Order no. 1.353
of 30 July 2020

on amendment and supplementation of Order of the Minister of Health no. 861/2014 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

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On seeing Approval Report no. NT 6.326 of 30.07.2020 of the Pharmaceutical and Medical Devices Directorate and notification no. 50.685E of 21 January 2020 of the National Agency for Medicines and Medical Devices, registered at the Ministry of Health with no. REG 2/517 of 22 January 2020,

taking into account provisions of Article 243 of Law 95/2006 on healthcare reform, republished, as further amended and supplemented,

taking into account provisions of Article 2 i) and Article 4 (5) 1 of Law no. 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions,

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

the minister of health hereby issues the following Order:

Art. I – Order of the Minister of Health no. 861/2014 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, published in the Official Gazette of Romania, Part I, no. 557 of 28 July 2014, as further amended and supplemented, is amended and shall read as follows:

1. Article 8 c) is amended and shall read as follows:

"c) New INNs, other than those for which applicants have submitted an application; The National Agency for Medicines and Medical Devices of Romania (NAMMDR) will notify marketing authorisation holders (MAHs) at least 10 working days before initiation of the evaluation procedure. The NAMMDR shall publish the list of products for which the ex officio evaluation procedure has been initiated on the NAMMDR website;".

2. A new Article, namely Article 8(1), is introduced after Article 8, as follows:

"Art. 8(1) - The NAMMDR will initiate the procedure for evaluating the reimbursed INNs in the List in order to move / exclude or mark / eliminate the ranking with (*), (**) (**1), for those medicinal products for which the specialised commissions within the Ministry of Health or the National Health Insurance House have notified the prescription outside the approved therapeutic indications or the exclusion of the medicinal product from the therapeutic guidelines with an impact on the FNUASS budget or for prescribed medicinal products that do not have a therapeutic protocol, respecting the indications, doses and contraindications in CPR, within the competence of the prescriber."

3. Annex 1, Article 1, points c), k), l), n) and p) are amended and shall read as follows:

"c) comparator – an INN included in the List of INNs of on-prescription medicinal products provided to insurants within the healthcare insurance system, irrespective of personal contribution, within the social health insurance system, as well as INNs relating to medicinal products provided in the frame of national healthcare programs, approved through Government Decision no. 720/2008, republished, with the same approved indication, meant for the same population group/subgroup as INNs assessed, as required. A product already reimbursed on the basis of cost-volume or cost-volume-result contracts can be considered as a comparator exclusively by comparing the prices available in CANAMED at the time of submission of the assessment dossier. If the comparator is a reimbursed product based on a cost-volume or cost-volume-result contract, the medicinal product subject to evaluation will be able to benefit from conditional reimbursement at most, even if the final score obtained as a result of the evaluation process would allow unconditional inclusion;

.....

k) reimbursement 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 (*), (**)1, or (**)2 ranking; the determination of the level of reimbursement for medicinal products whose indications are not limited to the categories of chronic diseases or national health programmes described in sub-list C, sections C1 and C2 of the List shall be carried out as follows: the cost of treatment / year is calculated, the minimum monthly cost is established, the level

of the patient's monthly personal contribution is established on the "percentage" of reimbursement related to sublists A, B and D of the minimum monthly cost; the maximum amount of indebtedness is established by applying 20% to the minimum gross income in force at the valuation date; if the personal contribution on the 20% clearing level is greater than or equal to 50% of the maximum amount of indebtedness, the next level of clearing is analysed; if the personal contribution at the 20% clearing level is less than 50% of the maximum amount owed, the product shall be included in sublist D; if the personal contribution on the 50% clearing level is greater than or equal to 50% of the maximum amount owed, the next level of clearing shall be considered; if the personal contribution at the 50% clearing level is less than 50% of the maximum amount owed, the product shall be included in sublist B; if the personal contribution at the 90% clearing level is greater than or equal to 50% of the maximum amount owed, the product shall be included at the 100% clearing level in a section of sublist C; if the personal contribution at the 90% clearing level is less than 50% of the maximum amount owed, the product shall be included in sublist A;

l) extension of indication – addition of a new pathology/disease for which the respective medicinal product with reimbursable INN has demonstrated safety and efficacy, included in the Summary of Product Characteristics reviewed by the European Medicinal products Agency or the National Agency for Medicines and Medical Devices of Romania;

.....

n) addition - inclusion in the same indication of another strength, another pharmaceutical form, a new population segment, modification of the line of treatment, inclusion of a new line of treatment for the medicinal product with a reimbursed INN, included in the List based on the assessment of medical technologies;

.....

p) removal/addition of the (*), (**)1 , or (**)2 ranking – change of conditions for prescriptions of treatment with medicinal products corresponding to reimbursable International Non-proprietary Names included in the List;

4. In Annex 1, under Article 1, a new point is introduced after point ab), point ac), which reads as follows:

"ac) advanced therapy medicinal product – a product defined otherwise than in line with Article 2 of Regulation (EC) no. 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 and of Directive of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use."

5. In Annex 1, under Article 5, points c) and d) are repealed.

6. In Annex 1, two new Articles are introduced after Article 5, Articles 6 and 7, which read as follows:

"Art. 6 - The evaluation criteria provided in Table 41 apply to the following situations:

a) generics without reimbursable INNs in the List;

b) biosimilars without reimbursable INNs in the List.

Art. 7 - The evaluation criteria provided in Table 9 apply in the following situations:

a) medicinal products corresponding to already reimbursed INNs with decisions for conditional inclusion, with ongoing cost-volume/cost-volume-result contracts, which have cumulatively lost data exclusivity and no longer benefit from patent protection and/or certificates for additional protection and their generic / generics meet/meets the marketing conditions on the Romanian territory;

b) medicinal products corresponding to already reimbursed INNs with decisions for conditional inclusion, with ongoing cost-volume/cost-volume-result contracts, which have cumulatively lost data exclusivity and no longer benefit from patent protection and/or certificates for additional protection and whose biosimilar(s) meet the requirements on the Romanian territory."

