annual fee and the fees for each procedure referred to in point (a) of Article 3(1). The Agency shall also provide specific analytical information on its revenue and expenditure related to pharmacovigilance activities, allowing the annual fee and the fees for each procedure referred to in point (a) of Article 3(1) to be distinguished.

Article 15

Transparency and monitoring

(1) The amounts and rates laid down in Parts I to IV of the Annex shall be published on the website of the Agency.

(2) The Executive Director of the Agency shall provide, as part of the annual activity report delivered to the European Parliament, the Council, the Commission and the Court of Auditors, the information on the components that may have a bearing on the costs to be covered by the fees provided for in this Regulation. That information shall include a cost breakdown related to the previous year and a forecast for the following year. The Agency shall also publish an overview of that information in its annual report.

(3) The Executive Director of the Agency shall also provide the Commission and the Management Board once per year with the performance information set out in Part V of the Annex based on the performance indicators referred to in paragraph 4 of this Article.

(4) By 18 July 2015 the Agency shall adopt a set of performance indicators taking into account the information listed in Part V of the Annex.

(5) The inflation rate, measured by means of the European Index of Consumer prices published by Eurostat pursuant to Regulation (EC) No 2494/95, shall be monitored in relation to the amounts set out in the Annex. The monitoring shall take place for the first time after this Regulation has been applied during a full calendar year, and thereafter it shall take place annually.

(6) Where justified in light of the monitoring referred to in paragraph 5 of this Article, the Commission shall adopt delegated acts adjusting the amounts of the fees and the amounts of the remuneration for rapporteurs and co-rapporteurs referred to in Parts I to IV of the Annex. Where the delegated act enters

into force before 1 July, those adjustments shall take effect as from 1 July. Where the delegated act enters into force after 30 June, they shall take effect as from the date of entry into force of the delegated act.

Article 16

Exercise of the delegation

(1) The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

(2) The power to adopt delegated acts referred to in Article 15(6) shall be conferred on the Commission for a period of five years from 17 July 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

(3) The delegation of power referred to in Article 15(6) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

(4) As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

(5) A delegated act adopted pursuant to Article 15(6) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 17

Transitional provisions

The fees referred to in Articles 4, 5 and 6 shall not apply to those procedures carried out at Union level for which the assessment has started before 26 August 2014.

Article 18

Entry into force and application

(1) This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

(2) The annual fee referred to in Article 7 shall be levied as from 1 July 2015.
This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 May 2014.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	D. KOURKOULAS

ANNEX

PART I

FEE FOR ASSESSMENT OF PERIODIC SAFETY UPDATE REPORTS REFERRED TO IN ART. 4

1. The fee for the assessment of periodic safety update reports shall be EUR 19 500 per procedure. From that amount, the remuneration for the rapporteur shall be EUR 13 100. That remuneration shall be shared, where applicable, between the rapporteur and the co-rapporteur(s).
2. For the purpose of calculating the amount to be levied on each marketing authorisation holder in application of Article 4(4), the Agency shall calculate the proportion of chargeable units held by each marketing authorisation holder concerned of the total number of chargeable units held by all marketing authorisation holders involved in the procedure.

   The share payable by each marketing authorisation holder shall be calculated by:

   (a) dividing the total amount of the fee among the marketing authorisation holders concerned proportionately to the number of chargeable units; and

   (b) subsequently applying the fee reduction as set out in point 3 of this Part and the fee exemption referred to in Article 1(4), where relevant.

3. In application of Article 4(5), small and medium-sized enterprises shall pay 60 % of the applicable amount.

4. Where the fee reduction or the fee exemption applies, the remuneration for the rapporteur and, where applicable, corapporteur(s) shall also be adapted proportionally. Where the Agency subsequently collects the full applicable amount, including the 10 % increase as provided for in Article 8(5), the remuneration for the rapporteur and, where applicable, co-rapporteur(s) shall also be adapted proportionally.

PART II

FEE FOR ASSESSMENT OF A POSTAUTHORISATION SAFETY STUDIES REFERRED TO IN ART. 5

1. The fee for the assessment of each post-authorisation safety study shall be EUR 43 000 to be paid in two instalments as follows:

   (a) EUR 17 200 shall be due at the date of the start of the procedure for the assessment of the draft protocol referred to in Article 107n of Directive 2001/83/EC; from that amount, the remuneration for the rapporteur shall be EUR 7 280, and that remuneration shall be shared, where applicable, between the rapporteur and the co-rapporteur(s);

   (b) EUR 25 800 shall be due at the date of the start of the procedure for the assessment of the final study report by the Pharmacovigilance Risk Assessment Committee as referred to in Article 107p of Directive 2001/83/EC; from that amount, the remuneration for the rapporteur shall be EUR 10 920, and that remuneration shall be shared, where applicable, between the rapporteur and the co-rapporteur(s).

2. Where marketing authorisation holders conduct a joint post-authorisation safety study as referred to in Article 5(3), the amount payable by each marketing authorisation holder shall be levied by the Agency by evenly dividing the total amount of the fee among those marketing authorisation holders. Where relevant, the fee reduction laid down in point 3 of this Part or, where appropriate, the fee exemption referred to in Article 1(4), shall be applied to the share payable by the marketing authorisation holder.
3. In application of Article 5(4), small and medium-sized enterprises shall pay 60 % of the applicable amount.
4. Where the fee reduction or the fee exemption applies, the remuneration for the rapporteur and, where applicable, corapporteur(s) shall also be adapted proportionally. Where the Agency subsequently collects the full applicable amount, including the 10 % increase as provided for in Article 8(5), the remuneration for the rapporteur and, where applicable, co-rapporteur(s) shall also be adapted proportionally.

PART III

FEE FOR ASSESSMENT IN THE CONTEXT OF REFERRALS INITIATED AS A RESULT OF THE EVALUATION OF PHARMACOVIGILANCE DATA REFERRED TO IN ARTICLE 6

1. The fee for the assessment of the procedure referred to in Article 6(1) shall be EUR 179 000 where one or two active substances and/or combinations of active substances are included in the assessment. That fee shall be increased by EUR 38 800 per each additional active substance or combination of active substances as of the third active substance or combination of substances. That fee shall not exceed EUR 295 400 irrespective of the number of active substances and/or combinations of active substances. From the amount of the fee, the total amount of remuneration for the rapporteur and the co-rapporteur(s) shall be as follows:

   (a) EUR 119 333 where one or two active substances and/or combinations of active substances are included in the assessment;
   (b) EUR 145 200 where three active substances and/or combinations of active substances are included in the assessment;
   (c) EUR 171 066 where four active substances and/or combinations of active substances are included in the assessment;
   (d) EUR 196 933 where five or more active substances and/or combinations of active substances are included in the assessment.

   Where one or two active substances and/or combinations of active substances are included in the assessment, the Agency shall remunerate the national competent authorities for the services provided by the rapporteur and corapporteur(s) by dividing equally the total amount of the remuneration.
   Where three or more active substances and/or combinations of active substances are included in the assessment, the Agency shall remunerate the national competent authorities for the services provided by the rapporteur and corapporteur(s) by:

   (a) dividing the total amount of the remuneration equally between the national competent authorities; and

   (b) subsequently increasing the resulting amount of the remuneration for the rapporteur by EUR 1 000 where three substances and/or combinations of active substances are included, by EUR 2 000 where four substances and/or combinations of active substances are included and by EUR 3 000 where five or more active substances and/or combinations of active substances are included. That increase shall be paid from the parts of the fee attributed to the Agency and the co-rapporteur(s), each of which shall contribute the same amount.

2. For the purpose of calculating the amount to be levied on each marketing authorisation holder in application of Article 6(4), the Agency shall calculate the proportion of chargeable units held by each marketing authorisation holder concerned of the total number of chargeable units held by all marketing authorisation holders involved in the procedure.

   The amount payable by each marketing authorisation holder shall be calculated by:

   (a) dividing the total amount of the fee among the marketing authorisation holders proportionately to the number of chargeable units; and

   (b) subsequently applying the fee reduction laid down in point 4 of this Part and the fee exemption referred to in Article 1(4), where relevant.

   Where the fee reduction or the fee exemption applies, the remuneration for the rapporteur and co-rapporteur(s) shall also be adapted proportionally. Where the Agency subsequently collects the full applicable amount, including the 10 % increase as provided for in Article 8(5), the remuneration for the rapporteur and co-rapporteur(s) shall be adapted proportionally.

3. In application of Article 6(5), the amount payable by the marketing authorisation holder shall be two thirds of the applicable fee laid down in point 1 of this PARTICLE Small and medium-sized enterprises shall pay 60 % of that amount.
   The total amount of remuneration for the rapporteur and the co-rapporteur(s) from either of the reduced amounts of the fee referred to in the first subparagraph shall correspond to the same proportion as the total amount of remuneration for the rapporteur and the co-rapporteur(s) from the fee laid down in point 1 of this Part for assessments involving one or two active substances and/or combinations of active substances.

The Agency shall divide that amount equally between the national competent authorities for the services provided by the rapporteur and the co-rapporteur(s).

4. In application of Article 6(6), small and medium-sized enterprises shall pay 60 % of the applicable amount.

PART IV

ANNUAL FEE FOR INFORMATION TECHNOLOGY SYSTEMS AND LITERATURE MONITORING REFERRED TO IN ARTICLE 7

1. The annual fee shall be EUR 67 per chargeable unit.

2. In application of Article 7(3), small and medium-sized enterprises shall pay 60 % of the applicable amount.

3. Holders of marketing authorisations for medicinal products referred to in Article 7(4) shall pay 80 % of the amount applicable to the chargeable units corresponding to those medicinal products.

PART V

PERFORMANCE INFORMATION

The following information shall relate to each calendar year:

Number of Agency staff involved in pharmacovigilance activities pursuant to Union legal acts applicable during the reference period, specifying staff allocated to activities corresponding to each of the fees referred to in Articles 4 to 7.
Number of hours outsourced to third parties with specification of the activities concerned and cost incurred.
Overall pharmacovigilance costs and a breakdown of staff and non-staff costs relating to activities corresponding to each of the fees referred to in Articles 4 to 7.
Number of procedures relating to the assessment of periodic safety update reports, as well as number of marketing authorisation holders and number of chargeable units per procedure; number of reports submitted per procedure and number of marketing authorisation holders that have submitted a joint periodic safety update report.
Number of procedures relating to the assessment of draft protocols and of final reports of post-authorisation safety studies; number of marketing authorisation holders having submitted a draft protocol; number of marketing authorisation holders having submitted a final study report; number of marketing authorisation holders that have submitted a joint study.
Number of procedures relating to the referrals initiated as a result of the evaluation of pharmacovigilance data as well as number of marketing authorisation holders and number of chargeable units involved per marketing authorisation holder and per procedure.
Number of marketing authorisation holders that have claimed a small and medium-sized enterprise status involved in each procedure; number of marketing authorisation holders whose claim has been denied. Number of marketing authorisation holders that have claimed a micro enterprise status; number of marketing authorisation holders whose claim for fee exemption has been denied.
Number of marketing authorisation holders of medicinal products referred to in Article 7(4) that have benefitted from reduced annual fees; number of chargeable units per marketing authorisation holder concerned.
Number of invoices sent out and annual fees charged in respect of the annual fee and average and overall amount invoiced to marketing authorisation holders. Number of marketing authorisation holders that have claimed a small and medium-sized enterprise or a micro enterprise status for each application of the annual fee; number of marketing authorisation holders whose claim has been denied.
Attribution of rapporteurships and co-rapporteurships per Member State per type of procedure.
Number of working hours spent by the rapporteur and the co-rapporteur(s) per procedure on the basis of information provided to the Agency by the national competent authorities concerned.

ORDER no. 1018 of 3 September 2014
on approval of Conditions for authorisation of human medicinal products for compassionate use, in accordance with provisions of Article 83 of Regulation (EC) no. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

ISSUED: THE MINISTRY OF HEALTH

PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA NO. 663 of 9 September 2014

On seeing Approval Report no. NB. 7.069/2014 of the Medicinal Product and Medical Device Policy Directorate and Notification no. 51.568E of the National Agency for Medicines and Medical Devices of 24 July 2014, registered at the Ministry of Health with no. 45.390,

taking into account provisions of Article 4 (2) a) of Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

based on Article 7 (4) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as amended,

the minister of health hereby issues the following Order:

ARTICLE 1

The Conditions for authorisation of human medicinal products for compassionate use, in accordance with provisions of Article 83 of Regulation (EC) no. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency are approved, in accordance with the Annex, which is integral part of this Order.

ARTICLE 2

This Order is to be published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health,
Dorel Săndesc,
State Secretary

Bucharest, 3 September 2014.
No. 1.018.

ANNEX 1

CONDITIONS
for authorisation of human medicinal products for compassionate use, in accordance with provisions of Article 83 of Regulation (EC) no. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

ARTICLE 1

For the purposes of this Order, terms used shall have the following meaning:

a) competent authority for assessment and authorisation of human medicinal products for compassionate use – the National Agency for Medicines and Medical Devices (NAMMD);

b) medicinal products for compassionate use – medicinal products for human use not authorised for marketing in Romania or another Member State, meeting conditions mentioned in this Annex, made available, for humanitarian reasons, to a group of patients with invalidating, chronic, severe or life-threatening diseases, whose proper therapy is not feasible using authorised products;

c) group of patients whose proper therapy is not feasible - patients who do not respond to or relapse on available existing treatments, also ineligible for enrolment in ongoing clinical trials;

d) medicinal product authorised for marketing - medicinal product for human use granted a marketing authorisation in Romania, in accordance with the law;

e) conditions for use – recommendations for specialist physicians concerning the manner of administration and safe and effective use of the medicinal product. Such recommendations include relevant information about clinical, pharmacological and pharmaceutical properties of the medicinal product as well as on conditions for patient monitoring;

f) manufacturing company – the manufacturer or their legal representative in Romania.

ARTICLE 2

(1) The human medicinal product for which authorisation is sought for compassionate use must be either the object of an application for marketing authorisation through centralised procedure or be included in a clinical trial phase allowing for accumulation of sufficient evidence in support of its administration under conditions of efficacy and safety for the proposed use, in at least one Member State.

(2) The following categories of medicinal products may be subject to an application for authorisation for compassionate use:

a) medicinal products for human use manufactured through one of the following biotechnological procedures:

1. recombinant DNA technology;

2. controlled expression of gene coding for biologically active proteins in prokaryotes and eukaryotes, including mammalian cell transformation;

3. methods based on hybridomas and monoclonal antibodies;

b) medicinal products for human use containing a new active substance not yet authorised in the EU and whose therapeutic indication is a treatment for each of the following diseases:

1. acquired immunodeficiency syndrome;

2. cancer;

3. neurodegenerative diseases;

4. diabetes;

5. autoimmune diseases and other malfunctions of the immune system;

6. viral diseases;

c) medicinal product for human use designated as an orphan medicinal product in line with provisions of Regulation (EC) no. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products;

d) advanced therapy medicinal product.

ARTICLE 3

(1) The manufacturing company applies for authorisation for use of the medicinal product for compassionate use.

(2) the manufacturing company submits an application for authorisation at the NAMMD offices, accompanied by the following information and documents, in Romanian or English, as required:

1. name and address of the implementing specialist physician(s) who support the need for authorisation for use of the human medicinal product for compassionate use;

2. name or code of the medicinal product, name(s) of active substance(s) depending on type and quantity, other ingredients (excipients), pharmaceutical form, dose, manner of administration and treatment schedule;

3. A request submitted on the physician’s behalf, including:

a) patient identification data;

b) description of patients’ disease, leading to severe/serious disability or is life-threatening, for which compassionate use is intended;

c) reasons for which proper care may not be provided to patients with authorised medicinal product(s) and rationale for use of the medicinal product for compassionate use;

d) reasons for which patients cannot be enrolled in ongoing clinical trials, as required;

e) description of medical facilities and staff qualification to ensure proper administration and storage of the product in accordance with the information in the investigator’s brochure, as required;

f) agreement of the healthcare unit regarding implementation of compassionate use involving the medicinal product for which authorisation for use is sought;

4. proof including information substantiating the quality of the medicinal product to be administered, in accordance with pharmaceutical regulations in force, and qualified person's statement concerning medicinal product manufacturing in compliance with legislation in force, in relation but not limited to such issues as: medicinal product qualitative and quantitative composition, test bulletins, copy of the manufacturer's Good Manufacturing Practice (GMP) Certificate, batch release site, GMP certificates for the packaging site, storage conditions, packaging shape and size, shelf life;

5. approval of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency or another competent authority in a Member State, as required;

6. additional details on:

a) authorised clinical trials on the medicinal product within the concerned therapeutic field, with mention of the EudraCT number;

b) the current investigator's brochure made available for investigators involved in clinical trials or the proposed Summary of Product Characteristics (SmPC) draft included in the application for marketing authorisation;

c) information and documents to be handed to patients, in Romanian; description of the informed consent procedure, following training by the specialist physician providing care to the respective patient, the informed consent form;

d) information on storage conditions, storage and safe use.

(3) The NAMMD may require any other information deemed useful for authorisation of use of a human medicinal product for compassionate use.

(4) The NAMMD issues the authorisation for use of a medicinal product for compassionate use in no more than 60 days after submission of all documents and information provided for in this Article.

ARTICLE 4

The decision on a group of patients' (in)eligibility for compassionate use and that concerning the unsuitability of regular authorised medicinal products to ensure proper treatment lies with the specialist physician(s) in care of the respective patients.

ARTICLE 5

In the absence of CHMP approval, the NAMMD shall require a recommendation from the Specialist Commission of the Ministry of Health specialised in the therapeutic area of the product for which authorisation for compassionate use is sought, concerning its suitability for use.

ARTICLE 6

(1) The authorisation is valid for 6 months and may be renewed or changed, as required.

(2) The application for renewal of authorisation as per paragraph (1) shall be submitted 30 days prior to its expiry.

ARTICLE 7

The authorisation may be suspended or revoked when conditions for its grant are no longer met.

ARTICLE 8

The manufacturing company must comply with the following obligations:

a) to ensure funding of compassionate use, including costs of expertise for obtaining EMA approval, as required;

b) to ensure compliance with regulations in force of batch manufacturing, import and release;

c) to ensure that the secondary packaging contains at least the following information, in Romanian or a different language of international use (English or French):

1. name of active substance(s) (if established) or code of the medicinal product;

2. identification of the manufacturing batch;

3. manner of administration;

4. expiry date;

5. storage conditions;

d) not to advertise the medicinal product for human use authorised for compassionate use;

e) to keep specific records concerning administration of the medicinal product authorised for compassionate use;

f) to notify the NAMMD on beginning of the use of the medicinal product authorised for compassionate use;

g) to immediately inform the NAMMD on any safety or quality issues;

h) to ensure that the medicinal product authorised for compassionate use is solely used in Romania;

i) not to market the medicinal product;

j) to document, no later than a week, all cases of severe adverse reactions reported by implementing the physician who has supported the authorisation for compassionate use or by the patient/caregivers and notify the NAMMD;

k) to document, no later than 15 days, all cases of non-serious adverse reactions reported by the implementing physician who has supported the authorisation for compassionate use or by the patient/caregivers and notify the NAMMD;

l) to immediately inform the NAMMD about any change in information concerning the authorised medicinal product and submit all appropriate documents;

m) to immediately inform the NAMMD and provide the grounds for the decision on early discontinuation of the use/availability of the medicinal product authorised for compassionate use;

n) to submit to the NAMMD a report on the safe use of the respective medicinal product for compassionate use, after expiry of the authorisation validity;

o) to archive all documents referring to the medicinal product, physician and patient/group of patients for 10 years after completion of the programme;

p) to allow inspections conducted by the granting competent authority;

q) to ensure immediate reporting to the NAMMD of any changes in the risk/benefit report, enabling prompt risk prevention measures.