7. In Annex 1, Table 1 is amended and shall read as follows:

"Table 1 - Criteria for addition of a reimbursable INN

No.	Criteria	Details
1.	Ensuring addressability for patients	It will be shown how to solve by adding the lack of access to treatment, compliance to treatment of certain categories of patients, population segments or disease stages.
2.	Proof of reimbursement in EU countries and Great Britain	Required to demonstrate the widespread use of the product in at least three Member States of the European Union and the United Kingdom and maintenance of a unified approach.
3.	Financial impact analysis	Shall be calculated in accordance with the methodology in Annex 2 to the Order.

NOTE:

1. For addition of another strength or pharmaceutical form related to the already assessed medicinal product, which is used within the same indication as the already assessed strength or pharmaceutical form, the positive assessment report is issued only for situations where this addition has a negative/neutral impact. In this case, the comparator is the medicinal product with the strength or pharmaceutical form corresponding to the already reimbursed INN included in the List based on the assessment of medical technologies.

2. In order to issue the decision to add to the List by the NAMMDR, for a new segment or population group / to modify the line of treatment / to include a new line of treatment for the medicinal product with a reimbursed INN, the criteria provided in no. 1 and 2 of Table 1 must be met cumulatively, and for the situation described under point 1, only the criterion provided in no. 3 of Table 1. "

8. In Annex 1, Table 2 is amended and shall read as follows:

Table 2 - Criteria for ranking reimbursed INNs as (*), (**)1 or (**)2		
No.	Criteria	Details
1.	High cost INNs (i) prescribed and dispensed based on therapeutic protocols entered into the Electronic Register of the Health Insurance House of high-cost medicinal products under monitoring	(**)2 Treatment with medicinal products corresponding to INNs ranked (**)2 is conducted based on therapeutic protocols established by specialised commissions of the Ministry of Health, subject to monitoring through the Register of the Health Insurance House of high-cost medicinal products and/or started in non-interventional studies carried out in Romania, for collection of real-life data for HTA purposes
2.	Costly INN(s) and/or for which an additional monitoring is required both in terms of pharmacovigilance and administration, whose prescription is made by the appointed physician only on the basis of a therapeutic protocol	(**) Treatment for medicinal products corresponding to INNs ranked (**) shall be performed on the basis of therapeutic protocols issued by special commissions of the Ministry of Health. (**) 1 Treatment for medicinal products corresponding to INNs ranked (**) 1 shall be performed on the basis of therapeutic protocols issued by special commissions of the Ministry of Health and specific forms.
3.	Low-cost INNs (ii) requiring medical prescription according to SmPC	(*) Treatment with medicinal products corresponding to INNs ranked (*) shall be initiated by the appointed physician within the limits of competence and can further be prescribed by the family physician based on the medical letter issued by the medical specialist.

(i) Products whose calculated monthly treatment cost* is > 2 x GDP**/capita/month.

(ii) Medicinal products whose calculated monthly treatment cost*) is below the gross minimum salary on the date of issuance of the decision for inclusion in the List.

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*) * Monthly treatment cost - total price of the INN calculated at the maximum retail price level with VAT, included in the Index of prices of medicinal products for human use approved on assessment date, according to doses and administration duration as provided in the SmPC, for one calendar month. The monthly treatment cost is calculated for each strength, pharmaceutical form or route of administration

of the respective INN. The (*), (**) 1 or (**) 2 ranking of reimbursed INNs depends on the pharmaceutical form with the highest monthly treatment cost. * * GDP Reference: the National Institute of Statistics, the latest published Statistical Yearbook of Romania

9. In Annex 1, Table 3 is amended and shall read as follows:

"Table 3 - Assessment criteria for reimbursed INNs included into the List			
Assessment criteria	Rating	A single rating selected	Scores may be summated
1. HTA based on therapeutic benefit estimate (SMR)			
1.1. INN with major/important SMR level (as assessed by the HAS) (BT 1)	0	Not to exceed 30 points	
1.2. INN not assessed by the HAS	10		
1.3. INN with moderate/low SMR level (as assessed by the HAS) (BT 2)	15		
1.4. INN with insufficient SMR level (as assessed by the HAS) (BT 3) or withdrawn from the List of medicinal products reimbursed within the social insurance system in France	30		
2. Cost-efficacy based HTA - Great Britain (NICE/SMC)			
2.1. INN approved, with no restrictions, by the Great Britain health technologies assessment authority or for which the MAH/MAH representative submits an affidavit attesting free of restriction reimbursement in Great Britain, with restrictions compared with the SmPC, also following a NICE class assessment or assessment of other types of reports/reviews performed by the NHS and related documentation.	0	Not to exceed 30 points	
2.2. INN not assessed by the Great Britain authority for assessment of health technologies (NICE/SMC).	10		
2.3. INN approved upon review, with restrictions in relation with 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)/for which approval for inclusion in the system has been withdrawn/included in the negative list of the Great Brittan National Healthcare Service (NHS)/has been withdrawn from the List of	30		

reimbursed medicinal products of the Great Brittan National Healthcare Service			
2.5. The INN has received a MA withdrawal decision.	50		
2.6. A INN for which the specialised commissions of the Ministry of Health informed the NAMMDR that there is no therapeutic benefit according to the analysis of existing documentation at European level or that the INN is no longer recommended in national/international clinical guidelines, as appropriate.	30		

10. In Annex 1, Table 4 is amended and shall read as follows:

" Table 4 - Assessment criteria for new INNs			
Assessment criteria	Rating	A single rating selected	Scores may be summated
1. HTA based on therapeutic benefit estimate (SMR)			
1.1. New INNs, reimbursable INNs with extension of indication, classified as BT1-major/important by the HAS	15	Not to exceed 15 points	
1.2. New INNs, reimbursable INNs with extension of indication, classified as BT2-moderate/low (nonetheless justifying reimbursement) by the HAS.	7		
1.3. New INNs, reimbursable INNs with extension of indication, classified as BT3 - insufficient according to HAS	0		
2. HTA based on cost-efficacy			
2.1. New INNs, reimbursable INNs with extension of indication, which have received a positive opinion, approved without restrictions in relation with the SmPC, by Great Britain authorities for assessment of health technologies (NICE/SMC) or for which the MAH/MAH representative submits an affidavit attesting free of restriction reimbursement in Great Britain, with restrictions compared with the SmPC, also following a NICE class assessment or assessment of other types of reports/reviews performed by the NHS and related documentation	15	Not to exceed 15 points	
2.2. New INNs, reimbursable INNs with extension of indication, which have received a positive opinion,	7		

with restrictions in relation with the SmPC, by Great Britain authorities for assessment of health technologies (NICE/SMC) or for which the MAH/MAH representative submits an affidavit attesting free of restriction reimbursement in Great Britain, with restrictions compared with the SmPC, also following a NICE class assessment or assessment of other types of reports/reviews performed by the NHS and related documentation			
2.3. New INNs, reimbursable INNs with extension of indication, care have received a negative opinion from the Great Britain authority for assessment of health technologies (NICE/SMC) or for which an assessment report has not been issued	0		
2.4. New INNs, reimbursable INNs with extension of indication, for which the assessment report of the authorities for assessment of medical technologies of Germany (IQWIG/G-BA) demonstrates an additional therapeutic benefit as opposed to the comparator (regardless of its size), approved without restrictions in relation with the SmPC and which are included into the GBA therapeutic guidelines and which have not been assessed by IQWIG, since the authority has not considered the assessment as being mandatory, approved without restrictions in relation with the SmPC	15	Not to exceed 15 points	
2.5. New INNs, reimbursable INNs with extension of indication, for which the assessment report of the authorities for assessment of medical technologies of Germany (IQWIG/G-BA) demonstrates an additional therapeutic benefit as opposed to the comparator (regardless of its size), with restrictions in relation with the SmPC, and which are included into the GBA therapeutic guidelines and which have not been assessed by IQWIG since the authority has not considered the assessment as being mandatory, with restrictions in relation with the SmPC	7		
2.6. New INNs, reimbursable INNs with extension of indication for which the evaluation report of the authorities for assessment of medical technologies in Germany (IQWIG / G-BA) does not demonstrate additional therapeutic benefit as opposed to the comparator or the benefit is less as opposed to the	0		

comparator or for which no evaluation report has been issued			
3. Status of INN reimbursement in Member States/Positive assessment report from the National Agency for Medicines and Medical Devices of Romania			
3.1. New INNs, reimbursable INNs with extension of indication, for which inclusion into the List of the new therapeutic indication is required, reimbursed in at least 14 Member States and Great Britain	25	Not to exceed 25 points	
3.2. New INNs, reimbursable INNs with extension of indication, reimbursed in 8-13 Member States and Great Britain	20		
3.3. New INNs, reimbursable INNs with extension of indication, reimbursed in 3-7 Member States and Great Britain	10		
3.4. New INNs, reimbursable INNs with extension of indication in less than 3 Member States and Great Britain	0		
3.5. New INNs, reimbursable INNs with extension of indication or fixed-dose combinations of already reimbursable INNs, for which the applicant submits the following documents: (i) a clinical trial authorisation and an intermediate/final report validating the conduct in Romania of a clinical trial of the medicinal product assessed for the submitted indication; (ii) A EUnetHTA assessment for the submitted indication; (iii) proof of notification to the NAMMDR of a non-interventional study for the collection of real data for the submitted indication.	45	Not to exceed 45 points. **)	
4. Therapy costs			
4.1. New INNs, reimbursable INNs with extension of indication, generating more than 5% savings as opposed to the comparator, per patient, within the timeframe used for calculation	30	Not to exceed 30 points	
4.2. New INNs, reimbursable INNs with extension of indication, with a neutral budgetary impact as opposed to the comparator, per patient, within the timeframe used for calculation, generating between 5% savings and up to 3% costs)	15		

4.3. New INNs, reimbursable INNs with extension of indication, generating more than 3% costs as opposed to the comparator, per patient, within the timeframe used for calculation	0		

NOTE:

1. For indications for which a medicinal product corresponding to some new INNs, reimbursable INNs with extension of indication, the marketing authorisation for the evaluated medicinal product was issued before 2011 and the medicinal product is reimbursed in the United Kingdom and Germany, 15 points are awarded ex officio on criterion 2 of the table for both NICE and IQWIG / G-BA.

2. 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. (In case of a double combination, the separate components should appear as reimbursed in the List, however one of the separate components should be reimbursed for the indication for which a fixed combination is submitted; in case of a triple combination, three separate components reimbursed in the List or a combination of one + double combination can be chosen, however both should be reimbursed in the List and it is mandatory that at least one of the separate components or the double combination be reimbursed for the indication for which a fixed combination is submitted).

3. The phrase "without restrictions on the summary of product characteristics" in criterion 2.4 means that all population subgroups have been allocated an additional therapeutic benefit regardless of its size (major, considerable, minor and non-quantifiable).

4. The phrase "with restrictions on the summary of product characteristics" under criterion 2.5 means that at least one population subgroup has not been allocated an additional therapeutic benefit.

5. The 45 points awarded in point 3.5 replace the score given for the reports of the medical technology assessment authorities of France (HAS), Great Britain (NICE / SMC) and Germany (IQWIG / G-BA) described under points 1 and 2 of Table 4.

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*) Cost / recommended daily dose (annual DDD) - the total price of the INN calculated at the level of the maximum retail price with WATT, Cost / recommended daily dose (annual DDD) present in the Index of Prices of Medicinal Products for Human Use approved on the date of evaluation, depending on the doses and duration of administration provided in the SmPC, for a calendar year. The cost / recommended daily dose (annual DDD) is for the same strength, pharmaceutical form or route of administration of INN and, if both the innovative medicinal product and the generic / biosimilar components of the fixed combination are available on the market, the amount of annual costs / DDD of the components taken separately is made at the level

of generic / biosimilar medicinal products with the lowest maximum retail prices with VAT present in the Index of prices of medicinal products for human use, approved at the date of evaluation.