ARTICLE 9

Compassionate use shall be completed in maximum one year since the date of authorisation by the NAMMD or at the same time as grant of a marketing authorisation for the respective product, whichever comes first.

ARTICLE 10

The duties of the specialist physician implementing compassionate use are as follows:

a) to ensure that compassionate use is carried out appropriately, in accordance with NAMMD approval;

b) to ensure that all measures and restrictions concerning the safe and effective use of the medicinal product are observed, and that everyone involved receives the necessary information in this respect;

c) to immediately inform the NAMMD about safety or quality issues;

d) not to advertise the program;

e) to keep specific records on administration of the medicinal product included in the programme;

f) to document all cases of adverse reactions identified or reported by the patient or caregivers and inform the NAMMD thereof in maximum 15 days (non-serious adverse reactions) and no later than a week (serious adverse reactions);

g) to establish causality between the occurrence of the adverse reaction and administration of a medicinal product for compassionate use;

h) to administer the medicinal product in accordance with conditions for use provided for by the company and which are integral part of the scientific dossier submitted to the competent authority for assessment of the application for compassionate use;

i) to stop medicinal product administration upon request of the NAMMD or the manufacturing company, if necessary;

j) to obtain, on patients‘ behalf, the informed consent forms, prior to treatment initiation, documented by signature thereof;

k) to obtain consent of the healthcare unit (where compassionate use is conducted);

l) to store the medicinal product in accordance with the product’s storage conditions, as provided for by the manufacturing company;

m) to preserve all documents related to the medicinal product and patient/patient group for 10 years after completion of the programme;

n) to allow inspections from competent authorities and the manufacturing companies granted approval for conduct of compassionate use;

o) to keep a strict inventory of product administration to patients (quantities, doses);

p) not to market the medicinal product.

ARTICLE 11

Changes of therapeutic indication, strength or pharmaceutical form of the medicinal product for compassionate use, as well as changes likely to impact patient safety can only be operated after grant of a new authorisation.

ARTICLE 12

Notwithstanding regulations concerning archiving of medical documents, key documents related to compassionate use shall be archived for minimum 10 years.

ARTICLE 13

Provision of the new medicinal product for the time between authorisation and its actual placement on the market shall be ensured by the manufacturing company.

ARTICLE 14

NAMMD authorisation for compassionate use does not pre-empt civil or criminal liability of the manufacturing company.

ARTICLE 15

The forms used for authorisation of medicinal products for compassionate use shall be published on the NAMMD website in 30 days as of publication of the Order.

ORDER no. 888 of 25 July 2014
on approval of fees payable to the National Agency for Medicines and Medical Devices for services related to medicinal products for human use

ISSUED: THE MINISTRY OF HEALTH

PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, no. 572 of 31 July 2014

On seeing the report for approval No. NB 5.816/2014 of the Medicinal Product and Medical Device Policy Directorate and Notification no. 50.401E of 2 July 2014, registered at the Ministry of Health no. 40.224 of 2 July 2014,

taking into account provisions of:

- Article 857 of Law 95/2006 on healthcare reform, as amended,
- Article 10 d) of Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended,
- Article 7 (4) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as amended,

the Minister of Health hereby issues the following Order:

ARTICLE 1

Fees payable to the National Agency for Medicines and Medical Devices for services related to medicinal products for human use are hereby approved, according to the Annex, which is integral part of this Order.

ARTICLE 2

(1) Fees payable according to the Annex by Romanian applicants for services provided by the National Agency for Medicines and Medical Devices are paid in LEI, as per the exchange rate of the National Bank of Romania on the day of invoice issuance.

(2) Fees payable according to the Annex by foreign applicants for services provided by the National Agency for Medicines and Medical Devices are paid in either foreign currency, or its equivalent in LEI, as per the exchange rate of the National Bank of Romania on the day of invoice issuance.

ARTICLE 3

In case of discontinuation of the procedure for marketing authorisation/marketing authorisation renewal/variation approval, the administrative procedure for management of the sums entered into NAMMD accounts is as follows:

a) for notification by applicants on withdrawal of the application for marketing authorisation/marketing authorisation renewal after payment of the fee for marketing authorisation/marketing authorisation renewal procedure, the fee for marketing authorisation/marketing authorisation renewal paid by applicants in accordance with provisions of Article 854 of Law 95/2006 on healthcare reform,

as amended, on submission of applications for marketing authorisation/marketing authorisation renewal shall be transferred by the National Agency for Medicines and Medical Devices to the state budget;

b) for notification by applicants on withdrawal of the application for marketing authorisation/marketing authorisation renewal after payment of the fee for marketing authorisation/marketing authorisation renewal procedure, the fee for marketing authorisation/marketing authorisation renewal paid by applicants, in accordance with provisions of point III of this Annex shall be managed as follows:

(i) for applications for discontinuation of the marketing authorisation/ marketing authorisation renewal procedure submitted prior to validation of the application for marketing authorisation/marketing authorisation renewal, upon request, the respective fee may be returned/redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

(ii) for applications for discontinuation of the marketing authorisation/ marketing authorisation renewal procedure submitted after validation of the application for marketing authorisation/marketing authorisation renewal, but prior to start of the procedure (for the mutual recognition/decentralised procedure) or, for the national procedure, respectively, no later than 90 calendar days as of actual fee payment, upon applicant's request, 90% of the fee may be returned/redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

(iii) for applications for discontinuation of the marketing authorisation/ marketing authorisation renewal procedure submitted after start of the procedure (for the mutual recognition/decentralised procedure) or, for the national procedure, respectively, no later than 90 calendar days as of actual fee payment, the fee paid is to be retained by the National Agency for Medicines and Medical Devices and may no longer be returned;

c) for notifications of withdrawal by the applicant of the application for approval of a variation after actual payment of the fee for conduct of the procedure for approval of the variation and after validation of the application for variation approval, but prior to NAMMD request for additional information, upon request, 90% of the fee may be returned/ redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

d) for notifications of withdrawal by the applicant of the application for approval of a variation after actual payment of the fee for conduct of the procedure for approval of the variation and after NAMMD request for additional information, the fee paid shall be retained by the National Agency for Medicines and Medical Devices and may no longer be returned.

ARTICLE 4

The administrative procedure for the management of fees paid into the NAMMD account for discontinuation of the procedure for assessment, authorisation and amendment of is as follows:

a) for notifications of withdrawal by the applicant of the application for authorisation of a clinical trial with a medicinal product for human use after payment of the fee for conduct of the procedure for authorisation of a clinical trial, the fee for authorisation of the clinical trial paid by applicants in accordance with provisions of point III of the Annex shall be managed as follows:

(i) for applications for discontinuation of the procedure for authorisation of a clinical trial with a medicinal product for human use submitted prior to validation of the application, upon request, the respective fee may be returned/redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

(ii) for applications for discontinuation of the procedure for authorisation of a clinical trial with a medicinal product for human use submitted after validation of the application for authorisation, but no later than 25 calendar days after start of the procedure, upon applicant's request, 90% of the fee may be returned/redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

(iii) for applications for discontinuation of the procedure for authorisation of a clinical trial with a medicinal product for human use submitted after day 25 as of start of the procedure, the fee paid shall be retained by the National Agency for Medicines and Medical Devices and may no longer be returned;

b) for applications for authorisation of a clinical trial with a medicinal product for human use rejected after the validation procedure, upon applicant's request, 90% of the fee may be returned/ redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

c) for notifications of withdrawal of the application for approval of a substantial amendment to a clinical trial with a medicinal product for human use after actual payment of the fee for conduct of the procedure for approval of the clinical trial amendment, the fee for assessment of the clinical trial amendment paid in accordance with provisions of point III of the Annex shall be managed as follows:

(i) for applications for discontinuation of procedure for approval of the clinical trial amendment submitted prior to validation of the application, upon request, the respective fee may be returned/redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

(ii for applications for discontinuation of procedure for approval of the clinical trial amendment submitted after validation of the application, but no later than 15 calendar days after start of the procedure, upon applicant's request, 90% of the fee may be returned/redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

(iii) for applications for discontinuation of the authorisation procedure submitted after 15 days after start of the procedure, the fee paid shall be retained by the National Agency for Medicines and Medical Devices and may no longer be returned;

d) for applications for approval of a substantial amendment to a clinical trial rejected after the validation procedure, upon applicant's request, 90% of the fee may be returned/redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices.

ARTICLE 5

On this Order coming into force, Order of the Minister of Health no. 716/2009 on approval of fees payable to the National Agency for Medicines and Medical Devices and of the fee for maintenance of marketing authorisation, published in the Official Gazette of Romania, Part I, no. 422 of 19 June 2009, as amended, is repealed.

ARTICLE 6

This Order is published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health,
Francisk Iulian Chiriac,
Secretary of State

Bucharest, 25 July 2014.
No. 888.

ANNEX 1

FEES
payable to the National Agency for Medicines and Medical Devices for services related to medicinal products for human use

I. Laboratory control of non-biological and biological medicinal products for human use and related activities

No.	Activity	Fee - Euro -
0	1	2
A.	Physico-chemical control	
1.	Liquid clarity and opalescence	30
2.	Concentration of aqueous/organic solvent-containing solutions for extraction through rotavapor distillation	50
3.	Alcoholic concentration of pharmaceutical preparations	47
4.	Control of macroscopic impurities in solutions for injection and infusion in vials and bottles/powders for injection and lyophilised medicinal products	11
5.	Control of limits of inorganic impurities and foreign organic substances	52
6.	Microscope control of size and shape of particles in suspension	12
7.	Micro-chemical/Microscope control of herbal medicinal products	26
8.	Organoleptic control (appearance, colour, taste, smell)	5
9.	De-fattening of herbal medicinal products for dosage purposes	19
10.	Relative density	12
11.	Determination of water, titration with Karl-Fischer reagent (calibration included)	54
12.	Chromatographic column determination	142
13.	Determination of apparent density in powders	14
14.	Determination of tablet size (thickness, diameter, length, width)	7
15.	Determination of tablet friability	12
16.	Granulometric determination in powders	14
17.	Determination of acidity, alkalinity limit	14
18.	Determination of number of doses per spray vials	11
19.	Determination of osmolality	13
20.	Determination of homogeneity in ointments, suppositories	6
21.	pH determination	20
22.	Determination of kinetic profile of active substance release from oral solid pharmaceutical forms with prolonged release	173
23.	Determination of purity of medicinal products for human use through high-performance liquid chromatography	323
24.	Determination of suppository resistance	22
25.	Determination of total fats	25
26.	Determination of dissolution time in lyophilised products	12
27.	Determination of emulsion type	12
28.	Determination of volatile oils from herbal medicinal products	10
29.	Determination of viscosity by ball/rotational/capillary viscosimeter	39
30.	Determination of sedimentation rate	16

31.	Suppository and ovule desegregation	33
32.	Desegregation of effervescent/gastro-soluble medicinal products	12
33.	Entero-soluble product desegregation	39
34.	Sample destruction for determination of inorganic impurity limits	24
35.	Physico-chemical determination in aquaeous environment/ acids in non-aquaeous environment/alkali in non-aquaeous environment	55
36.	Gas chromatographic dosage	209
37.	Gas chromatographic coupled with Head-Speace dosage	470
38.	Dosage through atomic absorption spectrophotometry	120
39.	Potentiometric dosage	75
40.	Dosage through high performance liquid chromatography	326
41.	Nitrogen determination in organic combinations	32
42.	Oxygen dosage	34
43.	Spectrophotometric identification in UV, visible or fluorimetric – in alcohol solution/in organic solvents/in aqueous solution	117
44.	Dosage of soluble substances in herbal medicinal products	20
45.	Dosage of tannins in herbal medicinal products	79
46.	Tightness of spray vials/of sachets with effervescent powder	12
47.	Extraction of active principles from pharmaceutical products/ herbal medicinal products for identification or dosage purposes	79
48.	Imbuement factor of herbal medicinal products	13
49.	Filtration through 0.30-0.50 µm porosity membrane filters	15
50.	Performance of the spraying system (spray)	14
51.	Identification through thin layer chromatography	38
52.	Identification through various chemical reactions: dinytrogenation/coupling/oxide-reduction/other types/anion identification/cation identification	22
53.	Identification and purity through gas-chromatography	200
54.	Spectrophotometric identification in I.R.	15
55.	Spectrophotometric identification in UV and visible in alcohol solution/in aqueous solution/in organic solvents	78
56.	Acetyl/Acidity/Bitterness/Ester/Hydroxyl Iodine/peroxide index	35
57.	Refraction index	19
58.	Saponification index	26
59.	Total weight per recipient (solutions, suspensions, emulsions, ointments)	17
60.	Loss through etuve or exsiccator drying	21
61.	Boiling point/Dropping point/Melting point for capillaries/ Melting point for suppositories	14
62.	Purity through thin layer chromatography	79
63.	Rotatory power	26
64.	Insoluble residue in chlorhydric acid 100 g/l/through calcination/through evaporation	34
65.	Hardmeter-determined tablet-resistance	6
66.	Solubility	20
67.	Non-saponifiable substances	60
68.	Water- or acid- soluble substances	17
69.	Dissolution test	85
70.	Content uniformity	35
71.	Unidose forms/Powder for injection mass uniformity	20
72.	Volume uniformity per vial, bottle	10

B.	Microbiological control	

73.	Microbiological activity of antibiotics-turbidimetric method	184
74.	Microbiological activity of antibiotics and vitamin - diffusion method	200
75.	Microbiological activity of vitamins-turbidimetric method	235
76.	Microbial contamination-direct seeding method	233
77.	Microbial contamination-membrane filtration method	287
78.	Efficacy control of antimicrobial preservatives	331
79.	Control of antibiotics sterility through the "Steritest" method of closed system membrane filtration	300
80.	Control of antibiotics sterility through the open system membrane filtration method (Millipore)	331
81.	Control of sterility of aqueous solutions and soluble powders through the "Steritest" method of closed system membrane filtration	264
82.	Control of sterility of aqueous solutions and soluble powders through the open system membrane filtration method(Millipore)	243
83.	Control of sterility of aqueous solutions and oily solutions in volumes up to 4 ml/4 ml and 10 ml/10 ml and40 ml of powders, ointments and creams through the direct seeding method	184
84.	Control of sterility of solutions for infusion or medicinal products with antimicrobial activity through the direct seeding method	204
85.	Control of sterility of oils and oily solutions, ointments and creams through the "Steritest" method of closed system membrane filtration	283
86.	Control of sterility of oils and oily solutions, ointments and creams through the open system membrane filtration method (Millipore)	261
87.	Determination of bactericide and fungicide activity of antiseptics and disinfectants	402
88.	Exposure of enterobacteria and certain other gram- negative bacteria	131
89.	Exposure of Clostridium/Salmonella/Escherichia Coli/ Pseudomonas aeruginosa/Staphylococcus aureus genre micro-organisms	151

C.	Pharmaco-toxicological control*)	
90.	Antigenicity control at 21 days	435
91.	Control of endotoxin content through the Kinetic Chromogenic/turbidimetric/gel-clot (L.A.L. test) method	491
92.	Control of pyrogenic impurities	496
93.	Control of pyrogenic impurities in 6 rabbits	929
94.	Control of local tolerance through intramuscular injection in rabbits	757
95.	Control of toxicity in 3 rabbits	375
96.	Determination of systemic toxicity in subacute experiments with anatomo-pathologic examination	1,876
97.	Local ocular tolerance in rabbits	547

D.	Radiopharmaceutical control	
98.	Radioactivity measurement	29
99.	Determination of radiochemical purity	91
100.	Determination of radionuclide purity	117

E.	Immunogenicity and pathological anatomy control	
101.	Control of specific activity (in vivo antigenic titre- U.B.) in 7 mice	152
102.	Control of in vivo immunogenicity in 12 guinea pigs	793

103.	Control of in vivo immunogenicity in 22 guinea pigs	1,266
104.	Non-pathogenicity control	347
105.	Control of in vivo innocuity in 5 mice and 2 guinea pigs	227
106.	Control of in vivo innocuity in 5 mice	98
107.	Control of in vivo specific toxicity in 5 guinea pigs	502

F.	Biological product control**)	
108.	Control of purity (blade) Gram smear	36
109.	Control of purity through seeding (tube testing)	83
110.	Control of in vitro specific activity (viral titre determination in monovalent vaccine: measles/mumps/rubella	255
111.	Control of in vitro specific activity-viral titre determination, polio vaccine	518
112.	Control of specific activity through double diffusion	163
113.	Control of concentration (nefelometry)	31
114.	Control of identity (blade) Ziel-Nielsen smear	42
115.	Control of identity and/or specific activity by counter-immunoelectrophoresis	215
116.	Control of identity and/or specific activity by immuno-electrophoresis	219
117.	Control of identity and/or titre through in tube agglutination	36
118.	Control of identity and/or titre through on-plate agglutination	29
119.	Control of purity through seeding (on plate)	69
120.	Control of protein purity through electrophoresis by Agarosa-Sebia gel	208
121.	Control of protein concentration through the biuret method	60
122.	Control of protein concentration through the Lowry method	121
123.	Control of aluminium content through the complexometric	107
124.	Determination of phenol content	116
125.	Control of free formaldehyde content	60
126.	Control of Thyomersal content	95
127.	Calibration curve for protein concentration (biuret method)	62
128.	Calibration curve for determination of phenol content	114
129.	Calibration curve for determination of Thyomersal content (dosage)	96
130.	Calibration curve for determination of protein concentration in influenza vaccine	179
131.	Calibration curve for determination of free formaldehyde content	64
132.	Determination of Na, K and Cl ionic concentration with AVL List analyzer	32
133.	Determination of haemaglutinin and ovalbumine identity and/or concentration through simple radial immunodiffusion IDRS in purified and inactivated influenza trivalent vaccine	177
134.	Determination of identity through the Ouchterlony radial double immunodiffusion method in vaccines	144
135.	Determination of protein concentration through the Bradford method	132
136.	Determination of vaccine potency through the ELISA method of antibody measurement in serum (on mice)	458
137.	Determination of vaccine potency through the ELISA method of antibody measurement in serum (on guinea pigs)	458
138.	Determination through seeding on solids for BCG products (identity, number of viable units, thermal stability, average survival rate)	337
139.	Identification/titre in anti A and anti B haemaglutinine (indirect method)	101

140.	Ph. Eur calibration curve for determination of free formaldehyde content	66
141.	Ph. Eur. free formaldehyde content control	64

*) The remaining specific materials are to be provided by the beneficiary (reference substance, international standard and certain calibrators).
**) The remaining specific materials are to be provided by the beneficiary (reference substance, immuno-plates, Cormay gel prot 100 kit).