**) Considering the heterogeneity of non-interventional studies on pathologies, patient population, objectives pursued, type of data collected, analysis and interpretation of results, it is almost impossible to develop a unitary methodology for all types of non-interventional studies. The protocols submitted by the applicants will be analysed by the Health Technology Assessment Department and the Clinical Trials Department of the National Agency for Medicines and Medical Devices of Romania. The National Agency for Medicines and Medical Devices of Romania may invite representatives of the National Health Insurance House and of the advisory commissions of the Ministry of Health for consultations. Their main objectives will be the evaluation of the additional clinical benefit, of the safety, of the quality of life, namely the collection of direct costs from the payer's perspective in order to perform pharmaco-economic analyses at the end of the study. The purpose of the working group is to analyse the design of the non-interventional study and to guide the applicant to a protocol for collecting real data from therapeutic practice in order to assess medical technologies. Non-interventional studies will have to comply with regulations of the Decision of the Scientific Council of the National Agency for Medicines and Medical Devices no. 6/2014 on authorisation by the National Agency for Medicines and Medical Devices of clinical trials / notification to the National Agency of Medicines and Medical Devices of non-interventional studies performed with medicinal products for human use in Romania, supplemented by Decision of the Scientific Council of the National Agency for Medicines and Medical Devices no. 25/2015. The maximum term in which the final opinion on the data collection protocol will be issued is 3 months from the date of submission of the study request by the applicant. The non-interventional study for collection of actual data will be conducted after inclusion of the medicinal product included in the study in the reimbursement system. "

11. In Annex 1, a new Table is introduced after Table 4, namely Table 41, which reads as follows:

"Table 41 - Assessment criteria for generics or biosimilars without reimbursable INNs in the List

Assessment criteria	Rating	A single rating selected	Scores may be summated.
1. HTA based on estimation of the therapeutic benefit (SMR)			
1.1. Generics without reimbursable INNs in the List, biosimilars with no reimbursable INN in the List, which have received the BT-1 classification - major/important from HAS, for the INN	15	Not to exceed 15 points	

1.2. Generics without reimbursable INNs in the List, biosimilars with no reimbursable INN in the List, which have received the BT-2 classification - moderate/low (but which justifies reimbursement) from HAS, for the INN	7		
1.3. Generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, which have received the BT-3 classification - insufficient according to HAS	0		
2. HTA based on cost-efficacy			
2.1. Generics without reimbursable INNs in the List, biosimilars with no reimbursable INN in the List, which have received a positive opinion, approved without restrictions in relation with the SmPC, by Great Britain authorities for assessment of health technologies (NICE/SMC), for the INN, or for which the MAH/MAH representative submits an affidavit attesting free of restriction reimbursement in Great Britain, with restrictions compared with the SmPC, also following a NICE class assessment or assessment of other types of reports/reviews performed by the NHS and related documentation	15	Not to exceed 15 points	
2.2. Generics without reimbursable INNs in the List, biosimilars with no reimbursable INN in the List, which have received a positive opinion, with restrictions in relation with the SmPC, from the Great Britain authority for assessment of health technologies (NICE/SMC), for the INN, or for which the MAH/MAH representative submits an affidavit attesting free of restriction reimbursement in Great Britain, with restrictions compared with the SmPC, also following a NICE class assessment or assessment of other types of reports/reviews performed by the NHS and related documentation	7		
2.3. Generics without reimbursable INNs in the List, biosimilars with no reimbursable INN in the List, which (i) have received a negative opinion from the Great Britain authority for assessment of health technologies (NICE or SMC) or (ii) for which no assessment report has been issued and for which the MAH/MAH representative has not issued an affidavit related to the reimbursement status in Great Britain	0		

2.4. Generics with no reimbursable INN in the List, biosimilars with no reimbursable INN in the List, for which the assessment report of the authorities for assessment of medical technologies of Germany (IQWIG/G-BA) demonstrates an additional therapeutic benefit as opposed to the comparator (regardless of its size), approved without restrictions in relation with the SmPC and which are included into the GBA therapeutic guidelines and have not been assessed by the IQWIG since the authority has not considered the assessment as being mandatory, approved without restrictions in relation with the SmPC	15	Not to exceed 15 points	
2.5. Generics without reimbursable INNs in the List, biosimilars with no reimbursable INN in the List, for which the assessment report of the authorities for assessment of medical technologies of Germany (IQWIG/G-BA) demonstrates an additional therapeutic benefit as opposed to the comparator (regardless of its size), with restrictions in relation with the SmPC and which are included into the GBA therapeutic guidelines and have not been assessed by the IQWIG since the authority has not considered the assessment as being mandatory, with restrictions in relation with the SmPC	7		
2.6. Generics without reimbursable INNs in the List, biosimilars without reimbursable INNs in the List, biosimilars with no reimbursable INN in the List, for which the assessment report of the authorities for assessment of medical technologies of Germany (IQWIG/G-BA) does not demonstrate an additional therapeutic benefit as opposed to the comparator or the benefit is smaller as opposed to the comparator or for which an assessment report has not been issued by the authorities for assessment of medical technologies of Germany (IQWIG/G-BA)	0		
3. The reimbursement status of the INN in EU Member States and Great Britain/positive assessment report issued by the National Agency for Medicines and Medical Devices of Romania			
3.1. Generics without reimbursable INNs in the List, biosimilars with no reimbursable INN in the List, requiring inclusion of the new therapeutic indication	25	Not to exceed 25 points.	

in the List reimbursed in at least 14 of the EU Member States and Great Britain			
3.2. Generics without reimbursable INNs in the List, biosimilars with no reimbursable INN in the List, reimbursed in 8 - 13 EU member states and Great Britain	20		
3.3. Generics without reimbursable INNs in the List, biosimilars with no reimbursable INN in the List, reimbursed in 3 - 7 EU member states and Great Britain	10		
3.4. Generics without reimbursable INNs in the List, biosimilars with no reimbursable INN in the List, reimbursed in less than 3 EU member states and Great Britain	0		
4. Therapy costs			
4.1. Generics or biosimilars with no reimbursable INN in the List, generating more than 30% savings as opposed to the comparator*), for generics, and more than 15% as opposed to the comparator*), for biologicals, per patient, per year	30	Not to exceed 30 points.	
4.2. Generics or biosimilars with no reimbursable INN in the List, generating between 30% savings and up to 3% costs as opposed to the comparator*), for generics, and between 15% savings and up to 3% costs as opposed to the comparator*), for biologicals, per patient, per year	15		
4.3. Generics or biosimilars with no reimbursable INN in the List, generating more than 3% costs as opposed to the comparator*), per patient, per year	0		

NOTE:

1. The phrase « without restrictions on the summary of product characteristics» under criterion 2.4 refers to the fact that an additional therapeutic benefit was allocated to all population subgroups regardless of its size (major, considerable, minor and non-quantifiable).

2. The phrase «with restrictions on the summary of product characteristics» under criterion 2.5 refers to the fact that no additional therapeutic benefit was allocated to at least one population subgroup.

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*) By way of exception, in case of generics and biosimilar products that do not have a reimbursed INN in the List, the comparator will be the innovative / biological drug for the same concentration, pharmaceutical form or route of administration.

The maximum price levels for the innovative or biological medicinal product will be established by the Ministry of Health, at the request of the National Agency for Medicines and Medical Devices of Romania, according to the rules for calculation of the maximum prices of medicinal products for human use approved by Minister Order for the month in which the application for assessment is submitted, and will be sent within maximum 30 days from the date of application. The maximum price levels for the innovative or biological medicinal product will be specified in the assessment report for the generic / biosimilar medicinal product. NOTE: for indications for which a generic or biosimilar medicinal product that does not have a reimbursed INN in the List, the MAH has submitted the documentation for assessment of health technologies in Table 41, and the marketing authorisation of the innovative or biological reference medicinal product related to the assessed INN was issued before 2011 and is reimbursed in the United Kingdom and Germany, 15 points are awarded ex officio according to criterion no. 2 in the Table for both NICE and IQWIG / G-BA."

12. In Annex 1, Table 5 is amended and shall read as follows:

"Table 5. - Assessment criteria for new INNs approved by the European Medicines Agency as orphan medicinal products or medicinal products for advanced therapy	
Criterion	Points
1. Treatment, prevention or diagnosis of diseases that do not affect more than 5 in 10.000 people in the EU or are life-threatening, are chronically debilitating or represent serious and chronic diseases of the body. In addition, there is no satisfactory method of diagnosis, prevention or treatment authorized in the EU for these diseases or, if such method exists, the medicinal product brings a significant benefit to those suffering from this disease or new INNs approved for advanced therapy medicinal products.	70
2. The applicant shall provide one of the following documents for the orphan medicinal product or the advanced therapy medicinal product: a) A clinical trial authorisation and an intermediate/final report validating the conduct in Romania of a clinical trial of the medicinal product assessed for the submitted indication; b) A EUnetHTA assessment for the submitted indication; c) An authorisation for use in last resort treatments in Romania for the medicinal product assessed for the submitted indication; d) The approval for donation released by the NAMMDR and the evidence of treatment with the donated medicinal product for a period of at least 12 months, for the submitted indication, for a proportion of at least 50% of the population eligible for treatment, according to the SmPC.	10
NOTE:	

The MAH may submit to the assessment dossier an estimate of the eligible population corresponding to the indication of the orphan medicinal product/advanced therapy medicinal product, indicating the sources of the submitted data. "

13. In Annex 1, a new table is introduced after Table 5, namely Table 51, which reads as follows:

"Table 51 - Criteria for assessment of newly approved INNs for the treatment of infectious diseases caused by pathogens that may cause epidemics / pandemics with a major impact on public health	
Criterion	Points
New INN approved for the treatment of infectious epidemic diseases	80"

14. In Annex 1, Table 7 is amended and shall read as follows:

"Table 7 - Criteria for assessment of new INNs for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative and for which there is no relevant comparator in the List			
Assessment criteria	Rating	A single rating selected	Scores may be summated
1. HTA based on therapeutic benefit estimate (SMR)			
1.1. New INNs, reimbursable INNs with extension of indication, for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative, which have received the classification BT 1 - major/important from HAS	15	Not to exceed 15 points	
1.2. New INNs, reimbursable INNs with extension of indication for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative, which have received the classification BT 2 - moderate/low (but which justifies reimbursement) from HAS	7		
1.3. New INNs, reimbursable INNs with extension of indication for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative, which have	0		

received the classification BT 3 - insufficient according to HAS			
2. HTA based on cost-efficacy			
2.1. New INNs, reimbursable INNs with extension of indication, for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative, which have received a positive opinion, approved without restrictions in relation with the SmPC, by Great Britain authorities for assessment of health technologies (NICE/SMC) or for which the MAH/MAH representative submits an affidavit attesting free of restriction reimbursement in Great Britain, with restrictions compared with the SmPC, also following a NICE class assessment or assessment of other types of reports/reviews performed by the NHS and related documentation	15	Not to exceed 15 points	
2.2. New INNs, reimbursable INNs with extension of indication, for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative, which have received a positive opinion, with restrictions in relation with the SmPC, from authorities for assessment of health technologies in Great Britain (NICE/SMC) or for which the MAH/MAH representative submits an affidavit attesting free of restriction reimbursement in Great Britain, with restrictions compared with the SmPC, also following a NICE class assessment or assessment of other types of reports/reviews performed by the NHS and related documentation	7		
2.3. New INNs, reimbursable INNs with extension of indication for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative, which have received a negative opinion from the Great Britain authority for assessment of health technologies (NICE/SMC) or which have not received a report	0		
2.4. New INNs, reimbursable INNs with extension of indication for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative, for which the assessment report of the authorities for assessment of medical technologies of Germany (IQWIG/G-BA)	15	Not to exceed 15 points	

demonstrates an additional therapeutic benefit as opposed to the comparator (regardless of its size), approved without restrictions in relation with the SmPC, and which are included into the GBA therapeutic guidelines and have not been assessed by the IQWIG since the authority has not considered the assessment as being mandatory, approved without restrictions in relation with the SmPC			
2.5. New INNs, reimbursable INNs with extension of indication, for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative, for which the assessment report of the authorities for assessment of medical technologies of Germany (IQWIG/G-BA) demonstrates an additional therapeutic benefit as opposed to the comparator (regardless of its size), with restrictions in relation with the SmPC, and which are included into the GBA therapeutic guidelines and have not been assessed by the IQWIG since the authority has not considered the assessment as being mandatory, with restrictions in relation with the SmPC	7		
2.6. New INNs, reimbursable INNs with extension of indication for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative, for which the assessment report of the authorities for assessment of medical technologies of Germany (IQWIG/G-BA) did not demonstrate an additional therapeutic benefit as opposed to the comparator or the benefit is smaller as opposed to the comparator or for which an assessment report has not been issued	0		
3. The INN reimbursement status in EU Member States and the United Kingdom / Positive Assessment Report issued by the National Agency for Medicines and Medical Devices (NAMMDR)			
3.1. New INNs, reimbursable INNs with extension of indication, for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative reimbursed in at least 14 member states of the EU and great Britain	25	Not to exceed 25 points.	
3.2. New INNs, reimbursable INNs with extension of indication, for the treatment of rare diseases or for evolutionary stages of some pathologies for which the	20		