II. Various inspections and related activities

No.	Activity	Fee*) -Euro-	Invar. compon.**)	Var. compon.***)
0	1	2	3	4
1.	Inspection for grant of Manufacturing authorisation to manufacturers of medicinal products for human use/ investigational medicinal products/raw materials in Romania (for sterile medicinal product manufacturing)	1,742	1,496	246
2.	Inspection for grant of Manufacturing authorisation to manufacturers of medicinal products for human use/ investigational medicinal products/raw materials in Romania (for non-sterile medicinal product manufacturing)	1,561	1,358	203
3.	Inspection for follow up of correction of noncompliances found on inspection for grant of the (total or partial) manufacturing authorisation to manufacturers of medicinal products for human use/investigational medicinal products/raw materials in Romania	1,348	1,348	-
4.	Inspection for grant of importing authorisation to importers of medicinal products for human use/ investigational medicinal products/ raw materials	778	778	-
5.	Inspection to medicinal product/ investigational medicinal product importers for check of release by the Qualified Person of medicinal product batches imported from third countries	360	360	-
6.	Inspection for grant of manufacturing authorisation to importers of medicinal products for human use/investigational medicinal products/raw materials conducting certain manufacturing operations (e.g. division, labelling, packaging, re-packaging, other parts of the manufacturing process)	863	863	-
7.	Inspection for grant of the Good Manufacturing Practice Certificate to third country manufacturers of medicinal products for human use/investigational medicinal products/raw materials for sterile product manufacturing	2,035	981	1,054
8.	Inspection for grant of the Good Manufacturing Practice Certificate to third country manufacturers of medicinal products for human use/investigational	1,753	882	871

	medicinal products/raw materials for manufacturing of non-sterile products			
9.	Inspection prior to grant of Marketing Authorisation	451	451	-
10.	Inspection for check of compliance with Good Clinical Practice Rules on a specialised site	1,046	514	532
11.	Inspection for follow up of correction of inspection finds after check of compliance with Good Clinical Practice Rules	514	514	-
12.	Inspection for authorisation of sites for independent physico-chemical and/or microbiological control/good laboratory practice certification (bioanalytical laboratories in bioequivalence centres/toxicology laboratories)	994	994	-
13.	Inspection for follow-up of correction of inspection finds for authorisation sites for independent control (physico-chemical and/ or microbiological)/good laboratory practice certification (bio-analytical laboratories in bioequivalence centres/toxicology laboratories)	800	800	-
14.	MAH Inspection for check of pharmacovigilance activity	1,117	1,117	-
15.	MAH Inspection for follow-up of correction of inspection finds in pharmacovigilance inspection	659	659	-
16.	Inspection for check of compliance with MAH obligations	400	400	-
17.	Inspection for check of compliance with Good Clinical Practice Rules on a clinical site of a bioequivalence centre	506	506	-
18.	Inspection for grant of wholesale distribution authorisation	750	750	-
19.	Inspection for follow-up of wholesale distributor’s performance	350	350	-
20.	Inspection for grant of wholesale distribution authorisation to brokers conducting sales, procurement and/or export of medicinal products	350	350	-
21.	Issuance of the Good Manufacturing Practice Compliance Certificate	81	81	-
22.	Approval of the Export declaration/ Additional export declaration	20	20	-
23.	Performance of changes, on request, in a document issued by the National Agency for Medicines and Medical Devices (e.g. changes to manufacturing/import authorisations and/or of annexes thereof, of authorisation of sites for independent control and/or of annexes thereof, of good laboratory practice certificates) or issuance of document duplicates (document loss/deterioration)	136	136	-
24.	Issuance of the Qualified Person Certificate	75	75	-
25.	Examination of documentation for exemption from application of legal provisions in force on medicinal product labelling/ packaging as per Order of the Minister of Public Health no. 872/2006 for approval of	75	75	-

	Norms for grant of exemption for specific medicinal products label and package leaflet from the obligation of wording in Romanian of certain particulars and the leaflet, for products not intended for supply to patient for self-administration			
26.	Inspection for certification of legibility tests providers	750	750	-

*) the inspection fee as resulted from summation of the two components (for one manufacturing flow).

**) Referring to general inspection aspects; charged only once, irrespective of the number of manufacturing flows.

***) Referring to one manufacturing flow and the calculation of the inspection fee, to be multiplied by the number of manufacturing flows inspected.

NOTE:

Fees do not include travelling expenses (transportation, accommodation, diplomatic visa fees etc.).

According to European legislation, such costs are paid by the beneficiary as far as the extra-community space is concerned.

III. Assessment of documentation for marketing authorisation/marketing authorisation renewal for medicinal products for human use and conduct of other activities

No.	Activity	Fee - Euro -
0	1	2
A.	Assessment of documentation for marketing authorisation/ marketing authorisation renewal through national procedure	
1.	Marketing authorisation through national procedure of medicinal products - full dossier, in accordance with Art. 702(4) of Law 95/2006 on healthcare reform, as amended, or Article 8(3) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use	9,500
1.a)	Marketing authorisation through national procedure of medicinal products - full dossier, in accordance with Art. 702(4) of Law No. 95/2006 on healthcare reform, as amended, or Article 8(3) of Directive 2001/83/EC – different pharmaceutical form, submitted at the same time as the initial application	4,750
1.b)	Marketing authorisation through national procedure of medicinal products - full dossier, in accordance with Art. 702(4) of Law No. 95/2006 on healthcare reform, as amended, or Article 8(3) of Directive 2001/83/EC – the second and following strengths, submitted at the same time as the initial application	2,830
2.	Marketing authorisation through national procedure of generic medicinal products, submitted according to Article 704(1) and (2)of Law 95/2006, as amended, or Article 10 (1) of Directive 2001/83/EC	5,700
2.a)	Marketing authorisation through national procedure of generic medicinal products, submitted according to Article 704(1) and (2) of Law 95/2006, as amended, or	2,900

	Article 10(1) of Directive 2001/83/EC–different pharmaceutical form submitted at the same time as the initial application	
2.b)	Marketing authorisation through national procedure of generic medicinal products, submitted according to Article 704(1) and (2) of Law 95/2006 as amended, or Article 10(1) of Directive 2001/83/EC – the second and following strengths submitted at the same time as the initial application	1,710
3.	Marketing authorisation through national procedure of medicinal products - "hybrid" (mixed) application, submitted according to Article 704(3) of Law No. 95/2006, as amended, or Article 10(3) of Directive 2001/83/EC	6,650
3.a)	Marketing authorisation through national procedure of medicinal products - "hybrid" (mixed) application, submitted according to Article 704(3) of Law No. 95/2006, as amended, or Article 10(3) of Directive 2001/83/EC- different pharmaceutical form, submitted at the same time as the initial application	3,325
3.b)	Marketing authorisation through national procedure of medicinal products - "hybrid" (mixed) application, submitted according to Article 704(3) of Law No. 95/2006, as amended, or Article 10(3) of Directive 2001/83/EC- the second and following strengths, submitted at the same time as the initial application	2,000
4.	Marketing authorisation through national procedure of biosimilar medicinal products, submitted according to Article 704 (4) of Law 95/2006, as amended, or Article 10(4) of Directive 2001/83/EC	6,650
4.a)	Marketing authorisation through national procedure of biosimilar medicinal products, submitted according to Article 704(4) of Law 95/2006, as amended, or Article 10(4) of Directive 2001/83/EC - different pharmaceutical form, submitted at the same time as the initial application	3,325
4.b)	Marketing authorisation through national procedure of biosimilar medicinal products, submitted according to Article 704(4) of Law 95/2006, as amended, or Article 10(4) of Directive 2001/83/EC – the second and following strengths submitted at the same time as the initial application	2,000
5.	Marketing authorisation through national procedure of well- established use medicinal products, submitted according to Article 705 of Law 95/2006, as amended, or Article 10(a), of Directive 2001/83/EC ("bibliographic" application)	6,650
5.a)	Marketing authorisation through national procedure of well- established use medicinal products, submitted according to Article 705 of Law 95/2006, as amended, or Article 10(a) of Directive 2001/83/EC ("bibliographic" application)–different pharmaceutical form, submitted at the same time as the initial application	3,325
5.b)	Marketing authorisation through national procedure of well- established use medicinal products, submitted according to Article 705 of Law 95/2006, as amended, or Article 10(a) of Directive 2001/83/EC ("bibliographic" application) – the second and following strengths, submitted at the same time as the initial application	2,000
6.	Marketing authorisation through national procedure of fixed 8.035 combination medicinal products, submitted according to Art. 706 of Law 95/2006, as amended, or Article 10(b) of Directive 2001/83/EC	8,035
6.a)	Marketing authorisation through national procedure of	4,005

	fixed combination medicinal products, submitted according to Art. 706 of Law 95/2006, as amended, or Article 10(b) of Directive 2001/83/EC – different pharmaceutical form, submitted at the same time as the initial application	
6.b)	Marketing authorisation through national procedure of fixed combination medicinal products, submitted according to Art. 706 of Law 95/2006, as amended, or Article 10(b) of Directive 2001/83/EC - the second and following strengths, submitted at the same time as the initial application	2,450
7.	Marketing authorisation through national procedure of informed consent medicinal products submitted according to Article 707 of Law 95/2006, as amended, or Article 10(c) of Directive 2001/83/EC	2,850
7.a)	Marketing authorisation through national procedure of informed consent medicinal products, submitted according to Article 707 of Law 95/2006, as amended, or Article 10(c) of Directive 2001/83/EC – different pharmaceutical form, submitted at the same time as the initial application	1,425
7.b)	Marketing authorisation through national procedure of informed consent medicinal pro ducts submitted according to Article 707 of Law 95/2006, as amended, or Article 10(c) of Directive 2001/83/EC – the second and following strengths, submitted at the same time as the initial application	900
8.	Marketing authorisation through national procedure of homeopathic medicinal products, submitted according to Art. 710 of Law 95/2006, as amended (marketing authorisation through simplified procedure)	1,920
9.	Marketing authorisation through national procedure of herbal medicinal products, submitted according to Article 714 of Law 95/2006, as amended (marketing authorisation through simplified procedure)	1,920
10.	Marketing authorisation through national procedure of medicinal products, submitted as line extensions of an already authorised medicinal product	4,100
11.	Marketing authorisation renewal through national procedure, according to Article 730(2) of Law 95/2006, as amended, or Article 24(2) of Directive 2001/83/EC	2,400
12.	Marketing authorisation renewal through national procedure of homeopathic medicinal products, submitted according to Article 710 of Law 95/2006, as amended (marketing authorisation through simplified procedure)	970
13.	Marketing authorisation renewal through national procedure of traditional herbal medicinal products according to Art. 714 of Law 95/2006, as amended (marketing authorisation through simplified procedure)	970
B.	Assessment of documentation for marketing authorisation/ marketing authorisation renewal through European procedures	
14.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – generic medicinal products [Article 10(1) of Directive 2001/83/EC or Article 704 (1) and (2) of Law 95/2006, as amended	8,050
14.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – generic medicinal products – different pharmaceutical form, submitted at the same time as the initial application [Article 10(1) of Directive 2001/83/EC or Article 704 (1)	4,830

	and (2) of Law 95/2006, as amended	
14.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – generic medicinal products – the second and following strengths, submitted at the same time as the initial application [Article 10(1) of Directive 2001/83/EC or Article 704 (1) and (2) of Law 95/2006, as amended	2,420
15.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "hybrid" (mixed) application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended	9,200
15.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "hybrid" (mixed) application - different pharmaceutical form, submitted at the same time as the initial application [Article 10(3) of Directive 2001/83/EC ARTICLE 704 (3) of Law 95/2006, as amended	5,520
15.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "hybrid" (mixed) application - the second and following strengths, submitted at the same time as the initial application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended	2,760
16.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "biosimilar medicinal product" [Article 10(4) of Directive 2001/83/EC or Article 704(4) of Law 95/2006, as amended]	9,200
16.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "biosimilar medicinal product" - different pharmaceutical form, submitted at the same time as the initial application [Article 10(4) of Directive 2001/83/EC or Article 704 (4) of Law 95/2006, as amended]	5,520
16.b)	Marketing authorisation of medicinal products through procedure or decentralised procedure with Romania as Reference Member State - "biosimilar medicinal product" – the second and following strengths, submitted at the same time as the initial application [Article 10(4) of Directive 2001/83/EC or Article 704(4) of Law 95/2006, as amended]	2,760
17.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "bibliographic" application [Article 10(a) of Directive 2001/83/EC or Art. 705 of Law 95/2006, as amended]	9,200
17.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "bibliographic" application - different pharmaceutical form, submitted at the same time as the initial application [Article 10(a) of Directive 2001/83/EC or Article 705 of Law 95/2006, as amended	5,520
17.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "bibliographic" application - the second and following strengths, submitted at the same time as the initial application	2,760

	[Article 10(a) of Directive 2001/83/EC or Article 705 of Law 95/2006, as amended]	
18.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – fixed combination [Art. 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended]	9,780
18.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – fixed combination - different pharmaceutical form, submitted at the same time as the initial application [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended]	5,870
18.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – fixed combination - the second and following strengths, submitted at the same time as the initial application [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended]	2,930
19.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "informed consent" [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended]	6,900
19.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "informed consent" - different pharmaceutical form, submitted at the same time as the initial application [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended]	4,140
19.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "informed consent" – the second and following strengths, submitted at the same time as the initial application [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended]	2,070
20.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – full dossier [Art. 8(3) of Directive 2001/83/EC or Article 702(4) of Law 95/2006, as amended]	7,500
20.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - full dossier – different pharmaceutical form, submitted at the same time as the initial application [Article 8(3) of Directive 2001/83/EC or Article 702(4) of Law 95/2006, as amended]	4,500
20.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - full dossier - the second and following strengths, submitted at the same time as the initial application [Article 8(3) of Directive 2001/83/EC or Article 702(4) of Law 95/2006, as amended]	2,250
21.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State– generic medicinal products [Article 10(1) of Directive 2001/83/EC or Article 704(1) and (2) of Law 95/2006, as amended]	5,200

21.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State–generic medicinal products – different pharmaceutical form, submitted at the same time as the initial application [Article 10(1) of Directive 2001/83/EC or Article 704(1) and (2) of Law 95/2006, as amended]	3,120
21.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State-generic medicinal products - the second and following strengths, submitted at the same time as the initial application [Article 10(1) of Directive 2001/83/EC or Article 704(1) and (2) of Law 95/2006, as amended]	1,560
22.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "hybrid" (mixed) application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended]	6,000
22.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – "hybrid" (mixed) application - different pharmaceutical form, submitted at the same time as the initial application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended]	3,600
22.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "hybrid" (mixed) application – the second and following strengths, submitted at the same time as the initial application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended]	1,800
23.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "biosimilar medicinal product" [Article 10(4) of Directive 2001/83/EC or Article 704(4) of Law 95/2006, as amended]	6,000
23.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "biosimilar medicinal product" - different pharmaceutical form, submitted at the same time as the initial application [Article 10(4) of Directive 2001/83/EC or Article 704(4) of Law 95/2006, as amended]	3,600
23.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "biosimilar medicinal product" - the second and following strengths, submitted at the same time as the initial application [Article 10(4) of Directive 2001/83/EC or Article 704(4) of Law 95/2006, as amended]	1,800
24.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "bibliographic" application [Article 10(a) of Directive 2001/83/EC or Art. 705 of Law 95/2006, as amended]	6,000
24.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "bibliographic" application - different pharmaceutical form, submitted at the same time as the initial application [Article 10(a) of Directive 2001/83/EC or Article 705 of Law 95/2006, as	3,600

	amended]	
24.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "bibliographic" application – the second and following strengths, submitted at the same time as the initial application [Article 10(a) of Directive 2001/83/EC or Article 705 of Law 95/2006, as amended]	1,800
25.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – fixed combination [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended]	6,400
25.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – fixed combination - different pharmaceutical form, submitted at the same time as the initial application [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended]	3,840
25.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – fixed combination - the second and following strengths, submitted at the same time as the initial application [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended]	1,920
26.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "informed consent" [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended]	3,750
26.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "informed consent" - different pharmaceutical form, submitted at the same time as the initial application [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended]	2,250
26.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "informed consent" – the second and following strengths, submitted at the same time as the initial application [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended]	1,130
27.	Marketing authorisation renewal for medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	2,100
27.a)	Marketing authorisation renewal for medicinal products through mutual recognition procedure and decentralised procedure with Romania as Reference Member State	4,305
C.	Authorisation of clinical trials, substantial amendments and approval of advertising material	
28.	Approval of clinical trials for investigational medicinal products not authorised worldwide (new substances). Phases I-III	1,250
29.	Approval of clinical trials for investigational medicinal products not authorised for marketing in Romania, authorised in other countries or authorised for marketing (known substances), but not used according to the Summary of Product Characteristics (SmPC) in force (regarding indications, dose, route of administration, treatment	1,000

	method, target group) Phases I – IV	
30.	Approval of clinical trials for medicinal products authorised in Romania, used according to SmPC in force. Phase IV	4,100
31.	Approval of bioequivalence studies	600
32.	Approval of substantial amendments (according to Order of the Minister of Public Health no. 904/2006 on approval of Rules relating to implementation of Good Clinical Practice trials on medicinal products for human use)	200
33.	Approval of advertising material for "over the counter" medicinal products (OTCs)	550
34	Approval of the educational material for medicinal products for human use	350
NOTE: Fees established under Sections 33 and 34 refer to approvals valid for 6 months after grant		
D.	Approval of variations	
35.	Approval of Type IA variations and Type IA variations defining the group for medicinal products authorised through national procedure	300
36.	Approval of Type IB and Type IB group defining variations for medicinal products authorised through national procedure	500
37.	Approval of Type II and Type II group defining variations for medicinal products authorised through national procedure	1,600
38.	Approval of Type IA variations included in the group for medicinal products authorised through national procedure	200
39.	Approval of Type IB variations included in the group for medicinal products authorised through national procedure	340
40.	Approval of Type II variations included in the group for medicinal products authorised through national procedure	1,070
41.	Approval of Type IA variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	460
42.	Approval of Type IB variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	760
43.	Approval of Type II variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	2,400
44.	Approval of Type IA variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	300
45.	Approval of Type IB variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	500
46.	Approval of Type II variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	1,060
47.	Approval of Type IA variation included in the group, other than the group defining variation, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	375

47.a)	Approval of Type IB variation included in the group, other than the group defining variation, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	750
47.b)	Approval of Type I variation included in the group, other than the group defining variation, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	2,400
48.	Approval of Type IA variation included in the group, other than the group defining variation, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	165
48.a)	Approval of Type IB variation included in the group, other than the group defining variation, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	225
48.b)	Approval of Type II variation included in the group, other than the group defining variation, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	825
NOTE: 1. For group variations, the fee is calculated for each marketing authorisation, by summing up the fee for the group defining variation and the fee for the variation included in the group for each group variation, other than the group defining variation 2. The fee for the group is the fee for the variation to marketing authorisation		
E.	Other activities	
49.	Approval of marketing authorisation transfer	400
50.	Approval of changes in primary and secondary packaging design and labelling, regarding changes to Leaflet and SmPC, other than resulting from Type IA, IB and II variations	250
51.	Grant of WHO format medicinal product certificate	230
52.	Setup and update of the Index of medicinal products for human use	230
NOTE: In case of failure to pay for the aforementioned service, the human medicinal product is not included /is excluded from the Index of medicinal products for human use.		
53.	Grant of parallel import authorisation	585
54.	Approval of parallel import authorisations	250
F.	Assessment of documentation for scientific approval, i.e. change of scientific approval of ancillary medicinal substances incorporated into a medical device	
55.	Scientific approval of ancillary medicinal substances incorporated into a medical device, not previously assessed by the National Agency for Medicines and Medical Devices	2,660
56.	Scientific approval of ancillary medicinal substances incorporated into a medical device for substances previously assessed by the NAMMD with a different manufacturer	1,330
57.	Scientific approval of ancillary medicinal substances incorporated into a medical device for substances previously assessed by the NAMMD with the same manufacturer	535
58.	Amendment of the scientific approval of ancillary medicinal substances incorporated into a medical device for	665

	substances not previously assessed by the NAMMD	
59.	Amendment of the scientific approval of ancillary medicinal substances incorporated into a medical device for substances previously assessed by the NAMMD with a different manufacturer	335
60.	Amendment of the scientific approval of ancillary medicinal substances incorporated into a medical device for substances previously assessed by the NAMMD with the same manufacturer	250
G.	Assessment of documentation for approval for inclusion of a medicinal product in the List of reimbursed and free medicinal products for insurants irrespective of contribution	
61.	Assessment of documentation for approval for inclusion of a medicinal product in the List of reimbursed and free medicinal products for insurants irrespective of contribution	1,304

ORDER no. 861 of 23 July 2014
on approval of criteria and methodology for assessment of health technologies, of documentation to be submitted by applicants, methodological means used in the assessment for inclusion, extension of indications, non-inclusion into or exclusion from the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs, as well as the means for appeal thereof

ISSUED: THE MINISTRY OF HEALTH

PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, no. 557 of 28 July 2014

On seeing Approval Report no. N.B. 5.681 of 22 July 2014 of the Pharmaceutical and Medical Devices Directorate and notification no. 50.957E of 21 July 2014 of the National Agency for Medicines and Medical Devices, registered at the Ministry of Health with no. 44.495 of 22 July 2014,

Taking into account provisions of:

- Article 232^1 of Law 95/2006 on healthcare reform, as amended,
- Article 2 (3) and (5) of Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

based on Article 7 (4) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as amended,

the Minister of Health hereby issues the following Order:

Article 1

The Assessment criteria are approved according to Annex 1 as regards health technologies for inclusion, extension of indications, non-inclusion into or exclusion from the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs, hereinafter the List.

Article 2

The methodology for assessment of health technologies for inclusion, extension of indications, medicinal product non-inclusion into or exclusion from the List, as well as the means for appeal thereof, as mentioned in Annex 2, is hereby approved.

Article 3

Documentation to be submitted by applicants, methodological means for assessment for inclusion, extension of indications, medicinal product non-inclusion into or exclusion from the List, as mentioned in Annex 3, is hereby approved.

Article 4

The template for the application to be submitted to the Registry Office of the National Agency for Medicines and Medical Devices concerning assessment of health technologies in support of the proposal for inclusion into the List of new INNs, reimbursable INNs with extension of indication, generics with non-reimbursable INNs, biosimilars with non-reimbursable INNs and fixed-dose combinations, as mentioned in Annex 4, is hereby approved.

Article 5

The General frame is hereby approved for conditioned inclusion into the List according to cost-volume/cost-volume-result contracts, as specified in Annex 5.

Article 6

(1) As of entry into force of this Order, assessment of health technologies for inclusion, extension of indications, medicinal product non-inclusion into or exclusion from the List is an ongoing process ensuring the access of patients to medicinal products within the social health insurance system.

(2) The National Agency for Medicines and Medical Devices is the national competent authority implementing, for decision making purposes, the mechanism for assessment of health technologies, in accordance with provisions of this Order, and proposes the List to the Ministry of Health, to be approved through Government Decision, in accordance with the law.

(3) Following assessment of each medicinal product for inclusion, extension of indications, non-inclusion into or exclusion from the List, the National Agency for Medicines and Medical Devices makes decisions in accordance with provisions of this Order.

Article 7

As of 2015, the List shall be updated, at least once a year, in accordance with Government budget policies and with national priorities established by the Ministry of Health and is approved through Government Decision, in accordance with the Law.

Article 8

The National Agency for Medicines and Medical Devices may initiate, *ex officio,* the assessment procedure of health technologies for inclusion, extension of indications, medicinal product non-inclusion into or exclusion from the List in the following situations:

a) INNs corresponding to medicinal products with safety amendments;

b) INNs corresponding to medicinal products which have changed their status upon release, from medicinal products released only on medical prescription to medicinal products released without medical prescription;

c) New INNs, other than those for which applicants have submitted an application;

d) Reimbursed INNs corresponding to medicinal products with new indications, other than those for which applicants have submitted an application;

e) Already reimbursable INNs, according to their value (of the budget impact) and number of units (with equal impact) of medicinal products released and discounted during the past year, solely based on medical prescription, from the allocated budget (Sole National Fund of Social Health Insurances - FNUASS).

Article 9

For 2014, reassessment of medicinal products for the List, under the conditions stipulated in this Order, is performed until 1 October 2014.

Article 10

The National Agency for Medicines and Medical Devices, the Ministry of Health, the special commissions of the Ministry of Health, directorates and institutions subordinated or coordinated by the Ministry of Health, as well as the National Health Insurance House, shall fulfil the provisions of this Order.

Article 11

Annexes 1 – 5 are integral parts of this Order.

Article 12

This Order is to be published in the Official Gazette of Romania, Part I.

*

This Order transposes issues related to establishment of the lists of medicinal products provided irrespective of personal contributions of insured persons, regulated by Article 6 of Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems, published in Official Journal of the European Union, L series no. 40 of 11 February 1989.

Minister of Health,
Nicolae Bănicioiu

Bucharest, 23 July 2014.
No. 861.

ANNEX 1

CRITERIA FOR ASSESSMENT
of health technologies on inclusion, extension of indications, non-inclusion or exclusion of medicinal products on/from the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs

ARTICLE 1

In line with this Annex, the following terms shall have the following meaning:

a) TB – therapeutic benefit (French: Service Medical Rendu); criteria employed by the institution conducting health technologies assessment in France (Haute Autorite de Sante - HAS), for medicinal product inclusion into/exclusion from the List of International Non-proprietary Names of medicinal products provided to insurants, irrespective of personal contribution, based on medical prescription, in the health insurance system frame, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programmes, hereinafter the List, and establishment of a reimbursement regimen; there are 3 TB levels: TB 1 - major/important; TB 2 - moderate/low (although justifying reimbursement); TB 3 - insufficient;

b) biosimilar - product similar to another already authorised biological product, known as a reference biological product and registered according to specific procedures;

c) comparator – an INN included in the List of INNs of medicinal products for insurants, irrespective of personal contribution, with the same approved indication, meant for the same population segment and with the same pharmacodynamic properties as INNs assessed;

d) clawback – quarterly contribution in accordance with Government Emergency Ordinance no. 77/2011 for establishing a contribution for funding of certain expenses of the healthcare system, as amended;

e) INN – international non-proprietary name recommended by the World Health Organisation;

f) Reimbursable INN - international non-proprietary name included in the List;

g) New INN - INN not included in the List;

h) Reimbursable INNs with extension of indication - INN included in the List, for which assessment is requested for inclusion of a new indication;

i) fixed-dose combination – association of two or several reimbursable INNs;

j) TN - trade name;

k) reimbursable status – the entire body of information concerning inclusion of a medicinal product into the sublists and sections provided in the List, the reimbursement percentage, manner of prescription; changes in reimbursement status of a reimbursable INN include: relocation, addition, exclusion or removal/addition of the ( ), (**), (***) or (****)marking;

l) extension of indication – addition of a new pathology/disease for which the respective INN has demonstrated safety and efficacy, also included in the Summary of Product Characteristics reviewed by the European Medicines Agency or the National Agency for Medicines and Medical Devices (extension of indication does not include the following: change of the age group, new population segment, change of treatment line, relocation/change of treatment line);

m) relocation - withdrawal of a reimbursable INN from a sublist/ List section and its inclusion into a different sublist/ List section;

n) addition – inclusion of a reimbursable INN in a different sublist/ List section as well, in addition to the previous one;

o) exclusion – withdrawal of reimbursable status of a reimbursable INN within the List;

p) removal/addition of the (*), (**), (***) or (****) marking – change of conditions for prescriptions of treatment with medicinal products corresponding to reimbursable International Non-proprietary Names included in the List; the line of treatment (e.g. management of advanced cancers) represents a particular treatment regimen, with either a single INN, or a combination of INNs. A line of treatment involves a varying number of cycles (which differs, according to disease), its duration varying therefore. Treatment initiation is performed with the first line of treatment, and subsequent lines of treatment (second, third a.s.o) may be instituted with every documentation of disease progression;

q) cycle of treatment - period including administration of a INN (possibly performed over one or several successive or different days) and the free-of-treatment period to next administration;

r) HTA - health technologies assessment;

s) HAS - Haute Autorite de Sante, the French institution performing health technologies assessment;

t) IQWIG - Institut für Qualität und Wirtschäftlichkeit im Gesundheitswesen, German institution performing health technologies assessment;

u) G-BA: der Gemeinsame Bundesausschuss (G-BA), German institution performing health technologies assessment;

v) NICE - National Institute of Health and Care Excellence, the institution performing health technologies assessment in England, Northern Ireland and Wales;

w) GDP – Gross Domestic Product, expressed in LEI and published by the National Institute of Statistics;

x) SmPC - Summary of Product Characteristics;

y) Scottish Medicines Consortium (SMC) - the institution performing health technologies assessment in Scotland.

ARTICLE 2

Relocation, inclusion, exclusion or removal/addition of the (*), (**), (***) or (****) marking system in reimbursable INNs included in the List are performed as per provisions of this Annex, by Decision of the National Agency for Medicines and Medical Devices, as approved by the specialised NAMMD structure responsible for health technologies.

ARTICLE 3

The National Agency for Medicines and Medical Devices requires elaboration of therapeutic protocols from Special Commissions of the Ministry of Health, in line with the decision for relocation, inclusion, exclusion or removal/addition of the (*), (**), (***) or (****) marking for reimbursable INNs included in the List.

ARTICLE 4

Specialised commissions of the Ministry of Health elaborate therapeutic protocols provided for in Article 3 no later than 30 days as of receipt of the application submitted by the National Agency for Medicines and Medical Devices.

ARTICLE 5

Assessment criteria specified in Table 4 apply to:

a) New INNs;

b) Reimbursable INN with new indication;

c) Generic medicinal products whose INNs are not reimbursable according to the List;

d) Biosimilars whose INNs are not reimbursable according to the List;

e) Fixed dose combinations.

Table 1 - Criteria for addition/relocation of reimbursable INNs

No.	Criteria	Details
1.	Determining patient addressability	Demonstrating resolution by addition/ re-location of lack of access to treatment of patient groups, population groups or stages of disease
2.	Similar reimbursement level	Additions/Relocations are considered at the same reimbursement level, at most, e.g. from 100% to 100% a.s.o.
3.	Proof of reimbursement in EU countries	Required to demonstrate extensive countries use of the product in Member States as well as for reasons of consistent approach

NOTE:

NAMMD Decision on change of reimbursement status requires meeting all criteria specified in Table 1.

Table 2 - Criteria for Reimbursable INNs marked (*), (**), (***) or (****)

No.	Criteria	Details
1.	High cost INNs(i) whose prescription and release require preliminary approval by specialised commissions of the National Health Insurance in line with therapeutic protocols on prescription of medicinal products corresponding to INNs included in the List, approved in accordance with the law	4**** Treatment with medicinal products corresponding to INNs marked (****) is conducted in line with therapeutic protocols established by specialised commissions of the Ministry of Health and approval by commissions of the National Health Insurance House
2.	Medium-cost INNs(ii) meant for a larger population group, whose prescription and release require prior approval of specialised commissions of county insurance houses, in line with therapeutic protocols on prescription of products corresponding to INNs in the List, approved in accordance with the law	3***Treatment with medicinal products corresponding to INNs marked(***)is conducted in line with therapeutic protocols established by specialised commissions of the Ministry of Health and approval by commissions of the county health insurance houses
3.	3.1. INNs prescribed by an assigned physician, based on a therapeutic protocol only, characterised by: a) Low cost (iii) b) Intended for large population groups	Treatment with medicinal products corresponding to INNs marked(**)is conducted in line with therapeutic protocols established by specialised commissions of the Ministry of Health
4.	Low-cost INNs (iv)requiring medical prescription according to SmPC	1* Treatment with medicinal products corresponding to INNs marked (*) is initiated by the specialist physician according to respective competence and may be prescribed further by the general practitioner based on the medical letter drafted by the specialist physician

(i) Products whose monthly treatment cost, calculated for manufacturer reimbursable price, is > 2 x GDP*)/capita/month; for one pharmaceutical form included in the group, the rule shall apply to the entire INN.

(ii) Products whose monthly treatment cost, calculated for manufacturer reimbursable price, is between 1 x and 2 x GDP*)/capita/month; for one pharmaceutical form included in the group, the rule shall apply to the entire INN.

(iii) Products whose monthly treatment cost, calculated for manufacturer reimbursable price, is between 1 x GDP*)/capita/month and the gross minimum wage on date of issuance of the decision for inclusion into the List.

(iv) Products whose monthly treatment cost, calculated for manufacturer price, is lower than the gross minimum wage on date of issuance of the decision for inclusion into the List.

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*) Reference for the Gross Domestic Product (GDP): the National Institute of Statistics, the most recently published Statistic Annual Book of Romania.

Table 3 – Assessment criteria for reimbursable INNs in the List

Assessment criteria	Rating	One rating chosen only	Scores may be summated
1. HTA based on estimate of the therapeutic benefit (SMR)			
1.1. INN assessed by the HAS with major/important SMR rating (BT 1)	0	Not exceeding 20 points	
1.2. INN not assessed by HAS	10		
1.3. INN assessed by the HAS with moderate/low SMR rating(BT 2)	15		
1.4. INN assessed by the HAS with insufficient SMR rating (BT 3)	20		
2. Cost-efficacy based HTA - GREAT BRITAIN (NICE/SMC)			
2.1. INN approved, without restrictions, by the Great Britain authority for assessment of health technologies	0	Not exceeding 20 points	
2.2. INN not assessed by the Great Britain authority for assessment of health technologies	10		
2.3. INN approved upon revision, with restrictions as compared to the SmPC, by the Great Britain authority for assessment of health technologies (NICE/SMC).	15		
2.4. INN not approved for inclusion in the reimbursement system by the Great Britain authority for assessment of health technologies (NICE/SMC)/Approval for inclusion in the system has been withdrawn.	20		
3. Cost-efficacy based HTA - Germany (IQWIG/G-BA)			
3.1. INN approved, without restrictions, by the German authority for assessment of health technologies (IQWIG/G-BA).			
3.2. INN not assessed by the German authority for assessment of health technologies (IQWIG/G-BA).	10	Not exceeding 20 points	
3.3. INN approved upon revision, with restrictions as compared to the SmPC, by the German authority for assessment of health technologies (IQWIG/G-BA).	15		
3.4. INN not approved for inclusion into the reimbursement system by the German HTA authority (IQWIG/G-BA)/Approval for inclusion in the system has been withdrawn.	20		
4. Negative assessment report			
INN for which, upon request by	20		

the National Agency for Medicines and Medical Devices, specialised commissions have recommended exclusion			

Table 4 - Assessment criteria for new INNs

Assessment criteria	Rating	One rating chosen only	Scores may be summated
1. HTA based on therapeutic benefit estimate (SMR)			
New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, bio-similars with no reimbursable INN in the List, classified as BT1-major/important by the HAS	15	Not exceeding 15 points	
1.2. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, bio-similars with no reimbursable INN in the List, classified as BT2-moderate/low (justifying reimbursement however) by the HAS.	7		
2. HTA based on cost-efficacy			
2.1. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, bio-similars with no reimbursable INN in the List, approved without restrictions as compared to the SmPC by Great Britain authorities for assessment of health technologies (NICE/SMC)	15	Not exceeding 15 points	
2.2. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, bio-similars with no reimbursable INN in the List, approved with restrictions as compared to SmPC by Great Britain authorities for assessment of health technologies	7		
2.3. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, bio-similars with no reimbursable INNs in the List approved without restrictions as compared to SmPC by German authorities for assessment of health technologies (IQWIG/G-BA)	15	Not exceeding 15 points	
2.4. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, bio-similars with no reimbursable INNs in the List, approved with restrictions as compared to SmPC by German authorities for assessment of health technologies (IQWIG/G-BA)	7		
3. Reimbursement status of INNs in Member States/Positive assessment report from the National Agency for Medicines and Medical Devices			
3.1. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, bio-similars with no reimbursable INNs in	25	Not exceeding 25 points	

the List, related to which inclusion into the List of the new therapeutic indication is required, reimbursed in at least 14 Member States			
3.2. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, bio-similars with no reimbursable INNs in the List, reimbursed in 8-13 Member States	20		
3.3. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, bio-similars with no reimbursable INNs in the List, reimbursed in 3-7 Member States	10		
3.4. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, bio-similars with no reimbursable INNs in the List, reimbursed in less than 3 Member States	0		
3.5. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, bio-similars with no reimbursable INNs in the List or fixed-dose combinations of already reimbursable INNs, for which the MAH has collected real-life data in line with methodologies approved by the National Agency for Medicines and Medical Devices on significant cohorts over at least one year, in Romania, based on which the National Agency for Medicines and Medical Devices has issued a positive assessment report for inclusion into the List	45	Not exceeding 45 points	
4. Therapy costs			
4.1. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, bio-similars with no reimbursable INNs in the List, generating more than 5% savings as per the medicinal product budget in the assessment year as opposed to the comparator	30	Not exceeding 45 points	
4.2. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, bio-similars with no reimbursable INNs in the List, with neutral budget impact as opposed to the comparator (+/-5%) of the medicinal product budget in the assessment year	15		
4.3. New INNs, reimbursable INNs with extension of indication, generics with no reimbursable INN in the List, bio-similars with no reimbursable INNs in the List, generating costs at least 5% higher than the medicinal product budget of the of assessment year, as opposed to the comparator	0		

NOTE:

For fixed dose combinations whose components have already been included in the List, only the cost-minimisation analysis shall be provided, comparing costs/ recommended daily dosage (annual RDDs) with costs/annual RDDs, separately for the components of the combination. The combination shall only be included in the List for costs/annual RDDs lower or no higher than the summated costs/annual RDDs of the separate components.

The 27 Member States for which reimbursement must be demonstrated are as follows:

1. Austria
2. Belgium
3. Bulgaria
4. Cyprus
5. Croatia
6. Czech Republic
7. Denmark
8. Estonia
9. Finland
10. France
11. Germany
12. Greece
13. Hungary
14. Ireland
15. Italy
16. Latvia
17. Lithuania
18. Luxembourg
19. Malta
20. Great Britain
21. Holland
22. Poland
23. Portugal
24. Slovakia
25. Slovenia
26. Spain
27. Sweden

ANNEX 2

METHODOLOGY FOR ASSESSMENT
of health technologies on inclusion, extension of indications, non-inclusion into or exclusion from the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs, as well as the means for appeal thereof

I. Methodology for assessment of health technologies on inclusion into the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs, of medicinal products corresponding to new INNs, as well as concerning extension of indications of medicinal products corresponding to reimbursable INNs.