INN is the only therapeutic alternative reimbursed in 8 - 13 member states of the EU and great Britain			
3.3. New INNs, reimbursable INNs with extension of indication, for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative reimbursed in 3 - 7 member states of the EU and great Britain	10		
3.4. New INNs, reimbursable INNs with extension of indication, for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative reimbursed in less than 3 member states of the EU and great Britain	0		
3.5. New INNs, reimbursable INNs with extension of indication, for which the applicant submits at least one of the following documents: (i) a clinical trial authorisation and an intermediate/final report validating the conduct in Romania of a clinical trial of the medicinal product assessed for the submitted indication; (ii) A EUnetHTA assessment for the submitted indication; (iii) proof of notification to the NAMMDR of a non-interventional study for the collection of real data for the submitted indication.	45	Not to exceed 45 points.*)	
4. Evolutionary stage of the pathology			
4.1. New INNs, reimbursable INNs with extension of indication, for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative in patients with an average life expectancy of less than 24 months / paediatric patients aged 0 to 12 months	10	Not to exceed 30 points.	
4.2. New INNs, reimbursable INNs with extension of indication, for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative, for which the treatment: a) increases the average survival by at least 3 months; or b) causes the remission to be maintained or to stop / slow down the evolution of the disease to the advanced stages of severity, for a period longer than 3 months	10		
4.3. New INNs, reimbursable INNs with extension of indication, for the treatment of rare diseases that do not	10		

affect more than 5 in 10.000 people in the EU or are life-threatening, are chronically debilitating or represent serious and chronic diseases of the body, according to information provided on the OrphaNet website or statistics from European countries / local statistics			

*) The 45 points substitute the rating granted for the reports of the authorities for assessment of medical technologies of France (HAS), Great Britain (NICE/SMC) and Germany (IQWIG/G-BA) described under points 1 and 2 of the Table.

NOTE:

1. For the indications for which a medicinal product corresponding to new INNs, reimbursable INNs with extension of indication, for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative, the documentation for the assessment of medical technologies was submitted in Table 7, and the marketing authorisation for the assessed medicinal product was issued before 2011 and the medicinal product is reimbursed in the United Kingdom and Germany, 15 points are granted ex officio, according to criterion no. 2 from the Table for both NICE and IQWIG/G-BA.

2. The phrase « without restrictions on the summary of product characteristics» under criterion 2.4 refers to the fact that an additional therapeutic benefit was allocated to all population subgroups regardless of its size (major, considerable, minor and unquantifiable).

3. The phrase «with restrictions on the summary of product characteristics» under criterion 2.5 refers to the fact that no additional therapeutic benefit was allocated to at least one population subgroup.

4. Given the heterogeneity of non-interventional studies on pathologies, patient population, the objectives pursued, the type of collected data, analysis and interpretation of results, it is almost impossible to develop a unitary methodology for all types of non-interventional studies. The protocols submitted by applicants will be analysed by the NAMMDR, which may invite representatives of the National Health Insurance House and the specialized commissions of the Ministry of Health for consultation on: assessment of the additional clinical benefit, safety, quality of life and collection of direct costs from the payer's perspective in order to perform pharmaco-economic analyses at the end of the study, in order to guide the applicant for the collection of real data from therapeutic practice, in order to evaluate medical technologies. The non-interventional study for the collection of real data will be carried out after inclusion of the medicinal product included in the study in the reimbursement system.

5. The criteria for issuance of a decision to include, extend indications or not include medicinal products approved by the European Medicines Agency as orphan medicinal products or medicinal products for treatment of rare diseases or for developmental stages of certain pathologies for which the respective INN is the only therapeutic alternative are the same as provided in section I letter B points 1 and 2 of Annex 2 to the Order."

15. In Annex 1, a new Table is introduced after Table 8, namely Table 9, which reads as follows:

"Table 9 - Assessment criteria for medicinal products corresponding to a reimbursed INN in the List, with a decision for conditional inclusion, with an ongoing cost-volume / cost-volume-result contract, which have cumulatively lost data exclusivity and no longer benefit from patent protection and / or certificates for additional protection and its generic(s), namely whose biosimilar meets the marketing conditions on the Romanian territory

Criterion		Points
1. Estimate of the budgetary impact		
1.1. Generics who have a reimbursed INN in the List with decision for conditional inclusion, biosimilars who have a reimbursed INN in the List, with decisions for conditional inclusion, generating more than 30% savings compared to the medicinal product in cost-volume / cost-volume-result for the generic, namely more than 15% savings for the biosimilar, per patient, per year	30	Not to exceed 30 points
1.2. Generics that have the INN reimbursed in the List, with decision for conditional inclusion, biosimilars who have a reimbursed INN in the List, with decisions for conditional inclusion, that generate less than 30% savings compared to the medicinal product in cost-volume / cost-volume-result for the generic, namely less than 15% savings for the biosimilar, per patient, per year	0	
2. The rating obtained by the INN reimbursed in the List on the decision of conditional inclusion in the List, based on which a cost-volume / cost-volume-result contract was concluded		

NOTE:
The assessment is performed by the NAMMDR upon notification by the Ministry of Health or the National Health Insurance House or upon notification of a marketing authorisation holder for a generic/biosimilar medicinal product reimbursed in the List, with a decision of conditional inclusion."

16. In Annex 2 section I, preamble of letter A is amended and shall read as follows:

"A. Stages of the medicinal product assessment process for new INNs for inclusion 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 programmes, hereinafter referred to as the List, and of medicinal products corresponding to the INNs reimbursed for the extension of the indications or

addition according to the criteria provided in Art. 1 n) of Annex 1 to the Order, generic medicinal products or biosimilars without reimbursable INNs in the List, orphan medicinal products, advanced therapy medicinal products, medicinal products corresponding to new INNs for the treatment of rare diseases or for evolutionary stages of some pathologies for which the INN is the only therapeutic alternative and for which there is no relevant comparator in the List of new plasma-derived INNs for the treatment of rare diseases for which the INN is the only therapeutic alternative ".