A. Steps of the process for assessment of medicinal products corresponding to new INNs for inclusion into the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, of International Non-proprietary Names of medicinal products provided in national health insurance programs, hereinafter the List, as well as of medicinal products corresponding to reimbursable INNs for extension of indications.

1. The applicants shall submit an application set up in accordance with the template mentioned in Annex 4 to this Order, in both electronic and paper format, addressed to the National Agency for Medicines and Medical Devices, to the attention of the specialised structure responsible for health technologies assessment.

2. The application shall be accompanied by the extensive documentation mentioned in Annex 3 to this Order, both electronically (on CD or DVD), as well as on paper.

3. The application is given a NAMMD registration number and the medicinal product undergoes the assessment procedure; the applicant shall be informed about the decision no later than 90 calendar days after receipt of complete documentation in support of the application.

4. If the price of the medicinal product subject to the application for assessment has not been approved until the date of application submission, the deadline mentioned under point 3 is extended by 90 days. The applicants shall provide the National Agency for Medicines and Medical Devices with adequate information. Should the information accompanying the application be inadequate, the deadline is suspended and the National Agency for Medicines and Medical Devices immediately informs the applicant on detailed additional information required.

5. The specialised structure responsible for health technologies assessment within the National Agency for Medicines and Medical Devices shall confirm receipt of the application and extensive documentation submitted by the applicant, no later than 5 calendar days as of submission thereof.

6. Confirmation of receipt of documents submitted by applicants is the responsibility of the specialised structure for health technologies assessment within the National Agency for Medicines and Medical Devices, and shall be performed by letter with confirmation receipt and by e-mail, with delivery and reading confirmation from the recipient.

7. Examination of health technologies assessment reports submitted by the applicant, review of reimbursement proof from Member States, calculation and analysis of therapy costs are performed by the National Agency for Medicines and Medical Devices, within maximum 30 calendar days as of document submission.

8. After completion of the review of health technologies assessment reports, of reimbursement proof from Member States and analysis of therapy costs, within maximum 30 calendar days after submission of the documentation, the specialised structure responsible for health technologies assessment within the National Agency for Medicines and Medical Devices confirms receipt of complete documentation to the applicant or, as required, informs the applicant about additional data and/or documents required, as well as schedule for technical meetings with Marketing Authorisation Holder representatives, if needed.

9. In case of incomplete documentation submitted or of irrelevant comparator used to calculate therapy costs for healthcare practice in Romania, within maximum 30 calendar days after submission of the documentation, the National Agency for Medicines and Medical Devices provides the applicant with an interim report requiring submission of additional documentation or completion of the documentation already submitted, as required.

10. Such interim report consists of a critical review of documentation submitted and proposals for amendment or supplementation, as required, including the comparator considered relevant for Romanian medical practice.

11. To substantiate choice of the comparator relevant for healthcare practice in Romania, the National Agency for Medicines and Medical Devices requires approval of consulting commissions of the Ministry of Health, within maximum 10 calendar days after submission of documentation by the applicant.

12. Consulting commissions of the Ministry of Health shall provide the National Agency for Medicines and Medical Devices the approval concerning choice of a comparator relevant for medical practice in Romania no later than 10 calendar days as of NAMMD request.

13. If request of additional information/documents and/or conduct of technical meetings with Marketing Authorisation Holder representatives are required, the deadline is suspended for the time before additional documentation is submitted or the scheduled meetings take place.

14. If the applicant submits additional documentation, the deadline for grant of NAMMD decision is delayed by the time calculated from suspension until submission of additional documentation required.

15. If additional documentation is not required, within maximum 90 calendar days as of receipt of the application, the National Agency for Medicines and Medical Devices posts a technical report on its website, under the dedicated section for health technologies assessment and makes an official notification of the applicant on the decision.

16. In case of products failing to obtain the minimum rating required for conditioned/unconditioned inclusion into the List, as required, and, in the same year as that of application submission, acquires however elements resulting in possible increase of the initially assigned rating, the Marketing Authorisation Holder may submit a new application accompanied by the extended documentation, but not more than once during the same calendar year.

17. In case, during the assessment period, new issues arise related to Criteria stipulated in this methodology, able to result in increased rating by assessment of health technologies, marketing authorisation holders may legally resume their initial application and submit additional documentation in proof of issues arising after the date of submission of the initial application.

18. Extended applications and documentation received are reviewed according to priority, according to the following prioritisation criteria:

a) orphan medicinal products;

b) medicinal products approved through expedited procedure by the European Medicines Agency;

c) medicinal products corresponding to INNs for specific treatment in case of diseases of major impact upon public health, mentioned in Law 95/2006 on healthcare reform, as amended, as well as in the National Health Strategy;

d) medicinal products corresponding to INNs with negative budget impact, as calculated;

e) chronology of submission of applications for assessment.

19. Applications submitted for inclusion into the List of medicinal products corresponding to new INNs and for extension of indications of medicinal products corresponding to reimbursable INNs, including change of current reimbursement status, are posted on the website of the National Agency for Medicines and Medical Devices, under the dedicated “Health technologies” section, in the order of registration.

20. The following data are introduced in the Table of applications submitted:

a) INN;

b) trade name;

c) indication;

d) date of application submission;

e) date for NAMMD response to the applicant.

21. The rating resulted for each criterion mentioned in Annex 1 to the Order is only granted for submission of complete documentation.

22. Therapy costs are estimated depending on the comparator relevant for medical practice in Romania. If the relevant comparator for medical practice in Romania is not found in documentation submitted by the applicant, this is mentioned in an interim report drafted by the National Agency for Medicines and Medical Devices, including the approval of consulting commissions of the Ministry of Health granted for substantiation of choice of relevant comparator.

23. Therapy costs are calculated by the National Agency for Medicines and Medical Devices, according to the following data:

Table 1 - Data required for calculation of therapy costs

	New reimbursable INN with new indication	New reimbursable INN with new indication in the context of a cost-volume mechanism	Comparator
Monthly therapy cost with the daily minimum dosage			
Monthly therapy cost with the daily maximum dosage			
Monthly average therapy costs			
Total number of patients for respective indication (pre-valent and incident)estimated for yearly treatment and 5-year estimations after inclusion into the List			
Average therapy duration per patient according to SmPC			

24. To accomplish respective tasks concerning health technologies assessment, the National Agency for Medicines and Medical Devices may require opinions and information from the specialised commissions of the Ministry of Health, specialised directorates of the Ministry of Health, of the National Health Insurance House and any institutions subordinated to or coordinated by the Ministry of Health.

25. The final assessment report is posted on the website of the National Agency for Medicines and Medical Devices, under the dedicated section for assessment of health technologies.

26. For inclusion into the List of medicinal products corresponding to new INNs as well as for extension of indications of medicinal products corresponding to reimbursable INNs, the maximum rating possible following assessment performed under the conditions of this methodology is 145 points.

27. The maximum rating possible for medicinal products corresponding to reimbursable INNs in the List, following assessment in line with the conditions of this methodology is 80 points.

28. As a national competent authority for assessment of health technologies, the National Agency for Medicines and Medical Devices proposes to the Ministry of Health the List approved through Government Decision, in accordance with the law, for implementation of decisions made in line with this methodology.

B. Issuance of the decision on medicinal product inclusion, extension of indications, non-inclusion into or exclusion from the List is performed according to the following criteria:

1. Criteria for decision for unconditioned inclusion:

a) rating equal to or higher than 80 points;

b) cost of the combination lower or equal with the summation of components (in case of fixed combinations with already reimbursable components).

2. Criteria for decision for conditioned inclusion:

a) rating between 60 and 79 points; in this case, medicinal products are only provided in the frame of the social health insurance system based on the following documents, as required:

(i) cost-volume contracts;

(ii) cost-volume-result contracts;

b) the decision for conditional inclusion is valid for the time of contracts mentioned under point 2 a).

3. Criteria for decision for non-inclusion into the List:

a) INNs (other than those in sublist C) meant for in-hospital treatment;

b) non-prescription medicinal products (OTCs), except for products with specific indication for rare diseases and those intended for children under 18, young adults aged 18-26, if students/high-school graduates, until beginning of the academic year, but for no longer than 3 months, apprentices or students, if not paid for labour undertaken, as well as pregnant and breastfeeding women;

c) INNs rated under 60 points by health technologies assessment performed in line with this methodology.

4. Criteria for issuance of the decision on exclusion from the List: obtaining a score equal to or higher than 50 points following health technologies assessment performed in line with this methodology.

5. Criteria for decision for maintenance in the List: rating lower than - equal to 49 points by health technologies assessment performed in line with this methodology.

6. Criteria for the decision for automatic change/addition:

a) Already reimbursable INNs which, according to the SmPC, refer to a different population group than that initially defined, according to the sublist/section in the List in which they are included (other age group or inclusion into severe/invalidating disease category);

b) medicinal products corresponding to INNs included into several sublists/sections, with dissimilar conditions for prescription and reimbursement;

c) INNs for which health technologies assessment performed in line with this methodology has established a different level of reimbursement than previously;

d) extension of already reimbursable indications (age groups, new patient groups within the same indications) by update of the prescription protocol for the respective INN (medicinal products marked **, *** or ****).

7. Criteria for decision for elimination/addition of the (*), (**), (***) or (****) marking:

a) medicinal products corresponding to already reimbursable INNs, considered therapeutic standards (first line of treatment) according to European and international guidelines in force;

b) medicinal products corresponding to already reimbursable INNs, intended for extremely severe pathologies (life-threatening/limited survival);

c) medicinal products corresponding to already reimbursable INNs with outdated patent protection terms, leading to registration of generics/biosimilars;

d) closure of cost-volume and cost-volume-result contracts to facilitate patient ready access to treatment alternatives (establishing the target-patient profile, maximum number of patients treatable and duration of treatment).

II. Means of appeal for decisions on assessment of health technologies concerning medicinal product inclusion, extension of indications, non-inclusion into or exclusion from the List

1. Decisions of the National Agency for Medicines and Medical Devices on medicinal product non-inclusion into the List contain a rationale, based on objective and verifiable criteria, including, if needed, any approval or recommendation of the specialised commissions of the Ministry of Health, underlying the decision, which is notified to the applicant within maximum 7 working days after issuance. Moreover, the applicant is informed on means of appeal available in accordance with legislation in force, as well as on respective deadlines.

2. Decisions of the National Agency for Medicines and Medical Devices to exclude a medicinal product from the List contain a rationale, based on objective and verifiable criteria. Such decisions together with, if needed, any approval or recommendation of the specialised commissions of the Ministry of Health underlying the decisions are notified to the applicant within maximum 7 working days after issuance, and the applicant is informed on means of appeal available in accordance with the legislation in force, as well as on respective deadlines.

3. In case of Marketing Authorisation Holder disagreement with the decision, within 7 working days as of receipt of the official notification by the national competent authority, they may submit an appeal to the National Agency for Medicines and Medical Devices.

4. Within 5 working days as of registration of the application submitted to the National Agency for Medicines and Medical Devices, a new commission for

resolution of appeals is established, as approved through Order of the Minister of Health, consisting of: representatives of the Ministry of Health, of the National Health Insurance House, of the National Agency for Medicines and Medical Devices, one delegate for each leading manufacturer and patient national associations. Delegates of national leading associations of medicinal product manufacturer and patient associations have are granted observer status, without voting right.

5. The National Agency for Medicines and Medical Devices informs the delegate of the appellant Marketing Authorisation Holder, in writing, on the date scheduled for the meeting of the commission for resolution of appeals, at least two working days before the actual date.

6. Commission decisions on resolution of appeals are made through open vote with simple majority, in a meeting with delegates of the Marketing Authorisation Holder, in maximum 15 working days after set-up of the commission for resolution of appeals.

7. The minutes of the meeting and the decision of the commission for resolution of appeals is officially notified to the applicant, within maximum 7 working days after actual meeting of the commission for resolution of appeals, and posted on the website of the National Agency for Medicines and Medical Devices, under the dedicated section “Health Technologies Assessment”.

8. In case of disagreement with the decision of the commission for resolution of appeals, the Marketing Authorisation Holder may further appeal to competent legal courts.

ANNEX 3

DOCUMENTATION
to be submitted by applicants, methodological means used in the assessment for medicinal product inclusion, extension of indications, non-inclusion into or exclusion from the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs

1. For inclusion into the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs of a new medicinal product/indication, the applicant is required to submit the application at the offices of the National Agency for Medicines and Medical Devices, to the attention of the specialised structure for health technologies assessment, in accordance with the template mentioned in Annex 4 to this Order.

2. In addition to the application specified under point 1, the applicant shall also submit the following documents:

a) health technologies assessment reports issued by authorised agencies in France, Great Britain and Germany;

b) data required for calculation of therapy costs, as shown in Table 1 of Annex 2 to this Order;

c) the Summary of Product Characteristics approved by the National Agency for Medicines and Medical Devices or, as required, for the centralised procedure, by the European Medicines Agency on behalf of the European Commission;

d) proof of reimbursement in Member States: link(s) which attesting the reimbursement status or, if the information is not public, a statutory declaration of the Marketing Authorisation Holder;

e) the price approved by the Ministry of Health (copy issued by the CANAMED, decision for price approval or proof for submission of the price dossier to the competent authority for approval of medicinal product prices);

f) proof of payment of the fee for health technologies assessment by the National Agency for Medicines and Medical Devices, approved in accordance with the law;

g) letter of Marketing Authorisation Holder commitment attesting their firm undertaking to become involved in a cost-volume or cost-volume-result mechanism, in case of individually calculated ratings allowing for conditioned inclusion into the List.

ANNEX 4

Template

APPLICATION

for health technologies assessment in support of proposals for inclusion of new INNs, reimbursable INNs with extension of indication, generics with non-reimbursable INNs in the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs (the List), biosimilars with non- reimbursable INNs in the List and fixed-dose combinations in the List

1. Medicinal product identification data

An individual application shall be submitted for each strength and pharmaceutical form of the medicinal product for human use.

Trade name:
International Non-proprietary Name:
ATC code:
MA issued on:
Patent expiry date:

2. Pharmaceutical form, strength, administration route and package size:

Pharmaceutical form:
Strength:
Administration route:

3. Data on medicinal product price

Retail price per package:
Retail price per therapeutic unit:

4. Marketing Authorisation Holder

Name of the company:
Contact person:
Address:
City:
Country:

Telephone number:

Fax number:

E-mail:

5. Medicinal product type

- ☐ New INN
- ☐ Known INN with new therapeutic indication
- ☐ Association of two or several INNs
- ☐ Biosimilar medicinal product with INN not in the List
- ☐ Generic medicinal product with INN not in the List

6. Section of the List for which inclusion is proposed

- ☐ Sub-list A
- ☐ Sub-list B
- ☐ Sub-list C
  - ☐ Section C1
  - ☐ Section C2
  - ☐ Section C3

7. Therapeutic indication

Therapeutic indication:

Minimum Daily Dose:

Maximum Daily Dose:

Defined Daily Dose (DDD):

Average Therapy Duration (according to SmPC):

8. Data on assessment of health technologies (only provide for reports from France, Great Britain and Germany)

9. Data on reimbursement in Member States (please consider all Member States)

Country:

Reimbursed:

Level of reimbursement

Conditions for prescription (restrictions included) (yes/no):

Prescription protocol:

I hereby declare that all details on information provided in this application are accurate and complete. At the same time, I fully understand that, for verification and confirmation of declarations herein, the National Agency for Medicines and Medical Devices may legally request any corroborating documents. It is also my understanding that, should this application be non-compliant with actual facts, I am liable for breach of criminal law provisions relating to misrepresentation.

10. Signature of the Applicant, stamp and date

Applicant’s signature and stamp ..... Date ...../...../.....

ANNEX 5

GENERAL FRAMEWORK
for conditioned inclusion into the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs, based on cost-volume/cost-volume-result contracts

1. Cost-volume and cost-volume-result contracts are mechanisms ensuring better population access to effective therapy, financial sustainability and predictability of health costs.

2. The following documents are considered cost-volume contracts:

a) contracts according to which Marketing Authorisation Holders undertake to provide free of charge a specified number of units, for a determined number of patients, for a certain period of time, under specific conditions;

b) contracts by means of which Marketing Authorisation Holders undertake provision of the medicinal product included in the List for a certain negotiated price, for a certain category of patients, for a certain period of time.

3. The following documents are considered cost-volume-result:

a) contracts according to which Marketing Authorisation Holders undertake to provide free of charge a specified number of units, for a determined number of patients, for a certain period of time, provided that a defined therapeutic target is met;

b) contracts according to which Marketing Authorisation Holders undertake to provide the medicinal product included in the List for a certain negotiated price, for a certain category of patients, for a certain period of time, provided that a defined therapeutic target is met.

4. Minimum information to be included in the contracts mentioned under points 2 and 3 are as follows:

a) contract type;

b) patient number and profile;

c) number of units granted at no cost or for a certain negotiated price;

d) negotiated price of medicinal products;

e) time period;

f) sanctions for parties in case of noncompliance with contract provisions.

5. Cost-volume and cost-volume-result contracts are negotiated between the marketing authorisation holder or their legal representative in Romania and representatives of the Ministry of Health and of the National Health Insurance House.

6. Representatives of the Ministry of Health and of the National Health Insurance House signatory of the contracts mentioned under points 2 and are assigned through Order of the Minister of Health and of the President of the National Health Insurance House.

ORDER no. 860 of 22 July 2014
on approval of the organisational structure of the National Agency for Medicines and Medical Devices

ISSUED: THE MINISTRY OF HEALTH
PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, no. 560 of 29 July 2014

Taking into account:

- provisions of Article 14 (2) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as amended;
- provisions of Article 10 e) of Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended;
- The approval of the Administration Council of the National Agency for Medicines and Medical Devices in the extraordinary meeting of 15 July 2014,
- The endorsement report of the Directorate for management and organisation of healthcare facilities no. NB 5657 of 22 July 2014,

based on Article 7 (4) of Government Decision no. 144/2010, as amended,

the minister of health hereby issues the following order:

ARTICLE 1

The organisational structure of the National Agency for Medicines and Medical Devices is approved, in accordance with the Annex, which is integral part of this Order.

ARTICLE 2

On this Order coming into force, Order of the Minister of Health no. 1.275/2010 on approval of the organisational structure of the National Agency for Medicines and Medical Devices, published in the Official Gazette of Romania, Part I, no. 678 of 6 October 2010, is repealed.

ARTICLE 3

The special directorates of the Ministry of Health and the National Agency for Medicines and Medical Devices shall carry out provisions of this Order.

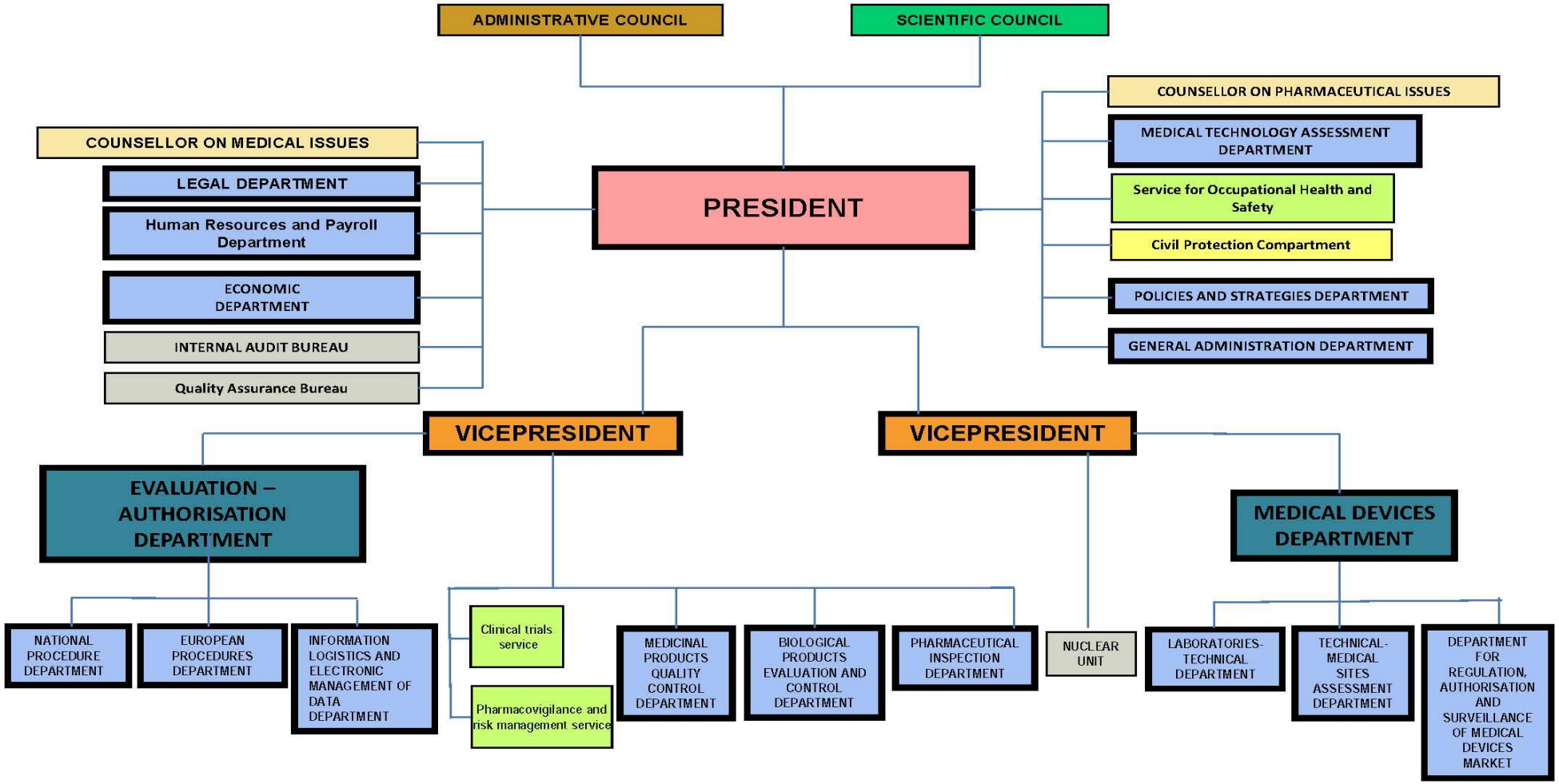
ARTICLE 4

This Order is to be published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health,
George Diga,
Secretary-General

Bucharest, 22 July 2014.
No. 860.

ANNEX 1



Organisational structure of the NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES

DECISION

no. 9/10.09.2014

on confirmation of adoption of non-ruling NAMMD Scientific Council Decisions, approved through written procedure

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 10.09.2014, in accordance with Article 12(5) of Government Decision No. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following :

DECISION

ARTICLE 1. – Adoption of the following non-ruling Scientific Council Decisions (SCDs) of the NAMMD, approved through written procedure, is confirmed:

- **SCD no. 3/10.05.2013** on approval of priority assessment through national procedure of marketing authorisation applications for International Non-proprietary Names (INNs) determined in short supply on the pharmaceutical market;
- **SCD no. 18/08.08.2013** on approval of the revised Guideline on evaluation of advertising of medicinal products for human use;
- **SCD no. 19/12.08.2013** on approval of the detailed Guideline concerning the various categories of variations to the terms of marketing authorisations and on their examination by the National Agency for Medicines and Medical Devices by national procedure for authorisation of medicinal products for human use, in accordance with Regulation (EC) no. 1234/2008 of the Commission, as amended through Regulation (EU) no. 712/2012;
- **SCD no. 22/12.08.2013** on approval of abbreviated Romanian Standard Terms for the labelling of parenteral, eye, ear and nasal preparations, in line with European Pharmacopoeia approved terms;
- **SCD no. 2/22.04.2014** on approval of Regulations for authorisation of sites for conduct of clinical trials on medicinal products for human use;
- **SCD no. 5/05.06.2014** on approval of the Guideline on Good Pharmacovigilance Practices – Annex I – Definitions, Rev. 2;
- **SCD no. 6/05.06.2014** on approval of the Regulations on the authorisation by the National Agency for Medicines and Medical Devices of clinical trials/notification to the National Agency for Medicines and Medical Devices of non-interventional studies on medicinal products for human use in Romania.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

Medicinal product batches recalled during the 3rd quarter of 2014

No.	Product recalled	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Date of recall
1	CORSODYL MINT MOUTHWASH	mouthwash	0.2g/ 1100 ml	chlohexidinum	GSK, Germany/ GSK, Great Britain	00280, 200117, 00360, 200236, 00461	Expiry of the 2-year shelf life (as shown in Order of the Minister of Health no. 279/2005) following NAMMD approval of MA variation no. 5522/2005/01 of 14.06.2014	Voluntary recall and destruction	7.06.2014
2	COLDREX MAXGRIP	tablets (box x 24 tablets)		COMBINATIONS	GSK, Ireland/ GSK, Great Britain	T388100191, T388100211, T388100301, T388110021, T388110031, T388110062, T388110071, T388110073, T388110081, T388110091, T388110231, T388110302, T388120051, T388120061	Expiry of the 2-year shelf life (as shown in Order of the Minister of Health no. 279/2005) following NAMMD approval of MA amendment no. 1755/2009/01-02-03 of 30.03.2012	Voluntary recall and destruction	9.07.2014
3	COLDREX MAXGRIP	tablets (box x 12 tablets)		COMBINATIONS	GSK, IRELAND/ GSK, Great Britain	T388100181, T388100311, T388110061, T388110072, T388120081	Expiry of the 2-year shelf life (as shown in Order of the Minister of Health no. 279/2005) following NAMMD approval of MA amendment no. 1755/2009/01-02-03 of 30.03.2012	Voluntary recall and destruction	9.07.2014
4	OTIS-T	ear drops		COMBINATIONS	TIS Farmaceutic SA	157060812, 186110912, 230091012, 258291012, 284141112, 003030113	The medicinal product contains *„lidocaine hydrochloride”*, an active substance manufactured by SIMS (Societa Italiana Medicali Scandicci SRL), manufacturer for whom the Italian competent authority has decided upon withdrawal of GMP certificate	Voluntary recall and destruction	8.08.2014
5	PRAMIPEXOL TORRENT	tablets	0.7 mg	pramipexolum	Heumann Pharma GmbH &CO. Generica KG, Germany/Torrent Pharma SRL, RO	BO64A001	Medicinal product found non-compliant following reanalysis of the product batch imported from India	Voluntary recall and destruction	4.08.2014
6	FLUMETOL	eye drops,		COMBINATIONS	Farmila-Thea	007015,	The medicinal product contains	Voluntary	4.08.2014

No.	Product recalled	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Date of recall
		suspension			Farmaceutici SPA, Italy/Thea Farma SPA, Italy	007013	"*tetrahydrozoline hydrochloride"*, an active substance manufactured by SIMS (Societa Italiana Medicali Scandicci SRL), manufacturer for whom the Italian competent authority has decided upon withdrawal of GMP certificate	recall and destruction	
7	SPERSALLERG	eye solution		combination	Novartis Pharma GmbH, Germany/ Laboratoires Thea, France	420930, 421611, 421632, 421970, 422149, 422398, 422626	The medicinal product contains "*tetrahydrozoline hydrochloride"*, an active substance manufactured by SIMS (Societa Italiana Medicali Scandicci SRL), manufacturer for whom the Italian competent authority has decided upon withdrawal of GMP certificate	Voluntary recall and destruction	4.08.2014
8	BIORINIL	nasal spray		COMBINATIONS	Farmila-Thea Farmaceutici SPA, Italy/Thea Farma SPA, Italy	022258, 022257, 022256, 022252, 022251, 022250, 022249, 022248, 022265, 022266, 022267, 022267A, 022268, 022269, 022270, 022271, 022272, 022273, 022274, 022275, 022276 022277A, 022277, 022281, 022282, 022289, 022247, 022246, 022245, 022244, 022243, 022242, 022240, 022239, 022238, 022237, 022236, 022235, 022234, 022233, 022232, 022248, 022229, 022228, 022227, 022226, 022225, 022222, 022221, 022220, 022220, 022219, 022218, 022217,	The medicinal product contains „ *Tetrahydrozoline Hydrochloride''*, an active substance manufactured by SIMS (Societa Italiana Medicali Scandicci SRL), manufacturer for whom the Italian competent authority has decided upon withdrawal of GMP certificate	Voluntary recall and destruction	4.08.2014

No.	Product recalled	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Date of recall
						022216, 022215, 022214, 022213			
9	COLDREX JUNIOR HOTREM	powder for oral suspension		COMBINATIONS	SmithKline Beecham SA, Spain/GSK Cons. Healthcare SRL, RO	2048, 3008, 3016, 3503	Expiry of the one-year deadline (as shown in Order of the Minister of Health no. 1810/2006) after NAMMD approval of the amendment to MA no. 8193/2006/01-02 of 20.08.2013 (transfer of the Marketing Authorisation Holder)	Voluntary recall and destruction	1.09.2014
10	Suspected counterfeit medicinal products distributed by Chemomed Intertrading S.R.L.	-	-	-	-	all batches	Suspected counterfeit medicinal products from an illegal supply chain (purchases from pharmacies performed by 4 wholesale distributors). Counterfeit products have entered the EU through this illegal supply chain	Recall by Chemomed Intertrading S.R.L. of all products distributed in Romania and the European Committee coming from wholesale distributors: Cross Pharm S.R.L., Agatha-Plus S.R.L., Benedict Pharma S.R.L. and Pharmax Interhealth S.R.L.	2.09.2014
11	STREPSILS PLUS	drops				AL227, AJ132 , AK592, AK597, AM701, AM702	The medicinal product contains *„lidocaine''*, active substance manufactured by SIMS (Societa Italiana Medicinali Scandicci SRL), manufacturer for whom the Italian competent authority has decided upon GMP certificate withdrawal	Voluntary recall and destruction	2.09.2014
12	SOLUȚIE RINGER LACTAT	sol. for infusion		COMBINATIONS	Infomed SRL		A foreign body (an insect) has been found in a bag containing sol. for infusion	Recall and destruction	9.2014

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 2nd quarter of 2014

During the 2nd quarter of 2014, 256 marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

A02 - Drugs for acid related disorders
A10 – Drugs used in diabetes
B02 – Antihemorrhagics
C01 – Cardiac therapy
C03 – Diuretics
C07 – Beta blocking agents
C08 – Calcium channel blockers
C09 – Agents acting on the renin-angiotensin system
C10 – Lipid modifying agents
G03 – Sex hormones and modulators of the genital system
G04 - Urologicals
H02 – Corticosteroids for systemic use
J01 – Antibacterial for systemic use
J02 – Antimycotics for systemic use
J05 – Antivirals for systemic use
L01 – Antineoplastic agents
L02 – Endocrine therapy
L04 – Imunosuppressants
M01 – Anti-inflammatory and antirheumatic products
M05 – Drugs for treatment of bone diseases
N01 - Anesthetics
N02 - Analgezics
N03 - Antiepileptics
N04 – Anti-parkinson drugs
N05 - Psycholeptics
N06 - Psychoanaleptics
N07 – Other nervous system drugs
P02 – Anthelmintics
R01 – Nasal preparations
R03 – Drugs for obstructive airway diseases
R05 – Cough and cold preparations
R06 – Antihistamines for systemic use
S01 - Ophthalmologicals
V08 – Contrast media

Medicinal products authorised for marketing during the 2nd quarter of 2014

INN	Invented name	Pharmaceutical form	Strength	Country	MA number		
ACETYLCYSTEINUM	ACC INJECT 300mg/3ml	nebuliser sol. for injection/inhalation	300mg/3ml	GERMANY	6604	2014	01
ACIDUM ACETYLSALICYLICUM	OLTROLA 75 mg	gastroresistant tablets	75mg	GREAT BRITAIN	6500	2014	07
ACIDUM ACETYLSALICYLICUM	OLTROLA 100 mg	gastroresistant tablets	100mg	GREAT BRITAIN	6501	2014	07
ACIDUM ACETYLSALICYLICUM+ ATORVASTATINUM+RAMIPRILUM	TRINOMIA 100 mg/20 mg/2.5 mg	capsules	00mg/20mg/2 .5mg	SPAIN	6486	2014	05
ACIDUM ACETYLSALICYLICUM+ ATORVASTATINUM+RAMIPRILUM	TRINOMIA 100 mg/20 mg/5 mg	capsules	100mg/20mg/ 5mg	SPAIN	6487	2014	05
ACIDUM ACETYLSALICYLICUM+ ATORVASTATINUM+RAMIPRILUM	TRINOMIA 100 mg/20 mg/10 mg	capsules	100mg/20mg/ 10mg	SPAIN	6488	2014	05
ALBENDAZOLUM	VERMIGAL NOVO 400 mg/10 ml	oral suspension	400mg/10ml	ROMANIA	6351	2014	01
ALFUZOSINUM	ALFUZOSINA AUROBINDO 10 mg	prolonged-release tablets	10mg	MALTA	6407	2014	05
AMBROXOLUM	MUCOSIN CU MIERE 15mg/5ml	syrup	15mg/5ml	CZECH REPUBLIC	6566	2014	01
AMLODIPINUM	AMLODIGAMMA 5 mg	tablets	5mg	GERMANY	6530	2014	05
AMLODIPINUM	AMLODIGAMMA 10 mg	tablets	10mg	GERMANY	6531	2014	05
AMPICILLINUM	STANDACILLIN 500 mg	powder for sol. for inj./infusion	500mg	AUSTRIA	6340	2014	02
ANASTROZOLUM	ELOZA 1 mg	film-coated tablets	1mg	CZECH REPUBLIC	6318	2014	08
ANASTROZOLUM	ANASTROZOL CIPLA 1 mg	film-coated tablets	1mg	GREAT BRITAIN	6607	2014	04
APOMORFINUM	DACEPTON 5 mg/ml	sol. for infusion	5mg/ml	GERMANY	6316	2014	05
AZITHROMYCINUM	AZITROMICINA TERAPIA 250 mg	film-coated tablets	250mg	ROMANIA	6396	2014	02
AZITHROMYCINUM	AZITROMICINA TERAPIA 500 mg	film-coated tablets	500mg	ROMANIA	6397	2014	02
AZITHROMYCINUM	AZITROMICINA TERAPIA 600 mg	film-coated tablets	600mg	ROMANIA	6398	2014	02
BACLOFENUM	LIORESAL 10 mg	tablets	10mg	GERMANY	6380	2014	01
BACLOFENUM	LIORESAL 25 mg	tablets	25mg	GERMANY	6381	2014	01

BENZOYLIS PEROXIDUM	BREVOXYL 40mg/g	cream	40mg/g	ROMANIA	6336	2014	05
BENZYDAMINUM	TANTUM VERDE CU GUST DE EUCALIPT 3 mg	pills	3mg	AUSTRIA	6497	2014	01
BENZYDAMINUM	TANTUM VERDE CU GUST DE PORTOCALĂ ŞI MIERE 3 mg	pills	3mg	AUSTRIA	6498	2014	01
BETAHISTINUM	BETAHISTINA ARCHIE SAMUEL 8 mg	tablets	8mg	CZECH REPUBLIC	6509	2014	02
BETAHISTINUM	BETAHISTINA ARCHIE SAMUEL 24 mg	tablets	24mg	CZECH REPUBLIC	6510	2014	01
BICALUTAMIDUM	BICALUTAMIDA CIPLA 50 mg	film-coated tablets	50mg	GREAT BRITAIN	6606	2014	03
BIMATOPROSTUM	BIMAGAN 0.3 mg/ml	eye drops, solution	0.3 mg/ml	ROMANIA	6317	2014	04
BISACODYLUM	DULCOLAX 10 mg	suppositories	10mg	GERMANY	6514	2014	01
BUTYLSCOPOLAMMONII BROMIDUM	SCOPANTIL 10 mg	tablets	10mg	ROMANIA	6466	2014	02
CARBAMAZEPINUM	CARBAMAZEPINA LPH 200 mg	tablets	200mg	ROMANIA	6556	2014	02
CEFACLORUM	CEFACLOR TERAPIA 500 mg	capsules	500mg	ROMANIA	6522	2014	01
CEFAZOLINUM	CEFAZOLINA HOSPIRA 1 g	powder for sol. for injection or infusion	1g	GREAT BRITAIN	6540	2014	04
CEFAZOLINUM	CEFAZOLINA HOSPIRA 2 g	powder for sol. for injection or infusion	2g	GREAT BRITAIN	6541	2014	04
CEFEPIMUM	CEFEPIME HOSPIRA 1 g	powder for sol. for injection or infusion	1g	GREAT BRITAIN	6408	2014	03
CEFEPIMUM	CEFEPIME HOSPIRA 2 g	powder for sol. for injection or infusion	2g	GREAT BRITAIN	6409	2014	03
CEFTRIAXONUM	CEFTRIAXONA HOSPIRA 500 mg	powder for sol. for injection	500mg	GREAT BRITAIN	6534	2014	04
CEFTRIAXONUM	CEFTRIAXONA HOSPIRA 1 g	powder for sol. for injection	1g	GREAT BRITAIN	6535	2014	04
CEFTRIAXONUM	CEFTRIAXONA HOSPIRA 2 g	powder for sol. for injection	2g	GREAT BRITAIN	6536	2014	04
CELECOXIBUM	CELECOXIB ACTAVIS 100 mg	capsules	100mg	ICELAND	6353	2014	06
CELECOXIBUM	CELECOXIB ACTAVIS 200 mg	capsules	200mg	ICELAND	6354	2014	06
CHLORAMBUCILUM	LEUKERAN 2 mg	film-coated tablets	2mg	IRELAND	6603	2014	01
CILOSTAZOLUM	NOCLAUD 50 mg	tablets	50mg	HUNGARY	6455	2014	02