17. In Annex 2 section I point A, a new point is introduced after point 2, point 21, which reads as follows:

"21. For a reimbursed INN in the List, with a decision of conditional inclusion, with an ongoing cost-volume / cost-volume-result contract, whose cumulative reference medicinal product has lost its data exclusivity and no longer benefit from patent protection and / or certificates for additional protection and whose generic(s), namely its biosimilar(s), meet(s) the marketing conditions on the Romanian territory, the NAMMDR initiates the assessment process after receiving the request, prepared in line with the template provided in Annex 4 to the Order, by a MAH, for a generic / biosimilar, or as a result of its notification by the Ministry of Health or the National Health Insurance House. "

18. In Annex 2 section I point A, points 7, 9, 10, 18, 22 and 23 are amended and shall read as follows:

"7. The preliminary analysis of the assessment reports of the medical technologies submitted by the applicant, the analysis of the reimbursement evidence from European Union member states, the calculation and analysis of the therapy cost are performed by the National Agency for Medicines and Medical Devices of Romania (NAMMDR), within maximum 30 calendar days from submission of the documents.

.....

9. If the submitted documentation is incomplete or an irrelevant comparator for the medical practice in Romania was used to calculate the therapy cost, the National Agency for Medicines and Medical Devices of Romania sends to the applicant, within maximum 30 calendar days from submission of the documentation, an information requesting submission of additional documentation or completion of the submitted documentation, as the case may be.

10. The information contains the critical analysis of the submitted documentation and the proposals for its amendment or supplementation, as the case may be, including the comparator considered relevant for medical practice in Romania, endorsed by the advisory commissions of the Ministry of Health.

.....

18. Requests and extended documentation received are analysed in order of priority, according to the following prioritization criteria:

1. medicinal products which have gone through a previous assessment process, concluded with a decision of non-inclusion, as a result of non-compliance

with maximum of two criteria, the decision being uncontested or not modified as a result of solving the appeal, for which the MAH presents elements that meet a more favourable rating, according to this Annex;

2. medicinal products for diseases in evolutionary stages of the disease without a therapeutic alternative in the List;

3. medicinal products approved through emergency procedure by the European Medicines Agency;

4. medicinal products corresponding to INNs for specific treatment in case of diseases with a major impact on public health, provided in Law no. 95/2006 on healthcare reform, republished, as further amended and supplemented, as well as in the National Health Strategy;

5. the chronological order in which the assessment applications have been submitted, for medicinal products which do not fall within the criteria provided in subpoints 1 - 4.

As regards the situations provided in subpoints 1 – 4, the analysis will be performed on each situation in the chronological order in which the assessment applications have been submitted.

.....

22. Therapy costs are estimated according to the relevant comparator for medical practice in Romania. If the relevant comparator for medical practice in Romania is not found in the documentation submitted by the applicant, this fact shall be mentioned in the information prepared by the NAMMDR, together with the opinion of the advisory commissions of the Ministry of Health, granted in order to substantiate the choice of the relevant comparator.

23. Therapy costs are calculated by the applicant and are submitted together with the assessment documentation to the NAMMDR, based on the following data:

Table 1 - Data needed to calculate therapy costs

	New INN, reimbursable INNs with extension of indication, generics or biosimilars without reimbursable INNs in the List	New INN, reimbursable INNs with extension of indication under the conditions of employment in a cost-volume / cost-volume mechanism - result	Comparator

The monthly therapy cost with the minimum daily dose			
The monthly therapy cost with the maximum daily dose			
The monthly cost of the recommended dose therapy			
The total number of patients for the respective indication (prevalence and incidence) estimated to be treated annually and estimates for a period of 5 years, after inclusion in the List			
Duration of therapy per patient, according to the SmPC, or median duration of treatment in the clinical trials on which the authorisation was based			

NOTE:

1. Therapy cost - the total price of INNs calculated at the maximum retail price level including VAT, present in the National Index of Prices of Medicinal Products for Human Use, approved on the date of assessment, depending on the doses and duration of administration provided in the SmPC, for a calendar year, per patient. The therapy cost is made on the recommended dose of the comparator which has the same approved indication and is addressed to the same population segment as the assessed medicinal product, and if the innovative medicinal product and the generics for the chosen comparator are both on the market, namely both the biological medicinal product and its biosimilar, the therapy cost is related to the generic / biosimilar medicinal product with the lowest maximum retail price with VAT present in the National Index of Prices of Medicinal Products for Human Use, approved at the date of assessment. If administration of an assessed therapeutic scheme in combination with other medicinal products related to reimbursed INNs is specified, in the SmPC, for the assessed INN or comparator, the therapy cost will be calculated for the entire therapeutic scheme. If in the SmPC, for the INN under evaluation or for the comparator, the recommended dose involves a period of induction of treatment and a period of its consolidation, the therapy cost per patient will be calculated for a period of three calendar years. If in the SmPC, for the INN under evaluation or for the comparator, the recommended dose for one of them involves a limited period of administration, of several months/years, and for the other an unlimited period of chronic administration, the therapy cost per patient will be calculated for a period of five calendar years.

2. By waiver from point 1, in case the MAH/MAH representative expresses his availability to conclude a protocol with the National Health Insurance House (CNAS) for co-financing of the treatment, according to Art. 220 (2) and Art. 221 (1)

m) of Law no. 95/2006 on healthcare reform, republished, as further amended and supplemented, the therapy cost will be calculated considering the cost resulting from the application of the conditions mentioned in the address of expression of availability. The expression of the availability to enter into a protocol with the NHIH will be submitted as part of the assessment dossier.

3. The therapy cost shall be calculated in accordance with point 1 and for medicinal products for which the addition criteria for a reimbursed INN, included in the List, based on the medical technologies assessment, apply.

4. In cases of addition of another strength or pharmaceutical form used for the same indication as the strength or pharmaceutical form already assessed, the comparator is the medicinal product with the strength or pharmaceutical form corresponding to the already reimbursed INN included in the List based on the assessment of medical technologies."