CILOSTAZOLUM	NOCLAUD 100 mg	tablets	100mg	HUNGARY	6456	2014	02
CILOSTAZOLUM	CILOSTAZOL GALENICA 100 mg	tablets	100mg	GREECE	6598	2014	01
CIPROFLOXACINUM	CIPROFLOXACINA EMBEDDED SIGNAL PROCESSING LTD 2 mg/ml	sol. for infusion	2mg/ml	GREAT BRITAIN	6572	2014	04
CISPLATINUM	CISPLATINA KABI 1 mg/ml	conc. for sol. for infusion	1mg/ml	GREAT BRITAIN	6533	2014	04
CLARITHROMYCINUM	KLABAX 500 mg	film-coated tablets	500mg	ROMANIA	6464	2014	01
CLARITHROMYCINUM	KLABAX 250 mg	film-coated tablets	250mg	ROMANIA	6463	2014	01
CLARITHROMYCINUM	KLABAX 250 mg/5 ml	granules for oral suspension	250mg/5ml	ROMANIA	6544	2014	02
CLARITHROMYCINUM	KLABAX 125 mg/5 ml	granules for oral suspension	125mg/5ml	ROMANIA	6543	2014	02
CLARITHROMYCINUM	KLABAX MR 500 mg	modified-release tablets	500mg	ROMANIA	6465	2014	01
CLOPIDOGRELUM	TROMBEX 75 mg	film-coated tablets	75mg	CZECH REPUBLIC	6478	2014	10
COMBINATIONS	SEPTOMIXINE	dental paste		FRANCE	6334	2014	01
COMBINATIONS	STREPSILS LEMON WITHOUT ZAHĂR	pills		GREAT BRITAIN	6526	2014	02
COMBINATIONS	NIDOFLOR	cream		ROMANIA	6578	2014	01
COMBINATIONS	FLUOCINOLON N ATB 0.25 mg/5 mg/g	ointment	0.25mg/5mg/g	ROMANIA	6579	2014	01
COMBINATIONS	PHOXILIUM 1.2 mmole/l phosphate	sol. for haemodialysis and haemofiltration	1.2mmol	SWEDEN	6413	2014	04
COMBINATIONS	STREPSILS	pills		GREAT BRITAIN	6450	2014	02
COMBINATIONS	AMINOPLASMAL 100 mg/ml CU ELECTROLITI	sol. for infusion	100mg/ml	GERMANY	6475	2014	03
COMBINATIONS	VENASTAT 50 mg	prolonged-release capsules	50mg	GERMANY	6511	2014	02
COMBINATIONS	AMINOPLASMAL HEPA 100 g/l	sol. for infusion	100g/l	GERMANY	6523	2014	02
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	BUFOMIX EASYHALER 160 µgr/4.5 µgr/ inhalation	inhalation powder	160µgr/ 4.5µgr	FINLAND	6471	2014	06
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	BUFOMIX EASYHALER 320 µgr/9 µgr/ inhalation	inhalation powder	320µgr/ 9µgr	FINLAND	6472	2014	03

COMBINATIONS (DROSPIRENONUM+ ETINILESTRADIOLUM)	CLEONITA 28, 3 mg/0.02 mg	film-coated tablets	3mg/0.02 mg	ICELAND	6470	2014	05
COMBINATIONS (DROSPIRENONUM+ ETINILESTRADIOLUM)	CLEOSENSA 3 mg/0.030 mg	film-coated tablets	3mg/0.030 mg	ICELAND	6469	2014	05
COMBINATIONS (DROSPIRENONUM+ ETINILESTRADIOLUM)	CLEONITA 3 mg/0.02 mg	film-coated tablets	3mg/0.02 mg	ICELAND	6468	2014	05
COMBINATIONS (ENALAPRILUM+ LERCANIDIPINUM)	CORIPREN 20 mg/20 mg	film-coated tablets	20mg/20mg	IRELAND	6559	2014	11
COMBINATIONS (ESTRADIOLUM + DIENOGESTUM)	QLAIRA	film-coated tablets		GERMANY	6582	2014	03
COMBINATIONS (FERROSI SULFAS+ ACIDUM ASCORBICUM)	SORBIFER DURULES 100 mg+60 mg	film-coated tablets	100mg+60mg	HUNGARY	6512	2014	01
COMBINATIONS (GESTODENUM+ ETINILESTRADIOLUM)	LOGEST 0.075 mg/0.02 mg	drops	0.075mg/0.02mg	GERMANY	6335	2014	01
COMBINATIONS (GESTODENUM+ ETINILESTRADIOLUM)	VONILLE 60 µgr/15 µgr	film-coated tablets	60µgr/15µgr	HUNGARY	6476	2014	03
COMBINATIONS (GESTODENUM+ ETINILESTRADIOLUM)	APLEEK	transdermal patch	13µgr/24 hr.+ 60µgr/24 hr	GERMANY	6542	2014	03
COMBINATIONS (IBUPROFENUM+FENILEFRINUM)	IBUPROFEN/CLORHIDRAT DE FENILEFRINA ZENTIVA 200 mg/5 mg	film-coated tablets	200mg/5mg	CZECH REPUBLIC	6362	2014	02
COMBINATIONS (LATANOPROSTUM+TIMOLOLUM)	GLAUTAN PLUS 50 µgr/ml + 5 mg/ml	eye drops, solution	50µgr/ml+5 mg/ml	ROMANIA	6422	2014	01
COMBINATIONS (LIPIDE)	LIPOFUNDIN MCT/LCT 200 mg/ml	emulsion for infusion	200mg/ml	GERMANY	6493	2014	04
COMBINATIONS (LOSARTANUM+AMLODIPINUM)	TENLORIS 50 mg/5 mg	film-coated tablets	50mg/5mg	SLOVENIA	6388	2014	06
COMBINATIONS (LOSARTANUM+AMLODIPINUM)	TENLORIS 50 mg/10 mg	film-coated tablets	50mg/10mg	SLOVENIA	6389	2014	06

COMBINATIONS (LOSARTANUM+AMLODIPINUM)	TENLORIS 100 mg/5 mg	film-coated tablets	100mg/5mg	SLOVENIA	6390	2014	06
COMBINATIONS (LOSARTANUM+AMLODIPINUM)	TENLORIS 100 mg/10 mg	film-coated tablets	100mg/10mg	SLOVENIA	6391	2014	06
COMBINATIONS (OXICODONUM+NALOXONUM)	TARGIN 5 mg/2.5mg	prolonged-release tablets	5mg/2.5mg	AUSTRIA	6399	2014	12
COMBINATIONS (OXICODONUM+NALOXONUM)	TARGIN 10 mg/5mg	prolonged-release tablets	10mg/5mg	AUSTRIA	6400	2014	12
COMBINATIONS (OXICODONUM+NALOXONUM)	TARGIN 20 mg/10mg	prolonged-release tablets	20mg/10mg	AUSTRIA	6401	2014	12
COMBINATIONS (OXICODONUM+NALOXONUM)	TARGIN 40 mg/20mg	prolonged-release tablets	40mg/20mg	AUSTRIA	6402	2014	12
COMBINATIONS (OXICODONUM+NALOXONUM)	TARGIN 2.5 mg/1.25 mg	prolonged-release tablets	2.5mg/1.25mg	AUSTRIA	6599	2014	11
COMBINATIONS (OXICODONUM+NALOXONUM)	TARGIN 15 mg/7.5 mg	prolonged-release tablets	15mg/7.5mg	AUSTRIA	6600	2014	11
COMBINATIONS (OXICODONUM+NALOXONUM)	TARGIN 30 mg/15 mg	prolonged-release tablets	30mg/15mg	AUSTRIA	6601	2014	11
COMBINATIONS (PERINDOPRILUM+AMLODIPINUM+ INDAPAMIDUM)	TRIPLIXAM	film-coated tablets	2.5mg/5mg/ 0.625mg	FRANCE	6481	2014	05
COMBINATIONS (PERINDOPRILUM+AMLODIPINUM+ INDAPAMIDUM)	TRIPLIXAM	film-coated tablets	5mg/5mg/1.25mg	FRANCE	6482	2014	05
COMBINATIONS (PERINDOPRILUM+AMLODIPINUM+ INDAPAMIDUM)	TRIPLIXAM	film-coated tablets	5mg/10mg/1.25mg	FRANCE	6483	2014	05
COMBINATIONS (PERINDOPRILUM+AMLODIPINUM+ INDAPAMIDUM)	TRIPLIXAM	film-coated tablets	10mg/5mg/2.5mg	FRANCE	6484	2014	05
COMBINATIONS (PERINDOPRILUM+AMLODIPINUM+ INDAPAMIDUM)	TRIPLIXAM	film-coated tablets	10mg/10mg/2.5mg	FRANCE	6485	2014	05
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMLORA 5 mg/5 mg	capsules	5mg/5mg	CZECH REPUBLIC	6608	2014	10

COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMLORA 5 mg/10 mg	capsules	5mg/10mg	CZECH REPUBLIC	6609	2014	10
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMLORA 10 mg/5 mg	capsules	10mg/5mg	CZECH REPUBLIC	6610	2014	10
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMLORA 10 mg/10 mg	capsules	10mg/10mg	CZECH REPUBLIC	6611	2014	10
DACARBAZINUM	DACARBAZINA LIPOMED 200 mg	powder for sol. for injection or infusion	200 mg	GERMANY	6357	2014	01
DESLORATADINUM	LORDESTIN 0.5 mg/ml	oral solution	0.5mg/ml	ROMANIA	6327	2014	03
DESOGESTRELUM	DESIRETT 75 µgr	film-coated tablets	75µgr	SPAIN	6539	2014	03
DICLOFENACUM	DICLOFENAC ARENA 25 mg	gastroresistant drops	25mg	ROMANIA	6360	2014	02
DICLOFENACUM	DICLOFENAC TERAPIA 10mg/g	gel	10mg/g	ROMANIA	6513	2014	01
DICLOFENACUM	DICLOFENAC ARENA 50 mg	gastroresistant drops	50mg	ROMANIA	6361	2014	03
DICLOFENACUM	DICLOFENAC MCC 10 mg/g	gel	10mg/g	ROMANIA	6495	2014	02
DICLOFENACUM	DICLOFENAC MCC 50 mg/g	gel	50mg/g	ROMANIA	6496	2014	02
DIOSMINUM	FLEVENOL 500 mg	film-coated tablets	500mg	LUXEMBOURG	6491	2014	02
DOBUTAMINUM	DOBUTAMINA PANPHARMA 250 mg/20 ml	conc. for sol. for infusion	250mg/20ml	FRANCE	6330	2014	03
DONEPEZILUM	PRIDIA 5 mg	film-coated tablets	5mg	ROMANIA	6489	2014	07
DONEPEZILUM	PRIDIA 10 mg	film-coated tablets	10mg	ROMANIA	6490	2014	07
DORNAZA ALFA	PULMOZYME 2500 U/2.5 ml	nebuliser solution	2500U/2.5ml	ROMANIA	6524	2014	01
DORZOLAMIDUM	DORZOLAMIDA ARENA 20 mg/ml	eye drops, solution	20mg/ml	ROMANIA	6557	2014	01
DUTASTERIDUM	DUTASTERIDA SANDOZ 0.5 mg	soft capsules	0.5mg	ROMANIA	6410	2014	12
ENALAPRILUM	ENAL 5 mg	tablets	5mg	ROMANIA	6337	2014	01
ENALAPRILUM	ENAL 10 mg	tablets	10mg	ROMANIA	6338	2014	01
ENALAPRILUM	ENAL 20 mg	tablets	20mg	ROMANIA	6339	2014	01
EPIRUBICINUM	EPIRUBICIN EBEWE 2 mg/ml	conc. for sol. for injection	2mg/ml	AUSTRIA	6494	2014	03
ERYTHROMYCINUM	ERITROMICINA ATB 200 mg	tablets	200mg	ROMANIA	6555	2014	02
ESCITALOPRAMUM	ESLOREX 5 mg	film-coated tablets	5mg	CZECH REPUBLIC	6392	2014	02
ESCITALOPRAMUM	ESLOREX 10 mg	film-coated tablets	10mg	CZECH REPUBLIC	6393	2014	02

ESCITALOPRAMUM	ESLOREX 15 mg	film-coated tablets	15mg	CZECH REPUBLIC	6394	2014	02
ESCITALOPRAMUM	ESLOREX 20 mg	film-coated tablets	20mg	CZECH REPUBLIC	6395	2014	02
ESCITALOPRAMUM	ESCITALOPRAM ACTAVIS 10 mg	film-coated tablets	10mg	ICELAND	6377	2014	12
ESCITALOPRAMUM	ESCITALOPRAM ACTAVIS 20 mg	film-coated tablets	20mg	ICELAND	6378	2014	11
ESCITALOPRAMUM	ELICEA 5 mg	film-coated tablets	5mg	SLOVENIA	6424	2014	09
ESCITALOPRAMUM	ELICEA 10 mg	film-coated tablets	10mg	SLOVENIA	6425	2014	09
ESCITALOPRAMUM	ELICEA 15 mg	film-coated tablets	15mg	SLOVENIA	6426	2014	09
ESCITALOPRAMUM	ELICEA 20 mg	film-coated tablets	20mg	SLOVENIA	6427	2014	09
ESCITALOPRAMUM	ESLOREX 5 mg	orodispersible tablets	5mg	CZECH REPUBLIC	6324	2014	10
ESCITALOPRAMUM	ESLOREX 10 mg	orodispersible tablets	10mg	CZECH REPUBLIC	6325	2014	10
ESCITALOPRAMUM	ESLOREX 20 mg	orodispersible tablets	20mg	CZECH REPUBLIC	6326	2014	10
ESCITALOPRAMUM	ESCITALOPRAM LABORMED 10 mg	orodispersible tablets	10mg	ROMANIA	6419	2014	01
ESCITALOPRAMUM	ESCITALOPRAM LABORMED 15 mg	orodispersible tablets	15mg	ROMANIA	6420	2014	01
ESCITALOPRAMUM	ESCITALOPRAM LABORMED 20 mg	orodispersible tablets	20mg	ROMANIA	6421	2014	01
ESCITALOPRAMUM	ESCITALOPRAM AUROBINDO 10 mg	film-coated tablets	10mg	GREAT BRITAIN	6436	2014	09
ESCITALOPRAMUM	ESCITALOPRAM TEVA 10 mg	orodispersible tablets	10mg	ROMANIA	6445	2014	11
ESCITALOPRAMUM	ESCITALOPRAM TEVA 20 mg	orodispersible tablets	20mg	ROMANIA	6446	2014	11
ESCITALOPRAMUM	SAVANDRA 5 mg	film-coated tablets	5mg	FRANCE	6457	2014	05
ESCITALOPRAMUM	SAVANDRA 10 mg	film-coated tablets	10mg	FRANCE	6458	2014	05
ESCITALOPRAMUM	SAVANDRA 15 mg	film-coated tablets	15mg	FRANCE	6459	2014	05
ESCITALOPRAMUM	SAVANDRA 20 mg	film-coated tablets	20mg	FRANCE	6460	2014	05
ESCITALOPRAMUM	SENTIPRA 5 mg	orodispersible tablets	5mg	ROMANIA	6593	2014	01
ESCITALOPRAMUM	SENTIPRA 10 mg	orodispersible tablets	10mg	ROMANIA	6594	2014	01
ESCITALOPRAMUM	SENTIPRA 15 mg	orodispersible tablets	15mg	ROMANIA	6595	2014	01
ESCITALOPRAMUM	SENTIPRA 20 mg	orodispersible tablets	20mg	ROMANIA	6596	2014	01

ETOPOSIDUM	ETOPOZIDA KABI 20 mg/ml	conc. for sol. for infusion	20mg/ml	GREAT BRITAIN	6356	2014	04
ETOPOSIDUM	ETOPOSID EBEWE 100 mg/5 ml	conc. for sol. for infusion	100mg/5ml	AUSTRIA	6437	2014	02
ETOPOSIDUM	ETOPOSID EBEWE200 mg/10 ml	conc. for sol. for infusion	200mg/10ml	AUSTRIA	6438	2014	02
ETOPOSIDUM	ETOPOSID ACCORD 20 mg/ml	conc. for sol. for infusion	20mg/ml	GREAT BRITAIN	6597	2014	02
FENTANYLUM	LUNALDIN 100 µgr	sublingual tablets	100µgr	HUNGARY	6515	2014	02
FENTANYLUM	LUNALDIN 200 µgr	sublingual tablets	200µgr	HUNGARY	6516	2014	02
FENTANYLUM	LUNALDIN 300 µgr	sublingual tablets	300µgr	HUNGARY	6517	2014	02
FENTANYLUM	LUNALDIN 600 µgr	sublingual tablets	600µgr	HUNGARY	6519	2014	02
FENTANYLUM	LUNALDIN 800 µgr	sublingual tablets	800µgr	HUNGARY	6520	2014	02
FENTANYLUM	FENTANYL TTS SANDOZ 25 µg/h	transdermal patch	25µg/h	ROMANIA	6451	2014	12
FENTANYLUM	FENTANYL TTS SANDOZ 75 µg/h	transdermal patch	75µg/h	ROMANIA	6453	2014	12
FENTANYLUM	FENTANYL TTS SANDOZ 50 µg/h	transdermal patch	50µg/h	ROMANIA	6452	2014	12
FENTANYLUM	FENTANYL TTS SANDOZ 100 µg/h	transdermal patch	100µg/h	ROMANIA	6454	2014	12
FENTANYLUM	LUNALDIN 400 µgr	sublingual tablets	400µgr	HUNGARY	6518	2014	02
FLUCONAZOLUM	FLUCONAZOLE B. BRAUN 2mg/ml	sol. for infusion	2mg/ml	GERMANY	6563	2014	09
FLUOXETINUM	FLUOXETIN ARENA 10 mg	capsules	10mg	ROMANIA	6320	2014	02
FLUOXETINUM	FLUOXETIN ARENA 20 mg	capsules	20mg	ROMANIA	6321	2014	02
FLUTICASONUM PROPIONAT	FLIXONASE 0.05 g/100 g	nasal spray, solution	0.05g/100g	GREAT BRITAIN	6605	2014	02
FORMOTEROLUM	FORTULIN NOVOLIZER 6 µgr/dose	inhalation powder	6µgr/dose	GERMANY	6580	2014	11
FORMOTEROLUM	FORTULIN NOVOLIZER 12 µgr/dose	inhalation powder	12µgr/dose	GERMANY	6581	2014	11
FUROSEMIDUM	FUROSEMID BIOEEL 40 mg	tablets	40mg	ROMANIA	6602	2014	01
GABAPENTINUM	GRIMODIN 600 mg	film-coated tablets	600mg	HUNGARY	6428	2014	03
GABAPENTINUM	GRIMODIN 800 mg	film-coated tablets	800mg	HUNGARY	6429	2014	03
HALOPERIDOLUM	HALOPERIDOL RICHTER 50 mg/ml	sol. for injection	50mg/ml	ROMANIA	6525	2014	01
HEPARINUM	HEPARIN NATRIUM 25000 RATIOPHARM	sol. for injection	25000 IU/5ml	ROMANIA	2	2014	01
IBUPROFENUM	SARIDON N 200	film-coated tablets	200mg	ROMANIA	6382	2014	03
IBUPROFENUM	SARIDON N 400	film-coated tablets	400mg	ROMANIA	6383	2014	03

IBUPROFENUM	IBUPROFEN POLPHARMA 100 mg/5 ml	oral suspension	100mg/5ml	POLAND	6480	2014	02
IRBESARTANUM	IRBEC 75 mg	tablets	75mg	SPAIN	6344	2014	04
IRBESARTANUM	IRBEC 150 mg	tablets	150mg	SPAIN	6345	2014	04
IRBESARTANUM	IRBEC 300 mg	tablets	300mg	SPAIN	6346	2014	04
IRBESARTANUM	IRBESARTAN LICONSA 75 mg	tablets	75mg	SPAIN	6341	2014	04
IRBESARTANUM	IRBESARTAN LICONSA 150 mg	tablets	150mg	SPAIN	6342	2014	04
IRBESARTANUM	IRBESARTAN LICONSA 300 mg	tablets	300mg	SPAIN	6343	2014	04
KETAMINUM	CALYPSOL 50mg/ml	sol. for injection	50mg/ml	ROMANIA	6439	2014	01
KETOPROFENUM	PROFENID 100 mg	film-coated tablets	100mg	FRANCE	6448	2014	01
LAMOTRIGINUM	LAMOTRIN 50 mg	orodispersible tablets	50mg	ICELAND	6552	2014	11
LAMOTRIGINUM	LAMOTRIN 100 mg	orodispersible tablets	100mg	ICELAND	6553	2014	11
LETROZOLUM	LETROZOL ALVOGEN 2.5 mg	film-coated tablets	2.5mg	LUXEMBOURG	6411	2014	09
LEUPRORELINUM	LUCRIN DEPOT 11.25mg	prolonged-release powder for suspension for injection	11.25mg	SPAIN	6568	2014	01
LEUPRORELINUM	LUCRIN DEPOT 3.75mg	prolonged-release powder for suspension for injection	3.75mg	SPAIN	6567	2014	01
LEVETIRACETAMUM	PREPALEPAN 5 mg/ml	sol. for infusion	5mg/ml	AUSTRIA	6573	2014	01
LEVETIRACETAMUM	PREPALEPAN 10 mg/ml	sol. for infusion	10mg/ml	AUSTRIA	6574	2014	01
LEVETIRACETAMUM	PREPALEPAN 15 mg/ml	sol. for infusion	15mg/ml	AUSTRIA	6575	2014	01
LEVOFLOXACINUM	L-OPTIC 5 mg/ml	eye drops, solution	5mg/ml	ROMANIA	6423	2014	01
LEVONORGESTRELUM	ALMIDONA 750 µgr	tablets	750µgr	ICELAND	6364	2014	01
LEVONORGESTRELUM	ALETIYONE 1500 µgr	tablets	1500µgr	SPAIN	6479	2014	01
LEVOSIMENDANUM	SIMDAX 2.5 mg/ml	conc. for sol. for infusion	2.5mg/ml	FINLAND	6449	2014	01
LINEZOLIDUM	LINEZOLID SANDOZ 2 mg/ml	sol. for infusion	2mg/ml	ROMANIA	6328	2014	12
LINEZOLIDUM	GRAMPOSIMIDE 2 mg/ml	sol. for infusion	2mg/ml	HOLLAND	6372	2014	12
LOPERAMIDUM	ENTERIUM 2 mg	capsules	2 mg	ROMANIA	6467	2014	01
LOPERAMIDUM	LOPERAMID LAROPHARM 1 mg/5 ml	oral solution	1mg/5ml	ROMANIA	6499	2014	01
LORATADINUM	LORATADINA LPH 10 mg	tablets	10mg	ROMANIA	6352	2014	01
MELOXICAMUM	MELOXICAM SANDOZ 7.5 mg	tablets	7.5mg	GERMANY	6440	2014	06
MELOXICAMUM	MELOXICAM SANDOZ 15 mg	tablets	15mg	GERMANY	6441	2014	06
MELOXICAMUM	MELOX 15 mg/1.5 ml	sol. for injection	15mg/ml	CYPRUS	6358	2014	03
MENOTROPINUM	MENOPUR 600 IU	powder and solvent for sol. for injection	600 IU	GERMANY	6587	2014	01

MENOTROPINUM	MENOPUR 1200 IU	powder and solvent for sol. for injection	1200 IU	GERMANY	6588	2014	01
MEROPENEMUM	MERONEM I.V. 500 mg	powder for i.v. sol. for injection/infusion	500mg	GREAT BRITAIN	6405	2014	02
MEROPENEMUM	MERONEM I.V. 1 g	powder for i.v. sol. for injection/infusion	1g	GREAT BRITAIN	6406	2014	02
METHOTREXATUM	METOJECT 50mg/ml	sol. for injection in pre-filled syringe	50mg/ml	GERMANY	6561	2014	160
METRONIDAZOLUM	GRINAZOLE 100 mg/g	dental paste	100 mg/g	FRANCE	6331	2014	01
METRONIDAZOLUM	METRONIDAZOL ARENA 250 mg (J01XD01)	tablets	250mg	ROMANIA	6350	2014	01
METRONIDAZOLUM	METRONIDAZOL ARENA 250 mg (P01AB1)	tablets	250mg	ROMANIA	6350	2014	02
MIRTAZAPINUM	MIRZATEN Q-TAB 15 mg	orodispersible tablets	15mg	SLOVENIA	6442	2014	18
MIRTAZAPINUM	MIRZATEN Q-TAB 30 mg	orodispersible tablets	30mg	SLOVENIA	6443	2014	18
MIRTAZAPINUM	MIRZATEN Q-TAB 45 mg	orodispersible tablets	45mg	SLOVENIA	6444	2014	18
MOMETASONUM	MOMETAZONA FUROAT CIPLA 50 µgr/dose	nasal spray, suspension	50µgr/dose	GREAT BRITAIN	6355	2014	01
MOXIFLOXACINUM	MOXIFLOXACINA KABI 400 mg/250 ml	sol. for infusion	400mg/250ml	ROMANIA	6412	2014	10
MOXIFLOXACINUM	MOFLAXA 400 mg	film-coated tablets	400mg	SLOVENIA	6560	2014	12
MOXIFLOXACINUM	MOXIFLOXACINA PHARMATHEN 400 mg	film-coated tablets	400mg	GREECE	6562	2014	09
OLODATEROLUM	STRIVERDI RESPIMAT 2.5 µgr	sol. for inhalation	2.5µgr	GERMANY	6414	2014	04
OMEPRAZOLUM	ORTANOL 40 mg	gastroresistant capsules	40mg	SLOVENIA	6492	2014	02
OXIGENUM	OXIGEN SOL 100%	cryogenic medical gas	100%	ITALY	6550	2014	02
OXIGENUM	OXIGEN SOL 100%	cryogenic medical gas in cylinder	100%	ITALY	6551	2014	01
OXIGENUM	OXIGEN SOL 100%	medical gas, compressed	100%	ITALY	6549	2014	36
OXYCODONUM	RELTEBON 10 mg	prolonged-release tablets	10mg	ICELAND	6368	2014	22
OXYCODONUM	RELTEBON 20 mg	prolonged-release tablets	20mg	ICELAND	6369	2014	22
OXYCODONUM	RELTEBON 40 mg	prolonged-release tablets	40mg	ICELAND	6370	2014	22
OXYCODONUM	RELTEBON 80 mg	prolonged-release tablets	80mg	ICELAND	6371	2014	22
OXYCODONUM	CLORHIDRAT DE OXICODONA TORRENT 10 mg	prolonged-release tablets	10mg	ROMANIA	6373	2014	22

OXYCODONUM	CLORHIDRAT DE OXICODONA TORRENT 40 mg	prolonged-release tablets	40mg	ROMANIA	6375	2014	22
OXYCODONUM	CLORHIDRAT DE OXICODONA TORRENT 80 mg	prolonged-release tablets	80mg	ROMANIA	6376	2014	22
PANTOPRAZOLUM	PANTOPRAZOL TORRENT 20 mg	gastroresistant tablets	20mg	ROMANIA	6347	2014	01
PANTOPRAZOLUM	PANTOPRAZOL TORRENT 40 mg	gastroresistant tablets	40mg	ROMANIA	6348	2014	01
PANTOPRAZOLUM	PANTOR 20 mg	gastroresistant tablets	20mg	ROMANIA	6349	2014	01
PANTOPRAZOLUM	PANTOPRAZOL BEXIMCO PHARMA 20 mg	gastroresistant tablets	20mg	GREAT BRITAIN	6502	2014	01
PANTOPRAZOLUM	PANTOPRAZOL BEXIMCO PHARMA 40 mg	gastroresistant tablets	40mg	GREAT BRITAIN	6503	2014	01
PARACETAMOLUM	PANADOL 1 g	film-coated tablets	1g	GREAT BRITAIN	6379	2014	01
PIROXICAMUM	PIROXICAM ATB 30mg/g	cream	30mg/g	ROMANIA	6528	2014	01
PIROXICAMUM	PIROXICAM ATB 5 mg/g	gel	5mg/g	ROMANIA	6527	2014	01
PRAMIPEXOLUM	CALMOLAN 0,26 mg	prolonged-release tablets	0,26mg	AUSTRIA	6504	2014	03
PRAMIPEXOLUM	CALMOLAN 0.52 mg	prolonged-release tablets	0.52mg	AUSTRIA	6505	2014	03
PRAMIPEXOLUM	CALMOLAN 1.05 mg	prolonged-release tablets	1.05mg	AUSTRIA	6506	2014	03
PRAMIPEXOLUM	CALMOLAN 2.1 mg	prolonged-release tablets	2.1mg	AUSTRIA	6507	2014	03
PRAMIPEXOLUM	CALMOLAN 3.15 mg	prolonged-release tablets	3.15mg	AUSTRIA	6508	2014	03
PRILOCAINUM	PRILOTEKAL 20 mg/ml	sol. for injection	20mg/ml	HOLLAND	6583	2014	01
PROPOFOLUM	PROPOFOL SANDOZ 10 mg/ml	emulsion for injection/infusion	10mg/ml	ROMANIA	6537	2014	05
PROPOFOLUM	PROPOFOL SANDOZ 20 mg/ml	emulsion for injection/infusion	20mg/ml	ROMANIA	6538	2014	02
PYRANTELUM	HELMINTOX 250 mg	film-coated tablets	250mg	FRANCE	6323	2014	01
PYRANTELUM	HELMINTOX 125 mg	film-coated tablets	125mg	FRANCE	6322	2014	01
QUETIAPINUM	HEDONIN 100 mg	film-coated tablets	100mg	AUSTRIA	6416	2014	03
QUETIAPINUM	HEDONIN 200 mg	film-coated tablets	200mg	AUSTRIA	6417	2014	03
QUETIAPINUM	HEDONIN 300 mg	film-coated tablets	300mg	AUSTRIA	6418	2014	02
QUETIAPINUM	HEDONIN 25 mg	film-coated tablets	25mg	AUSTRIA	6415	2014	02
QUETIAPINUM	EUFRENIN 50 mg	prolonged-release tablets	50mg	ROMANIA	6329	2014	18
RAMIPRILUM	RAMIPRIL AUROBINDO 5 mg	tablets	5mg	MALTA	6547	2014	15
RAMIPRILUM	RAMIPRIL AUROBINDO 10 mg	tablets	10mg	MALTA	6548	2014	11
RIBAVIRINUM	VILARIB 200 mg	film-coated tablets	200mg	POLAND	6365	2014	01
RIBAVIRINUM	VILARIB 400 mg	film-coated tablets	400mg	POLAND	6366	2014	01

RIBAVIRINUM	VILARIB 600 mg	film-coated tablets	600mg	POLAND	6367	2014	01
RIFAXIMINUM	NORMIX 200mg/10ml	granules for oral suspension	200mg/10ml	ITALY	6554	2014	01
RIMANTADINUM	REMAVIR 50 mg	tablets	50mg	ROMANIA	6569	2014	01
RIVASTIGMINUM	RIVASTIGMINA SANDOZ 4.6 mg/24 ore	transdermal patch	4.6mg/24ore	ROMANIA	6584	2014	04
RIVASTIGMINUM	RIVASTIGMINA SANDOZ 9.5 mg/24 ore	transdermal patch	9.5mg/24ore	ROMANIA	6585	2014	04
RIVASTIGMINUM	RIVASTIGMINA DR. REDDY'S 4.6 mg/24 ore	transdermal patch	4.6mg/24ore	ROMANIA	6570	2014	06
RIVASTIGMINUM	RIVASTIGMINA DR. REDDY'S 9.5 mg/24 ore	transdermal patch	4.6mg/24ore	ROMANIA	6571	2014	06
ROSUVASTATINUM	ROZUCOR 5 mg	film-coated tablets	5mg	ROMANIA	6384	2014	18
ROSUVASTATINUM	ROZUCOR 10 mg	film-coated tablets	10mg	ROMANIA	6385	2014	18
ROSUVASTATINUM	ROZUCOR 20 mg	film-coated tablets	20mg	ROMANIA	6386	2014	18
ROSUVASTATINUM	ROZUCOR 40 mg	film-coated tablets	40mg	ROMANIA	6387	2014	18
SERTRALINUM	SETALOFT 50 mg	film-coated tablets	50mg	ICELAND	6461	2014	19
SERTRALINUM	SETALOFT 100 mg	film-coated tablets	100mg	ICELAND	6462	2014	19
SERTRALINUM	SERTRALINA PFIZER 50 mg	film-coated tablets	50mg	GREAT BRITAIN	6473	2014	16
SERTRALINUM	SERTRALINA PFIZER 100 mg	film-coated tablets	100mg	GREAT BRITAIN	6474	2014	16
SPIRONOLACTONUM	SPIRONOLACTONA TERAPIA 25 mg	film-coated tablets	25mg	ROMANIA	6359	2014	01
SPIRONOLACTONUM	SPIRONOLACTONA BIOEEL 50 mg	tablets	50mg	ROMANIA	6576	2014	01
SPIRONOLACTONUM	SPIRONOLACTONA BIOEEL 100 mg	tablets	100mg	ROMANIA	6577	2014	01
TC 99 M - ACID DIRMERCOPTO SUCCINIC	TECHNESCAN DMSA 1.2 mg	kit for radiopharmaceutical preparation	1.2mg	HOLLAND	6521	2014	01
TENOFOVIRUM DISOPROXIL FUMARATE	TENOFOVIR DISOPROXIL TEVA 245 mg	film-coated tablets	245mg	ROMANIA	6532	2014	18
TOLTERODINUM	DETRUSITOL SR 4 mg	prolonged-release capsules	4mg	GREAT BRITAIN	6404	2014	05
TOLTERODINUM	DETRUSITOL SR 2 mg	prolonged-release capsules	2mg	GREAT BRITAIN	6403	2014	05
TOPIRAMATUM	LUSITRAX 25 mg	film-coated tablets	25mg	ROMANIA	6589	2014	03

TOPIRAMATUM	LUSITRAX 50 mg	film-coated tablets	50mg	ROMANIA	6590	2014	03
TOPIRAMATUM	LUSITRAX 100mg	film-coated tablets	100mg	ROMANIA	6591	2014	03
TOPIRAMATUM	LUSITRAX 200mg	film-coated tablets	200mg	ROMANIA	6592	2014	02
TRIPTORELINUM	GONAPEPTYL ZILNIC 0.1 mg/1 ml	sol. for injection	0.1mg/1ml	GERMANY	6319	2014	02
VACCIN BCG	BCG VACCINE	powder and solvent for suspension for injection		ROMANIA	88	2014	01
VACCIN DIFTERO-TETANO-PERTUSSIS ACELULAR	ADACEL	suspension for injection		FRANCE	6447	2014	03
VACCIN HEPATITIC B	ENGERIX B 10 µg/0.5 ml	suspension for injection	10µg/0.5 ml	BELGIUM	6545	2014	17
VACCIN HEPATITIC B	ENGERIX B 20 µg/ml	suspension for injection	20µg/ml	BELGIUM	6546	2014	19
VALGANCICLOVIRUM	VALGANCICLOVIR TEVA 450 mg	film-coated tablets	450mg	ROMANIA	6363	2014	03
VALGANCICLOVIRUM	VALCYTE 50 mg/ml	powder for oral solution	50mg/ml	ROMANIA	6586	2014	01
VORICONAZOLUM	VORICONAZOL DR. REDDY'S 50 mg	film-coated tablets	50mg	ROMANIA	6564	2014	23
VORICONAZOLUM	VORICONAZOL DR. REDDY'S 200 mg	film-coated tablets	200mg	ROMANIA	6565	2014	23
XYLOMETAZOLINUM	BIXTONIM XYLO 0.5 mg/ml	nasal spray, solution	0.5mg/ml	ROMANIA	6332	2014	01
XYLOMETAZOLINUM	BIXTONIM XYLO 1 mg/ml	nasal spray, solution	1mg/ml	ROMANIA	6333	2014	01
ZIPRASIDONUM	ZYPSILA 20 mg	capsules	20mg	SLOVENIA	6430	2014	09
ZIPRASIDONUM	ZYPSILA 40 mg	capsules	40mg	SLOVENIA	6431	2014	09
ZIPRASIDONUM	ZYPSILA 60 mg	capsules	60mg	SLOVENIA	6432	2014	09
ZIPRASIDONUM	ZYPSILA 80 mg	capsules	80mg	SLOVENIA	6433	2014	09
ZOLPIDEMUM	ZOLPIDEM AUROBINDO 5 mg	film-coated tablets	5mg	MALTA	6434	2014	09
ZOLPIDEMUM	ZOLPIDEM AUROBINDO 10 mg	film-coated tablets	10mg	MALTA	6435	2014	09

Medicinal products authorised through centralised procedure by the EMA for which a marketing price was established in Romania during the 2nd quarter of 2014

INN	Invented name	Pharmaceutical form	Strength	Manufacturer	Country	MA number		
COMBINATIONS CANAGLIFLOZINUM + METFORMINUM	VOKANAMET 50mg/850mg	film-coated tablets	50mg+850mg	JANSSEN-CILAG INTERNATIONAL NV	BELGIUM	918	2014	02
COMBINATIONS CANAGLIFLOZINUM + METFORMINUM	VOKANAMET 50mg/1000mg	film-coated tablets	50mg+1000mg	JANSSEN-CILAG INTERNATIONAL NV	BELGIUM	918	2014	05
COMBINATIONS CANAGLIFLOZINUM + METFORMINUM	VOKANAMET 150mg/850mg	film-coated tablets	150mg+850mg	JANSSEN-CILAG INTERNATIONAL NV	BELGIUM	918	2014	08
COMBINATIONS CANAGLIFLOZINUM + METFORMINUM	VOKANAMET 150mg/1000mg	film-coated tablets	150mg+1000mg	JANSSEN-CILAG INTERNATIONAL NV	BELGIUM	918	2014	11
COMBINATIONS UMECLIDINIUM+ VILANTEROL	ANORO 55µgr /22µgr	inhalation powder	55µgr /22µgr	GLAXO GROUP LIMITED	GREAT BRITAIN	898	2014	01
DOLUTEGRAVIRUM	TIVICAY 50mg	film-coated tablets	50mg	VIIV HEALTHCARE UK LIMITED	GREAT BRITAIN	892	2014	01
EMPAGLIFLOZINUM	JARDIANCE 10mg	film-coated tablets	10mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	930	2014	14
EMPAGLIFLOZINUM	JARDIANCE 25mg	film-coated tablets	25mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	930	2014	05
SIMEPREVIRUM	OLYSIO	capsules	150mg	JANSSEN CILAG INTERNATIONAL NV	BELGIUM	924	2014	02