19. In Annex 2 section I point A, a new point is introduced after point 24, namely point 241, which reads as follows:

"241. The NAMMDR consults with the specialised commissions within the Ministry of Health and takes into account their opinions, in line with the legal provisions in force, in the following situations:

a) when the point of view of the NAMMDR differs from that of the marketing authorisation holder regarding the choice of the comparator;

b) in order to validate the eligible population, according to the document submitted by the MAH, for calculation of the budgetary impact;

c) for positioning the medicinal product in the therapeutic strategy.

The opinion of the specialised commission communicated to the NAMMDR will be accompanied by bibliographical references supporting the substantiation of the opinion."

20. Point b) of Annex 2 section I point B point 5 is amended and shall read as follows:

"b) Obtaining a rating between 30 and 49 points following assessment of medical technologies carried out under the conditions of this methodology leads to the transfer of the INN to another sublist; the new reimbursement level is established in accordance with the methodology provided in Art. 1 k) from Annex 1 to order".

21. In Annex 2 section I point B, point 6 is amended and shall read as follows:

"6. Criteria for issuing the decision for addition:

a) a medicinal product corresponding to an already reimbursed INN which, according to the SmPC, is addressed to another population segment for the indication for which it was included in the List based on the assessment of health technologies;

b) a medicinal product corresponding to an already reimbursed INN which, according to the SmPC, can be administered in other treatment lines for the

indication for which it was included in the List based on the assessment of health technologies;

c) a medicinal product corresponding to an INN already reimbursed with strengths and / or other pharmaceutical forms than the strengths and / or pharmaceutical forms related to the indication for which it was included in the List based on the assessment of health technologies;

22. In Annex 2 section I point B, the introductory part of point 7 is amended and shall read as follows:

"7. Criteria for issuance of a decision for removal / addition of the ranking with (*), (**), (**) 1 or (**) 2:".

23. In Annex 2 section I point B, two new points are introduced after point 7, points 8 and 9, which read as follows:

"8. If, for the same indication mentioned in the SmPC, at the time of submission of the documentation for assessment, a medicinal product related to a new INN or corresponding to an expanded reimbursed INN for which the documentation was submitted for assessment in Table 4, 41 or Table 7 of Annex 1 to the Order, is administered in two or more treatment regimens or in two or more treatment lines on the same indication and the same population segment / subgroup, the decision of unconditional inclusion is issued only if the rating required for unconditional admission to the List is obtained, for all treatment regimens / lines. In the other cases, a conditional inclusion decision will be issued for all treatment regimens / treatment lines. In order to implement this methodology, treatment schemes/lines must be included simultaneously in the SmPC; if a new regimen / treatment line is added to the medicinal product for assessment after submission of the assessment documentation following approval of the European Medicines Agency after the initial MA has been obtained, it will be evaluated under the "addition" procedure.

9. If the comparator for a medicinal product with a new INN or reimbursable INNs with extension of indication, evaluated on Table 4 of Annex no. 1 to the Order, is a medicinal product corresponding to a reimbursed INN based on a cost-volume / cost-volume-result contract, a decision of conditional inclusion in the List is issued even if the rating obtained after assessment would allow unconditional inclusion in the List. "

24. In Annex 2 section II, a new point is introduced after point 3, namely point 31, which reads as follows:

"31. If the court orders by executory decision the obligation of the NAMMDR to resolve a request made by a petitioner to include a drug in the List, NAMMD will proceed with priority to analyse the application and issue a reasoned assessment report, which will be the basis of the decision, according to the template in Annex 6 to the Order. The decision is communicated to the petitioner within a maximum of 7 working days from its issuance. The applicant shall also be informed about the available means of appeal in line with the

legislation in force and about the deadlines allowed for the exercise of means of appeal. "

25. In Annex 3 point 2, point d) is amended and shall read as follows:

"d) proof of reimbursement in the Member States of the European Union - the affidavit of the marketing authorisation holder in respect of the countries in which the medicinal product is reimbursed according to that indication;"

26. Annex 6 is amended and replaced with the Annex which is integral part of this Order.

27. Throughout the order, the phrase "National Agency for Medicines and Medical Devices" is replaced by the "National Agency for Medicines and Medical Devices of Romania", the phrase "Health Technologies Assessment Department" is replaced by "specialised structure with responsibilities in health technologies assessment", and the phrase" calendar" is replaced by "working".

Art. II - (1) In order to ensure adequate safeguard of patients' right to life, for applications submitted before entry into force of this Order which are not solved by issuing a decision on the inclusion, non-inclusion, addition, removal or exclusion of medicinal products in / from the List, if the provisions of this Order are more favourable, the marketing authorisation holder may choose by submitting a request to the National Agency for Medicines and Medical Devices of Romania (NAMMDR) to resolve the application according to the provisions of this Order.

(2) The application by which the marketing authorisation holder expresses his option according to paragraph (1) shall be submitted to the NAMMDR within maximum 10 days from entry into force of this Order, under the sanction of revocation, and shall be resolved according to the order of priority established by this Order.

Art. III - This Order shall be published in the Official Gazette of Romania, Part I

pp. Minister of Health,
Romică Andrei Baciu,
Secretary of State

Annex
(Annex 6 to Order no. 861/2014)

THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES OF ROMANIA

DECISION no. ….. /…..

On seeing Application no. …… submitted to the National Agency for Medicines and Medical Devices of Romania concerning the medicinal product …….. .,

Taking into account the Assessment report set out by the Department for Health Technologies Assessment of the National Agency for Medicines and Medical Devices pursuant to provisions of Order no 861/ 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, as further amended and supplemented,

based on Article 7 (4) of Law 144/2010 on reorganisation of the National Agency for Medicines and Medical Devices of Romania, as amended, and on amendment of certain regulatory documents,

the President of the National Agency for Medicines and Medical Devices of Romania hereby decides on:

1. - Unconditional inclusion
- Non-inclusion
- Exclusion
- Conditional inclusion
- Extension of indications
- Addition/Relocation of a reimbursable INN
- Ranking of a reimbursable INN as (*), (**)1 or (**)2 of the INN:…….
- elimination of the ranking of a reimbursed INN with (*), (**), (**)1, (**)2

of INN: .....,
Pharmaceutical form: ……
Strength: …….
For the indication: ……..in the proposed 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, sublist with reimbursable level ..... .

2. This Decision shall be communicated to the Applicant, the minister of Health and the National Health Insurance House.

President of the National Agency for Medicines and Medical Devices

……

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Processed by CL

C.J. DA